LAST COPY

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 57971 Telex: 625852-625853 FAO I Cables: Foodagri Rome Facsimile: (6) 57973152-5782610

ALINORM 93/13A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twentieth Session
Geneva 28 June - 7 July 1993

REPORT OF THE TWENTY-SIXTH SESSION OF THE
CODEX COMMITTEE ON FOOD HYGIENE
Washington D.C., 1 - 5 March 1993

Note: This document incorporates Codex Circular Letter 1993/7-FH

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 57971 Telex: 625852-625853 FAO I Cables: Foodagri Rome Facsimile: (6) 57973152-5782610

ALINORM 93/13A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twentieth Session
Geneva 28 June - 7 July 1993

REPORT OF THE TWENTY-SIXTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE
Washington D.C., 1 - 5 March 1993

Note: This document incorporates Codex Circular Letter 1993/7-FH

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME Tel.: 57971 Telex: 625852-625853 FAO I Cables: Foodagri Rome Facsimile: (6) 57973152-5782610

CX 4/20.2

CX 1993/7-FH
April 1993

TO:
- Codex Contact Points
- Participants at the 26th session of the Codex Committee on Food Hygiene
- Interested International Organizations

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

SUBJECT: Distribution of the Report of the 26th Session of the Committee on Food Hygiene (ALINORM 93/13A)

A. MATTERS FOR ADOPTION BY THE 20th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Code and Guidelines at Step 8 of the Procedure

1a. Draft Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods (para. 52, Appendix III)

1b. Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979 (Rev.1-1989): consequential amendment to the definition of the Scope (para. 44, Appendix III).

2. Proposed Draft Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System (para. 42, Appendix II). The Guidelines were advanced to Step 5 and in view of the detailed revision they had gone through, the Committee recommended that the Commission consider omitting Steps 6 and 7 and adopting the document at Step 8.

Governments wishing to propose amendments or comments on the above documents should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Procedural Manual of the Codex Alimentarius Commission) to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, before 31 May 1993.

Terms of Reference of the Committee on Food Hygiene

3. Amendment of the Terms of Reference of the Committee (para.13).

Proposed Draft Code at Step 5 of the Procedure

4. Proposed Draft Code of Hygienic Practice for Spices and Condiments (para. 71, Appendix V).

Governments are invited to comment specifically on Section 8. End-Product Specifications, and to provide information which the Committee might use to develop microbiological criteria for treated spices, taking into account the Principles for the Elaboration and Application of Microbiological Criteria for Foods contained in the Procedural Manual (para. 70).

Governments wishing to submit comments on the implications which the above document may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of Worldwide Standards at Step 5 to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, before 31 May 1993.

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

Proposed Draft Codes at Step 3 of the Procedure

5. Proposed Draft Revised International Code of Practice - General Principles of Food Hygiene (para. 28).

6. Proposed Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-Life (para. 55).

C. REQUEST FOR COMMENTS AND INFORMATION

Proposed Draft Code at Step 3 of the Procedure

7. Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese (para. 61, Appendix IV).

Governments are invited to provide information on the risk assessment procedures and monitoring applied to ensure the safety of cheese made with raw milk and thermized milk.

Other matters

8. Measures for the control of *Listeria monocytogenes* (par. 86).

Governments are requested to make specific proposals for control measures for L. monocytogenes in foods moving in international trade and information on their experience in reducing the incidence of Listeriosis through measures taken at the national level.

Governments and international organizations wishing to submit comments and information on points 7. and 8. are invited to do so not later than 30 September 1993 to the Chairman of the Committee at the following address:

Dr. D.L. Archer
Deputy Director
Center for Food Safety and Applied Nutrition (HFF-1)
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

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

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 26th Session of the Codex Committee on Food Hygiene are as follows:

Matters for consideration by the Commission:

The Committee:

- agreed to advance to Step 8 the **Draft Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods** (para. 52, Appendix III)
- recommended a consequential amendment to the Scope and Definition of the **Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods** (para. 44, Appendix III)
- agreed to advance to Step 5 the **Proposed Draft Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System** and recommended that the Commission consider omitting Steps 6 and 7 and adopting the document at Step 8 (para. 42, Appendix II)
- agreed to advance to Step 5 the **Proposed Draft Code of Hygienic Practice for Spices and Condiments** (para. 71, Appendix V)
- recommended an amendment to its Terms of Reference (para. 13)
- agreed to endorse proposed microbiological specifications for quick-frozen cooked crab meat (pars. 15)

Other Matters of Interest to the Commission:

The Committee:

- agreed to return to Step 3 the **Proposed Draft Revised International Code of Practice - General Principles of Food Hygiene**, to be completed and circulated for comments (para.26-28)
- agreed to return to Step 3 the **Proposed Draft Code of Hygienic Practice for Refrigerated Foods with Extended Shelf-Life**, and to have a new draft prepared and circulated for further comments (para. 55)
- agreed to circulate for comments at Step 3 the **Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese** (para. 61, Appendix IV)
- considered the **Draft Regional Codes of Practice for Street-Vended Foods** prepared by the Coordinating Committees. It agreed that Coordinating Committees should be invited to reconsider their approach to this matter to determine whether regional codes in their present form were actually needed, to establish priorities when examining food safety issues related to street foods, and to leave the establishment of detailed codes to local authorities (para. 80)
- considered the information provided by governments on national policies regarding *Listeria monocytogenes* and agreed to request specific proposals regarding control measures for foods in international trade and information on experience in reducing the incidence of this pathogen at the national level (para. 86)
- agreed that the current **Principles for the Establishment and Application of Microbiological Criteria for Foods** should be revised, in the light of new concepts such as HACCP, and with a view to clarifying the status of the criteria with respect to food moving in international trade (para. 87)

TABLE OF CONTENTS

TABLE OF CONTENTS (Cont.d)

INTRODUCTION

1. The Codex Committee on Food Hygiene held its Twenty-Sixth Session in Washington, D.C., from 1 to 5 March 1993 at the kind invitation of the Government of the United States of America. The Session was chaired by Dr. Douglas Archer, Deputy Director of the Center for Food Safety and Applied Nutrition, United States Food and Drug Administration. It was attended by 82 delegates representing 26 Member Countries of the Codex Alimentarius Commission and 12 observers from 9 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. At the invitation of the Chairman the Committee was addressed by Patricia M. Griffin, M.D., Enteric Diseases Branch, Center for Disease Control and Prevention, Atlanta, who presented a paper on "*Escherichia coli* 0157:H7 - A new and Emerging Pathogen of Worldwide Importance".

4. Dr. Griffin noted that *E. coli* 0157:H7 caused non-bloody diarrhoea, bloody diarrhoea, hemolytic uremic syndrome (HUS - a type of kidney failure), and death. The organism was easily identified using sorbitol-MacConkey medium, but few clinical laboratories used this medium; so most illnesses, therefore, were never correctly diagnosed. Ground beef was the major food vehicle, but many illnesses had been linked to other foods, and still other food vehicles would likely be identified in the future.

5. *E. coli* 0157:H7 was described as a new and emerging pathogen. It was first recognized as a cause of human illness in 1982. The incidence of infections due to this organism was increasing, and becoming recognized as a worldwide problem.

6. Dr. Griffin suggested that governments might wish to consider CDC's recommendations for the United States when thinking about their national policies. In the United States studies of the ecology of the organism on farms were recommended, as were studies to determine how meat was contaminated in slaughtering and processing. The CDC also recommended that clinical laboratories culture all stool specimens from persons with bloody diarrhea for this organism, that States make infection with this organism reportable, that outbreaks and sporadic cases be investigated, and that consumers and restaurants cook ground beef until the pink color was gone.

ADOPTION OF THE AGENDA (Agenda Item 2)

7. The Committee had before it the Provisional Agenda for the Session (CX/FH 93/1). At the request of the following Delegations a number of matters were included for discussion under Agenda Item 12 - Other Business and Future Work:

- Salmonella Control (Sweden)
- Actions to be taken in response to microbiological and related emergencies in international trade (The Netherlands)
- Review of the Principles for the Establishment and Application of Microbiological Criteria for Foods (Procedural Manual, Seventh Edition, pages 148-156) and a strategic assessment of their application (The Netherlands, United Kingdom, United States)
- Statement on the proposed Codex Committee on Milk and Milk Products (New Zealand).

8. The Committee adopted the Agenda with these additions and with a minor rearrangement of the order of the items discussed.

9. In order to facilitate its discussions, the Committee agreed to establish the following *ad hoc* Working Groups:

- General Principles of Food Hygiene and HACCP (United Kingdom, Chairman)
- Street Foods
- Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-life.

MATTERS OF INTEREST TO THE COMMITTEE (Agenda Item 3)

(a) Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO)

10. The Secretariat reported on Joint FAO/WHO activities undertaken since the previous Session of the Committee, as outlined in document CX/FH 93/2. Foremost among these was the International Conference on Nutrition (ICN), held in Rome from 5 to 11 December 1992. The Representatives of FAO and WHO provided information on a number of their activities especially in relation to providing advice on food hygiene matters to Member countries through training activities such as seminars and workshops and technical documentation. The Representative of FAO reported specifically on the Organization's activities related to the cholera epidemic in Latin America and the Caribbean; it was reported that in excess of US$ 2 million was made available by the Director-General of FAO for technical assistance through the Technical Cooperation Programme to countries within the region to assure domestic, imported and exported food products were free of *V. cholera*. FAO activities and studies related to improving street vended foods in 10 member countries, along with the assistance provided at the regional level in drafting Codes of Practice for Street Foods in Asia, Africa and Latin America and the Caribbean were also reported upon. The Representative of WHO reported that WHO's Global Task Force on Cholera Control had published its guidelines on the formulation of national policies on the control of cholera, guidelines on cholera control and a brochure on "Cholera: Basic facts for travellers". Attention was drawn to the publication of WHO advice on food safety for infant feeding and on the guidance in identifying hazards and assessing risks associated with food production and storage as part of the development of HACCP programmes. An up-dated evaluation of safety and nutritional quality issues associated with food irradiation had also been carried out. The Representative also reported that WHO had provided substantial input to the UN Conference on Environment and Development in a report on "Health and the Environment". The activities of the Pan-American Health Organization on food safety and food protection in the region of Latin America and the Caribbean were also described (Conference Room Document 1).

(b) Matters of interest arising from other Codex Committees

11. The Committee had before it documents CX/FH 93/2-Add.1 and Add.2 presenting matters of interest arising from other Codex committees since the last session of the Committee (October 1991).

Terms of Reference of the Committee

12. The Secretariat recalled that the 19th Session of the Commission had requested general subject committees to examine their terms of reference in the perspective of the horizontal approach to be followed in Codex work. The 10th Session of the Committee on General Principles had proposed to amend the terms

of reference of CCFH in order to make it clear that it could act independently from commodity committees, and this proposal was put forward for consideration by the Committee.

13. The Committee agreed to propose the following amendment to its terms of reference, and to forward this proposal for adoption by the 20th Session of the Commission:

(b)(iii) to draft provisions on hygiene applicable to specific food items or food groups, whether coming within the terms of reference of a Codex Committee or not.

(c) delete

(d) becomes (c)

Microbiological specifications for quick frozen cooked crab meat

14. The Secretariat recalled that the Committee on Fish and Fishery Products had considered the establishment of microbiological specifications for quick frozen cooked crab meat at its previous sessions. Government comments were requested after its 19th Session and considered at its 20th Session, when the Committee agreed to propose maximum levels for Salmonella and *Staphylococcus aureus* and to submit this matter to the Committee on Food Hygiene for advice. Government comments in reply to CL 1992/19-FH were presented in document CX/FH 92/2-Add.1.

15. The delegation of the United States was of the opinion that the number of sample units to be examined for the detection of Salmonella should not be n = 5 but n = 30. The Committee however did not accept this proposal and agreed to endorse the levels established by CCFFP for Salmonella and *Stahpylococcus aureus* as follows:

Salmonella	*Staphylococcus aureus*
n = 5	n = 5
c = 0	c = 2
m = 0	m = 100 per g
M = 0	M = 1000 per g

16. The delegation of Switzerland suggested enterobacteriaceae as appropriate microbiological criteria to indicate both incomplete heat treatment and post-processing contamination. It was pointed out that *S. aureus* was a better indicator of post-processing contamination than thermo-tolerant coliforms and the Committee decided not to specify the use of thermo-tolerant coliform and *E.coli*.

17. The Committee noted that some government comments were in favor of the establishment of criteria for *Listeria monocytogenes*, but agreed to consider this question at a later time.

Other matters of interest

18. The Committee was further informed of the main conclusions of the Committee on Food Additives and Contaminants, the Committee on General Principles, the Committee on Food Import and Export Inspection and Certification Systems, and the Committee on Methods of Analysis and Sampling.

19. The Committee noted that the Proposed Draft Regional Codes of Practice for Street-Vended Foods prepared by the Regional Coordinating Committees for Asia and Africa would be considered under Agenda Item 10.

c) **Matters arising from international organizations**

International Dairy Federation (IDF)

20. The Observer of the International Dairy Federation informed the Committee of the activities of this organization with respect to the hygiene of the production and processing of milk and milk products, including the bacteriological quality of raw milk, hygienic design, equipment and maintenance in dairy plants, codes of hygienic practice and methods for the detection of pathogens.

International Commission for Microbiological Specifications for Foods (ICMSF)

21. The Observer of the International Commission for Microbiological Specifications for Foods (ICMSF) informed the Committee that its book Microorganisms in Foods. Vol.2 (1986), giving guidance on microbiological criteria for foods moving in international trade, did not address contamination by *Listeria monocytogenes* at the time but that ICMSF had recently drafted the following guidelines: "Consideration of Recommendations for the Control of *Listeria monocytogenes*", which would be presented under Agenda Item 11, dealing with this pathogen.

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

22. The Committee had before it document CL 1992/30-FH containing an outline of the draft revised Code. Government comments in reply to this Circular Letter were presented in documents CX/FH 93/3 (Côte d'Ivoire, Denmark, New Zealand, Norway, United States, International Dairy Federation) and Conference Room Documents 2 (Canada, Sweden) and 10 (Thailand).

23. The delegation of the United Kingdom presented the revised General Principles of Food Hygiene which had been drafted following the decision of the last session of the Committee to undertake a comprehensive revision of the existing Code. It had been agreed that the new Code should be broadly based, without excessive detail; identify potential hazards; explain the public health reason for its provisions; integrate the HACCP principles and take into account all technologies which might reduce the incidence of foodborne diseases. The Delegation recalled that the aim of the document was to provide essential requirements which would generally apply everywhere in the food chain, irrespective of the type of production, processing or distribution. It was pointed out that the general approach, structure and sequence of the General Principles should be considered first, as the Committee had to reach a consensus on these points before developing the detailed Code. In this regard, the Delegation indicated that two individual sections had been drafted in detail only as an example of the proposed revised text.

24. Many delegations expressed their appreciation of the extensive and important work carried out by the delegation of the United Kingdom, in this area of high priority for the activities of the Committee, and reasserted the necessity to proceed with the completion of the revised General Principles, which would define its future work on food hygiene.

25. The Committee agreed that the aim of the Code was to ensure food safety, which was understood as minimizing health hazards; as well as to ensure wholesomeness as it relates to fitness for human consumption (for example, absence of objectionable foreign matter). The Committee established an *ad hoc* Working Group to consider the comments and proposals made for further development of the

revised General Principles, without attempting to undertake detailed drafting at this time. The Delegation of the United Kingdom reported that the Working Group had agreed on the following main points:

- The document should follow the logic of the food chain so that it would be easily recognized by its users. Each key element would indicate the management responsibilities appropriate for the control of hazards, but those elements which would apply to several stages of the chain, such as training and consumer awareness, would be covered in appropriate Sections. The document would be flexible in its approach and would be written in a manner that it would apply to all food businesses, large or small.

- Each Section would indicate the objectives to be aimed at and the public health rationale behind these objectives.

- Critical parameters would include references to time, temperature and other parameters such as humidity. A section on raw materials would be included.

- The Scope of the General Principles would continue to provide for the control of factors which would cause food to be considered "unwholesome" as containing, for example, unwanted and objectionable foreign matter or showing signs of decomposition. For this reason the Code would continue to refer to "**Food Hygiene**" rather than "Food Safety" in its title. Care would be taken to ensure that aspects of consumer preference or relative nutritional adequacy would not be included or covered by the use of terms such as "wholesome".

- Such a substantial revision of the General Principles of Food Hygiene as a framework document for other Codex Codes would require the development of a strategy for revising and amending existing codes and for developing new codes for areas such as primary production. Such codes should not repeat the overall structure of the General Principles, but should only specify additional requirements, or derogations, specific to products or processes covered by these codes. Microbiological criteria contained in existing codes would also have to be re-examined in this perspective as well as in the context of other new developments (See also paragraph 87-89).

26. The Committee warmly welcomed the approach recommended by the Working Group. It agreed that a comprehensively revised document should be prepared by the Delegation of the United Kingdom for circulation at the earliest possible opportunity for comments at Step 3. It encouraged governments and interested international organizations to give the fullest consideration to providing written comments so that this draft could be considered at its next Session with a view to its adoption by the 21st Session of the Commission in 1995. It requested the Secretariat to prepare a document outlining the strategy to be followed in the amendment and/or revision of existing Codes in relation to the new General Principles and for prioritized development of new codes.

27. The Delegation of the Netherlands expressed the view that the revised General Principles of Food Hygiene should not contain expressions such as "where appropriate" or "where necessary". The Delegation stated that all such statements should be made in the form of specific statements or derogations. The Committee agreed that this would not be practical and noted that the expressions were explicitly used in the context of the overriding objectives of food safety and wholesomeness.

Status of the Proposed Draft Revised International Code of Practice - General Principles of Food Hygiene

28. The Committee returned the draft to Step 3 of the Codex Procedure, but indicated that it would be reviewed at its next Session with a view to adoption by the Commission in 1995.

DRAFT PRINCIPLES AND APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) SYSTEM (Agenda Item 5)

29. The Committee had before it the Draft Principles and Application of the HACCP System, as contained in Appendix VI of ALINORM 93/13. Government comments at Step 3 in reply to CL 1991/27-FH were presented in document CX/FH 93/5 (Canada, Hungary, Thailand, United States) and CRD 3 (Canada).

30. While presenting the documents, the Secretariat noted that the comments indicated a general consensus on the application of the HACCP system, but that consideration should be given to the exact nature of this document to determine whether reference should be made to "principles" or if it was more in the nature of guidelines. The Committee had an exchange of views on this matter and agreed that all questions relating to HACCP would be considered in depth by the ad hoc Working Group.

31. The Observer of the EEC informed the Committee that the EEC Directives on food hygiene for fishery, milk and meat products followed the same principles as the HACCP document, as did the general legislation on food hygiene about to be adopted. This type of monitoring would be required of the food industry in EEC countries, as the Community was implementing these principles for fishery, milk and meat products. Similar requirements would be made in the future for imported products. Reference to an internationally accepted document was therefore of great importance.

32. The delegation of the United Kingdom presented to the Committee the conclusions of the Working Group which had met during the present session and pointed out that no change had been introduced in the essential approach of the document. The Committee considered these proposals and adopted the following amendments.

33. The Committee agreed to refer in the title to "Guidelines for the Application of the HACCP System" instead of "Draft Principles" as the document described operational steps to be followed in application of the principles. It was also noted that reference to the principles of HACCP would be taken into account in the Revised General Principles of Food Hygiene and a reference to the Guidelines would be made in an appropriate section of the Procedural Manual.

Preamble

34. The Committee agreed that the second paragraph should begin with the general statement "HACCP can be applied throughout the food chain" without specific reference to the food industry. It was further agreed to add food technologists to the list of experts included in the HACCP team and given as an example.

35. The Committee requested the Secretariat to obtain the views of ISO on the compatibility of the HACCP system with ISO 9000. It was agreed that this procedure should not delay the elaboration of the document within Codex.

Definitions

36. The reference to "target levels" was replaced by "critical limits" as a value separating acceptability from unacceptability.

Application of the Principles of HACCP

37. In point 7. of the logic sequence the Committee agreed to add a sentence to the effect that the process or product should be modified when a hazard had been identified and no preventative measure existed.

Training

38. It was agreed to include primary producers in the list of sectors concerned regarding the training for the application of HACCP.

39. The title of the Diagram was defined as "Logic Sequence for Application of HACCP", and the presentation was slightly modified to clarify the sequence of the steps and identification of the Critical Control Points.

40. The Committee agreed that the HACCP Checklist was better described as a HACCP Worksheet, and a column dealing with Records was added, as well as a Section 4. on "Verification".

41. The Committee adopted the amendments to the Proposed Draft Guidelines and there was general consensus on the importance of this document as a reference, in the perspective of the present approach to food safety and the revision of the general Principles of Food Hygiene.

Status of the Proposed Draft Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System

42. The Committee agreed to advance the proposed Draft Guidelines to Step 5 of the Procedure, with a recommendation that the Commission adopt it at Step 8 by omitting Steps 6 and 7. The Proposed Draft Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System are attached to the present report as Appendix II.

CONSIDERATION OF THE DRAFT CODE OF HYGIENIC PRACTICE FOR ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID FOODS (Agenda Item 6)

43. The Committee at its 25th Session had considered a Draft Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods (ALINORM 93/13, paras. 18-20). In view of the diversity of technical points which needed consideration the Committee agreed to circulate a revised draft of the Code to governments for comments and to consider these at its present Session. Comments in reply to Circular Letter CL 1991/27-FH were incorporated into a revised draft text, CX/FH 93/5. Further comments were available to the Committee in document CX/FH 93/5-Add.1 and Conference Room Documents 4 and 10 (Canada, Thailand, Sweden).

SECTION I - SCOPE

44. It was agreed to establish a general Introduction to the document incorporating some of the general comments in the previous statement of Scope. It was also agreed that the document should apply only to low-acid foods which had a water activity (a_w) of greater than 0.85. An amendment was made to the Definition of "Low-Acid Food" accordingly, and a direct reference made to this definition in the Scope. It was noted that similar consequential amendments would need to be

made in the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979 (Rev.1-1989)), and the Committee recommended to the Commission that such changes be made.

SECTION II - DEFINITIONS

45. The definitions of "Acid Food" and "Acidified low-acid food" were deleted as no reference to these expressions was made in the document. The definition of "Low-acid Food" was amended as noted above, and the following definitions were amended to ensure technical accuracy and completeness:

- "Aseptic processing and packaging"
- "Equilibrium pH"
- "Hold Section"
- "Potable water"
- "Product-to-product regenerator"
- "Steam seal"

46. The Committee did not accept a proposal to amend the definition of "Commercial sterility", as this was a well-understood term and one which was used in the Low-Acid Canned Foods Code, nor a proposal to extend the definition of "Low-acid foods" to include alcoholic beverages.

SECTION III - HYGIENIC REQUIREMENTS IN THE PRODUCTION/HARVESTING AREAS;
SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES;
SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS; and
SECTION VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

47. These sections were adopted without amendment, except for a technical amendment to Section 4.7 "Sterile Gas Supply". The Committee noted that Section 4.7.1 called for the performance of the filters ensuring the sterile gas supply to be verified periodically by the use of appropriate test methods. It requested the Secretariat to approach the relevant international organizations (ISO, AOAC International) to ask their advice on appropriate, validated test methods which could be referred to for the application of this Code.

SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

48. A series of technical amendments were made throughout this Section. Section 7.4.3.1 was deleted. The Committee was unable to accept a proposal that records concerning the establishment of a scheduled process (Section 7.5.2.1) should not be kept permanently, but only for five years; it noted that these records were necessary for scheduled processes in use and for the development of new scheduled processes.

SECTION VIII - QUALITY ASSURANCE

49. No changes were made to this Section.

SECTION IX - STORAGE AND TRANSPORT OF THE FINISHED PRODUCT; and
SECTION X - LABORATORY CONTROL PROCEDURES

50. The preamble to Section IX was replaced by a more comprehensive statement explaining the reason for special care to be taken in the handling of the finished product in view of the nature of materials often used in aseptic packaging. It was also agreed that incubation tests (Section 10.5) could be carried out at other time/temperature combinations than those recommended in the Code taking into account local conditions as established by the processor.

SECTION XI - END-PRODUCT SPECIFICATIONS; and
SECTION XII - REFERENCES

51. The Committee agreed to make direct reference only to established Codex texts and to indicate that other references could be consulted for further information. It was noted that the large majority of available texts to which international reference could be made were available in English only, and the Committee encouraged interested institutions to develop reference texts for the use of non-English speaking countries.

Status of the Draft Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods

52. The Committee agreed to advance the Draft Code to Step 8 of the Procedure for adoption by the Commission. The full text of the Draft Code may be found as Appendix III to the present report.

CONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR REFRIGERATED PACKAGED FOODS WITH EXTENDED SHELF-LIFE AT STEP 4 (Agenda Item 7)

53. The Committee had before it the Proposed Draft Code of Hygienic Practice as contained in ALINORM 93/13 - Appendix V, government comments received in reply to Circular Letter CL 1991/27-FH as contained in document CX/FH 93/6 (Canada, Poland, Thailand, United States) and in Conference Room Document No. 5 (Canada, France, Sweden). In order to facilitate discussion of the document, the Committee agreed to convene a Working Group to consider the comments and to propose changes in the draft.

54. The Delegation of Canada, reporting on behalf of the Working Group, indicated that major amendments to the document would be required, especially in view of a re-evaluation of the Scope of the document and the foods to be covered by it. In general, it had been decided that these would be low-acid, heat-treated foods which may or may not be hermetically sealed with a declared shelf-life of more than five days under refrigerated conditions. Certain foods would be excluded, for example shelf-stable canned foods, cured, smoked products, milk and milk products. Mixtures of foods which otherwise were covered but contained one or more of the excluded foods would still be covered by the code. The Working Group recommended deletion of the microbiological specifications contained in the draft until a general decision was taken with respect to microbiological criteria (see para. 87-89). It had agreed that the pasteurization values should be retained, but only as an example of an acceptable process.

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

55. The Committee agreed that a revised draft of the code should be prepared on the basis of these recommendations by the Delegations of Canada and France and that it should be distributed for government comments at Step 3.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED/UNRIPENED CHEESE AND RIPENED SOFT CHEESE (Agenda Item 8)

56. The Committee had for its consideration document CX/FH 93/7 presenting the aforesaid Code and Conference Room Document 6 containing the comments of Canada.

57. The Secretariat recalled that the 25th Session of the Committee had discussed a Proposed Draft Code and agreed that this text should be revised to take into account the conclusions reached during the session. It had been agreed that the delegation of the Netherlands would draft a revised Code dealing with hygienic

requirements for the production of uncured/unripened cheese and ripened soft cheese, and that the delegation of France would prepare an annex dealing with specific provisions relating to cheese made with raw milk. Due to the complexity of the issues involved to carry out this work and to time constraints, it had not been possible to circulate this document for comments at Step 3 before the present session. The Delegations of the Netherlands and France presented the working paper and pointed out that as indicated during the last session, they had addressed the question of primary production, in particular the primary production of milk that is used for the production of raw milk cheese, as well as processing and that both parts of the Code presented the application of the HACCP system to the production of this type of cheese.

58. The Delegations of Australia, Japan, New Zealand, Norway, Sweden and the United States indicated that the use of raw milk was regarded as a public health hazard in their countries. In some of these the production of cheese made with raw milk was not allowed.

59. Some delegations were of the opinion that the document should be divided into two separate codes; it was also suggested that the establishment of a separate code on primary production be considered. The Chairman pointed out that the present draft included a separate annex on cheese made with raw milk, and had been prepared in accordance with the decision of the last session of the Committee, where this question had been discussed. The delegation of Denmark expressed the view that the Code should include a reference to cheese made with thermized milk.

60. The Observer of the European Community informed the Committee that it welcomed this Proposed Draft, as it appeared necessary to rely on a code of general hygienic practice for cheese and specific provisions for cheese made with raw milk. These aspects were addressed in Council Directive 92/46/EEC (September 1992). However, at this stage, the Observer indicated that some points differed substantially from EEC regulations, especially as to animal health of milk-producing animals; holding and milking hygiene; hygienic specifications for raw milk as a raw material; microbiological criteria applying to the end-product. The Delegations of France and the Netherlands were of the view that the establishment of a separate code would be redundant, as the two codes were linked and that the specific provisions relating to raw milk could be dealt with as one particular type of cheese production. The delegations of Norway, Sweden and the United States expressed the view that cheese made with raw milk should be labelled as such to provide adequate information to the consumer.

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

61. The Committee agreed that the Proposed Draft Code should remain in its present form to be circulated for comments at Step 3 of the Procedure. The Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese is attached to the present report as Appendix IV.

62. At the suggestion of the delegation of the United States, the Committee agreed to request 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.

CONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS (Agenda Item 9)

63. The Commission at its 18th Session (1989) had noted that a Code of Hygienic Practice for Spices and Condiments had been initiated by the International Organization for Standardization (ISO). In view of the Commission's mandate to

coordinate all food standards matters, especially those concerning protection of the consumers' health and facilitating international trade, the Commission requested the Committee on Food Hygiene to take over the further elaboration of this Code. The proposed draft Code had previously been considered by the Committee at its 24th and 25th Sessions (see ALINORM 91/13 and 93/13). At the 25th Session, it was agreed that the Secretariat would initiate the preparation of a new draft with the cooperation of exporting and importing countries.

64. The Committee had before it the draft Code provided by the Secretariat (CX/FH 93/8) and comments on this draft made in reply to Circular Letter CL 1992/35-FH as contained in document CX/FH 93/8 - Add.1 and Conference Room Document 7 (Thailand, USA, Canada, Hungary, Norway, Sweden and the European Spice Association).

SECTION 1 - SCOPE; and
SECTION 2 - DEFINITIONS

65. The Committee agreed that the Scope of the Code should be limited to dried spices and condiments and blends thereof, as these were the main subject of public health concern for which a Code of Hygienic Practice was necessary. It agreed therefore to delete references throughout the text to essential oils, oleoresins and other spice products. The definitions of "Spices and Condiments" and "Spice Blends" were simplified by deleting superfluous detail.

SECTION 3 - HYGIENIC REQUIREMENTS IN THE PRODUCTION/HARVESTING AREA

66. Technical amendments were made to a number of paragraphs in this Section to take into account the written comments received. It was proposed that paragraph 3.4 Packaging should be reworded in more general terms to indicate the nature of the hazards associated with inappropriate or inadequate packaging and to state that these risks should be minimized. The Delegation of the United States expressed the opinion that containerized shipments could not be ventilated; that thorough drying of spices before shipments helped in this regard, but technological development was still needed to solve the problem.

SECTION 4 - ESTABLISHMENT: DESIGN AND FACILITIES;
SECTION 5 - ESTABLISHMENT: HYGIENE REQUIREMENTS; and
SECTION 6 - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

67. The Committee agreed that in these Sections the common text of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 2 (1986)) should be used until such time as the newly revised version of this basic text was adopted by the Commission, at which time it would be appropriate to replace these Sections by appropriate references to the General Principles.

SECTION 7 - HYGIENIC PROCESSING REQUIREMENTS

68. Several Delegations questioned the inclusion of specific reference to fumigation and irradiation as examples of means of control of microbiological contamination or pest infestation. It was noted that irradiation of foods including spices was prohibited in a number of countries, and that certain fumigation treatments posed potential health hazards. The Committee noted that a number of alternative treatments were already developed and in practical use. The delegation of Denmark expressed the view that products moving in international trade should be accompanied by a certificate indicating the treatment which had been used. The reference was deleted. The Committee agreed to retain the reference to the Code of Good Irradiation Practice for the Control of Pathogens and Other

Microflora in Spices, Herbs and Other Vegetable Seasonings (ICGFI Document No.5), as it was recognized that in countries where irradiation was permitted adherence to this Code would be appropriate.

SECTION 8 - END-PRODUCT SPECIFICATIONS

69. The Committee noted the several written comments proposing the deletion of the microbiological criteria contained in the Proposed Draft Code. These views were supported by a number of Delegations which pointed out that inadequate data were available to establish appropriate microbiological criteria, and that in any case there were significant technical problems in undertaking the required microbiological analyses. These Delegations stated that the general expression "products should be free from pathogenic micro-organisms in levels which may represent a hazard to health", currently included in Section 7.8.3 of the Proposed Draft Code provided the best guidance under the circumstances. Several other Delegations stated that specific numeric criteria were needed and could be established especially for spices which had been treated with the purpose of reducing contamination.

70. The delegation of the Netherlands suggested that microbiological criteria for raw spices were not necessary, but that criteria for spices which had undergone a treatment might be useful. The Committee agreed to transfer Section 7.8.3 to the main Section on End-Product Specifications and to add to it the requirement that the products "should not contain levels of insect, bird or rodent contamination which indicate that spices have been prepared, packed or held under unsanitary conditions". Governments were invited to comment specifically on these provisions, and to provide information which the Committee might be able to use to develop numeric microbiological criteria for treated spices, taking into account the Principles for the Elaboration and Application of Microbiological Criteria for Foods contained in the Procedural Manual.

Status of the Proposed Draft Code of Hygienic Practice for Spices and Condiments

71. The Committee agreed to advance the revised Proposed Draft Code, as contained in Appendix V to this report, to Step 5 of the Codex Procedure.

CONSIDERATION OF A CODE OF HYGIENIC PRACTICE FOR STREET-VENDED FOODS (Agenda Item 10)

72. The Committee had before it the Draft Codes of Practice for Street Foods prepared by the Coordinating Committees for Africa (ALINORM 93/28, Appendix IV), Asia (ALINORM 93/15, Appendix II), Latin America and the Caribbean (ALINORM 93/36, Appendix IV-Corrigendum), as well as the WHO "Essential Safety Requirements for Street-Vended Foods" (WHO/HPP/FOR 92.3), and the comments of Thailand in CRD 10.

73. The Secretariat recalled that the Draft Code of Hygienic Practice for Street-Vended Foods prepared by the Coordinating Committee for Latin America and the Caribbean (CCLAC) had been adopted at Step 5 by the Commission (19th Session) and would be considered at Step 7 by the next session of CCLAC. The 8th Session of the Coordinating Committee for Asia (CCASIA) had considered proposals for a Regional Code, currently at Step 3. The 10th Session of the Coordinating Committee for Africa (CCAFRICA) had considered a Proposed Draft Code of Practice for Street Foods in Africa, currently at Step 3. It had been agreed that the advice of CCFH would be sought on the draft codes in the process of elaboration. The 25th Session of CCFH had agreed that a general model code taking into account the elements contained in the Draft Regional Codes should be prepared, for consideration at its next session. The 39th Session of the Executive Committee had requested that the document prepared by CCASIA and the WHO "Essential requirements" be submitted to CCFH and that FAO and WHO should work in cooperation on this issue to carry out

this important work. The Codex Secretariat contacted both parent organizations to consider the feasibility of establishing a joint code of a general character. This had not been possible, and no general document was prepared for the present session. The Secretariat also pointed out that, in view of the wide differences between the regions concerned, it did not appear feasible or useful on a practical level to prepare a general code, and that the regional approach, supported by the Coordinating Committees, should be considered.

74. The Representative of WHO recalled that the last session of the Committee had requested WHO to prepare a general document on street foods and that a draft of the "Essential Requirements" had been presented to CCASIA, and distributed to several WHO Member countries. He indicated that in view of the important economic, political, social and cultural differences between the countries concerned, it was not possible to establish a general model code, nor was it feasible even to prepare a model regional code, as wide differences could be observed within the regions as well. Although regional codes were currently being developed by the Coordinating Committees, the elaboration of codes of hygienic practice was better left to the local authorities. In this perspective, WHO had prepared the document on Essential Requirements, which was more in the nature of guidelines to help national or local authorities to define their policies in this matter. With respect to the present Draft Regional Codes, the Representative expressed the view that these texts did not adequately address the issues of food safety relating to street foods, especially as they did not classify and prioritize hazards associated with different types of foods, and that Regional Committees should therefore reconsider their policy in this matter.

75. The Representative of FAO informed the Committee of the extensive FAO activities relating to street-vended foods in various parts of the world so as to cover safety and quality, while taking into account economic and social factors, and recalled that an FAO Expert Consultation on Street Foods in Yogyakarta, Indonesia (December 1988) had made a number of important recommendations which were currently being applied, especially through field programs in developing countries. He indicated that the WHO "Essential Requirements" as they stood could be used for training purposes as could other documents dealing with this subject but did not give sufficient detail and guidance for practical application where food safety was concerned; moreover, socio-economic aspects were greatly emphasized whereas these should be adequately balanced with considerations relating to food hygiene. The Representative noted that the WHO document was not a general model code as referred to by the last session of the Committee, and was of the opinion that the elaboration of a general code was not feasible; he consequently suggested that the Committee reexamine this issue in the present context.

76. In order to facilitate the work of the Committee on this issue, the Chairman proposed the establishment of a working group and the delegation of the United States presented the conclusions of the Working Group to the Committee.

77. Some delegations were of the opinion that the question of street foods should not be considered by the Committee as it did not affect international trade. The Chairman recalled that the Commission had specifically requested that this matter be taken up by Codex, in view of its importance for public health, and that the Committee had already worked on food hygiene matters not related to international trade but of particular concern to developing countries. He further indicated that the mandate of the Codex Alimentarius Commission, in implementing the Joint FAO/WHO Food Standards Programme, was to protect the health of the consumer and was not limited to trade matters.

78. Several delegations expressed their concern that the provisions contained in the regional codes would not be applicable in practice; it was felt that they provided excessive detail in certain areas and that, as a whole, detailed codes

were not an adequate answer to food safety issues related to street foods. There was general consensus on the necessity of developing training of street food vendors and consumer education.

79. The Committee agreed that a general or global model code for street-vended foods was inappropriate, as could be regional codes. A general document directed to national or local authorities having jurisdiction provided a better approach and the WHO "Essential Requirements" could be a starting point for the establishment of such a document, in cooperation with FAO and with the input of interested countries. However, in reply to a question relating to procedure and as a matter of clarification, the Secretariat indicated that this document was not a Codex document elaborated through the Codex Procedure, as defined in the Procedural Manual, and could not be circulated as such.

80. The Committee agreed that Regional Coordinating Committees should be invited to reconsider their approach to the question of street-vended foods to determine whether regional codes in their present form were actually needed, to establish priorities when examining food safety issues related to street foods, and to leave the establishment of detailed codes to local authorities in the countries concerned.

CONSIDERATION OF RECOMMENDATIONS FOR THE CONTROL OF *LISTERIA MONOCYTOGENES* (Agenda Item 11)

81. The 25th Session of the Committee on Food Hygiene had considered national and expert recommendations on *Listeria monocytogenes* and agreed that the application of the HACCP system in Codes of practice was appropriate to ensure control of Listeria, but that HACCP procedures required due consideration of the nature of the food and its intended use. The Committee had called for international organizations and institutions to continue work on analytical and surveillance methodologies, and for Member countries to develop training and consumer education for a better understanding of the risks. The establishment and application of quantitative tolerances was considered and it appeared that different points of view existed on this question. The Committee agreed that information should be collected on the tolerances used by Member countries, the commodities to which they applied and any sampling plans and methodologies that were used, for consideration at the next session.

82. Comments received in reply to Circular Letter CL 1992/35-FH were contained in document CX/FH 93/10 (France, Hungary, Norway, Switzerland), Conference Room Documents 8 (New Zealand, United States), 10 (Thailand) and 12 (ICMSF); additional information was provided to the Committee by Sweden, Spain, The Netherlands and the United Kingdom. The Committee considered whether or not sufficient information was available for a numeric criterion for *L. monocytogenes* at the present time.

83. The Committee noted that some countries had established practical control levels, which they applied within their own jurisdiction, in order to reduce contamination as much as possible in certain specified foods. Some of these countries expressed the view that low levels of *L. monocytogenes* did no harm if present in foods which did not support its growth. The delegation of the Netherlands indicated that in their national Food Law, the standard for *L. monocytogenes* in ready to eat products applied at the "use-by date" as declared in the labelling. Other delegations, including Japan, opposed the establishment of numerical tolerances for pathogens.

84. The Committee considered that there were insufficient data and inadequate scientific consensus at present to reach a conclusion about establishing maximum quantitative levels or limits for *L. monocytogenes* in food which could be applicable internationally. There was a consensus that a HACCP-based approach was

the preferred approach for the control of *L. monocytogenes*. There was also a consensus that consumer education was required, especially public health advice to vulnerable groups (pregnant or immuno-compromised persons).

85. The Committee noted the opinions of those delegations which considered that a "zero tolerance" for *L. monocytogenes* would be a barrier to trade; however, the Delegation of the United Kingdom noted that the arbitrary imposition of tolerances would equally be a barrier and unreasonable burden to both industry and national food control authorities as it had not been demonstrated that such controls had any effect in reducing the incidence of food-borne illness caused by *L. monocytogenes*. The delegation of Canada questioned whether or not effective HACCP controls could be guaranteed in food moving in international trade, and the attention of the Committee was drawn to the Draft Principles for Import and Export Inspection and Certification (ALINORM 93/30, Appendix 3) which were being considered by the Commission for adoption, and which could be used to address this matter.

86. The Committee noted the paper prepared by the ICMSF on a "decision tree" approach to the control of *L. monocytogenes*. It agreed to circulate this paper for comments. It furthermore agreed 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 measures at the national level. It agreed to discuss the matter in light of these comments at its next session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 12)

(a) Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods

87. The Delegation of The Netherlands introduced a paper (Conference Room Document 11) which discussed the possibility of revising the Codex Principles for the Establishment and Application of Microbiological Criteria for Foods (Procedural Manual, 7th Edition, 1989, pages 148-156). The paper noted that many of the types of criteria contained in the Principles were out of date and had originally been established mainly with end-product testing in mind. Furthermore new concepts, such as HACCP, required new criteria to be defined. The Delegation also stated that the regulatory status of the criteria to be applied to food moving in international trade was unclear, and that this could become a problem when harmonizing standards as foreseen under the proposed new GATT agreements.

88. The Delegation of Sweden pointed out that many of the micro-organisms identified in existing Codex microbiological criteria were now more precisely defined, and precise taxonomic definitions would be needed to allow the use of modern analytical techniques such as gene probes.

89. The Committee agreed that the Principles and the existing Codex microbiological criteria should be reviewed. It requested the Secretariat, working in collaboration with the ICMSF, to prepare a paper for discussion at the Committee's next Session.

(b) Salmonella Control

90. The Delegation of Sweden reported on control measures undertaken in that country for the control of Salmonella in Foods. It was noted that a paper on the subject (CX/EURO 92/11) had been presented to the Eighteenth Session of the Regional Coordinating Committee for Europe, Stockholm, May 1992, and that the Regional Committee had agreed that the paper should be presented to the Committee

on Food Hygiene for information. The Delegation pointed out that measures taken in Sweden had effectively reduced the incidence of Salmonella outbreaks in that country.

(c) Emergency actions concerning international trade in foods following outbreaks of cholera

91. It was noted that the Committee on Food Hygiene at its 25th Session had agreed that it would be appropriate for Codex to provide advice to Member Countries on actions which could be taken by both importers and exporters in the case of a major outbreak of food-borne disease or widespread contamination of food due to environmental or industrial causes, in particular to prevent unnecessary restrictions to international trade (ALINORM 93/13, paragraph 83). The Committee had requested a paper to be prepared for consideration by the Executive Committee. It had also noted that WHO was preparing a document on "Guidance on Formulation of National Policy on the Control of Cholera".

92. The Executive Committee, at its 39th Session, Geneva, June 1992, welcomed the proposal of the Committee on Food Hygiene, but recommended that such guidance should be prepared by the Codex Committee on Food Import and Export Inspection and Certification Systems on the basis of technical advice to be provided by the Codex Committee on Food Hygiene. The Executive Committee also welcomed the publication of the WHO Policy document, copies of which have since been widely distributed[1] (ALINORM 93/3, paragraphs 59-62).

93. The First Session of the Codex Committee on Food Import and Export Inspection and Certification Systems considered a document (CCFICS Conference Room Document 4) which provided background information on problems caused in international trade in foods as a consequence of the outbreak of cholera in Latin America, the WHO Guidance document, and a paper prepared by the FAO/PAHO/WHO Joint Technical Consultation on Food Safety and Trade in View of the Cholera Epidemic in the Americas held in Buenos Aires, April 1992. The Committee on Food Import and Export Inspection and Certification Systems agreed that, irrespective of the nature of the situation, guidelines for information exchange in food control emergency situations were essential and would be included on the Committee's work programme (ALINORM 93/30, paragraphs 71-72).

(d) Proposed Codex Committee on Milk and Milk Products

94. The Delegation of New Zealand announced that it had officially notified the Directors-General of FAO and WHO of its interest in hosting the proposed Codex Committee on Milk and Milk Products should the Commission decide to change the status of the FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products to that of a Codex Committee. The Chairman noted that in addition to New Zealand, the governments of France, Germany and Norway had also made formal notification of their interest in hosting the proposed Committee. The Committee on Food Hygiene noted that a decision on whether the status of the Committee would be changed and the subsequent appointment of a host government would be taken by the 20th Session of the Commission.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 13)

95. The Committee noted that its 27th Session was tentatively scheduled to be held from 17 to 21 October 1994 in Washington, D.C..

---

1 Copies of this document were available to participants at the present Session.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Document Reference in ALINORM 93/13A
Draft Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods	8	Governments 20th CAC	para. 52, Appendix III
Proposed Draft Guidelines for the Application of the HACCP System	5/8	Governments 20th CAC	para. 42, Appendix II
Proposed Draft Code of Hygienic Practice for Spices and Condiments	5	Governments 20th CAC	para. 71, Appendix V
Proposed Draft International Code of Practice - General Principles of Food Hygiene	3	United Kingdom Secretariat Governments 27th CCFH	para. 28
Proposed Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-Life	3	Canada/France Governments 27th CCFH	para. 55
Proposed Draft Code of Hygienic Practice for Uncured/Unripened Cheese and Ripened Soft Cheese	3	Governments 27th CCFH	para. 61, Appendix IV
Recommendations for the control of *Listeria monocytogenes*	-	Governments 27th CCFH	para. 86
Proposed Draft Regional Codes of Hygienic Practice for Street-Vended Foods	6 3 3	CCLAC CCAFRICA CCASIA	para. 80
Revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods	-	Secretariat ICMSF 27th CCFH	para. 89

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

Chairman
Président
Presidente

Dr. Douglas L. Archer
Deputy Director for Programs (HFS-2)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204
United States

Assistant to chairman
Assistant du Président
Asesor del Presidente

Mr. Charles W. Cooper
Director
International Activities Staff (HFS-585)
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204
United States

MEMBER COUNTRIES
PAYS MEMBRES
PAISES MIEMBROS

AUSTRALIA
AUSTRALIE

Mr. Nimal Abhayaratna
Principal Science Administrator
Food Inspection Branch
Australian Quarantine and Inspection Service
GPO Box 858
ACT 2601
Canberra, Australia

Ms. Elizabeth Flynn
Director, Assessments
National Food Authority
GPO Box 7186
Canberra Mail Centre
ACT 2601
Canberra, Australia

BELGIUM
BELGIQUE
BELGICA

Mr. Benoit Horion
Food Inspection Officer
Cite Administrative de l'Etat
1010 Brussells, Belgium

BRAZIL
BRESIL
BRASIL

Mr. Adauto Lima Rodrigues
Ministry of Agriculture
Esplanada dos Ministerios
Anexo do Mara 4º Andar (Floor)
Sala (Room) 408
Brasilia, Brasil

CANADA

Dr. Bruce Brown
Bureau of Microbial Hazards
Food Directorate
Health Protection Branch
Health and Welfare Canada
Sir Frederick Banting Building
Ottawa, Ontario K1A OL2, Canada

Mr. Adrien Gervais
Chief
Scientific and Technical Services Branch
Inspection Services Directorate
Fisheries and Oceans Canada
200 Kent Street
Ottawa, Ontario K1A OE6, Canada

CANADA (Cont.d)

Mr. Bertrand Gagnon
Chief, Food Preservations Systems
Agri-Food Safety and Strategies
Division
Food Inspection Directorate
Agriculture Canada
Halldon House
2255 Carling Avenue
Ottawa, Ontario K1A 0Y9, Canada

Dr. Joost Harwig
Director, Bureau of Microbial Hazards
Food Directorate
Health Protection Branch
Sir Frederick Banting Building
Ottawa, Ontario K1A 0L2, Canada

Ms. Reta Moyer
Further Poultry Processors
Association of Canada
500-2319 St. Laurent Blvd
Ottawa, Ontario K1G 4K6, Canada

Ms. Nadine Levin
Office of Enforcement
Environment Canada
351 St. Joseph Boulevard
Hull, Quebec K1A 0H3, Canada

DENMARK
DANEMARK
DINAMARCA

Sven Qvist
Chief Microbiologist
Ministry of Agriculture
Danish Veterinary Service
Food Control Laboratory
Howitzvej 13, Postboks 56
DK-2000 Frederiksberg, Denmark

Christina Galliano
Senior Scientific Adviser
National Food Agency of Denmark
Morkhoj Bygade 19
DK 2860 Soborg, Denmark

Miss Jeanineke Dahl Kristensen
Food Scientist
Fish Inspection Service
Dronningens Tvaergade 21
P.O. Box 9050
1022 Copenhagen, Denmark

EGYPT
EGYPTE
EGIPTO

Dr. Zeinab Niazi
Chairman of Dept of Food Hygiene
Animal Health Research Institute
Agric. Research Center
Nadi-El Said Street
Dokki, Giza, Egypt

Mr. Hassan Khamis Soliman
Agricultural Engineer
Technical Sector Manager of Alexandria
Oil and Soap Company
Alexandria, Egypt

Dr. Ihrahim Antar
Agricultural Counselor
Embassy of Egypt
1350 Conn. Ave. N.W.
Washington, D.C. 20036, U.S.

FINLAND
FINLANDE
FINLANDIA

Mr. Pekka Pakkala
Assistant Director
National Food Administration
Box 5
00531 Helsinki, Finland

Dr. Jorma Hirn
Professor
National Veterinary and Food Institute
Box 368, 00101 Helsinki, Finland

FRANCE
FRANCIA

Monsieur Pierre H. Veit
Ministere de L'Economie et des
Finances
Direction Generale De La Concurrence,
De La Consommation Et De La Repression
Des Fraudes (DGCCRF)
59 Boulevard Vincent Auriol
Teledoc 051
75703 Paris Cedex 13, France

FRANCE (Cont.d)

Madame Christine Roegel
Veterinaire Inspecteur en Chef
Ministere de l'agriculture et du developpement rural
Directeur des Services Veterinaires du Haut-Rhin
21 rue d'Agen BP464
68020 Colmar Cedex, France

Madame Cecile Lahellec
Directeur du Laboratoire Central d'Hygiene Alimentaire/CNEVA
43 rue de Dantzig
75015 Paris, France

Monsieur Poirson
Attache Veterinaire
Ambassade de France aux Etats-Unis (Embassy of France)
4101 Reservoir Road, NW
Washington, DC, U.S.

Monsieur Francois Falconnet
Delegue Scientifique et technique
Chambre Syndicale des Industries de la Conserve
44 rue d'Alesia
75682 Paris Cedex 14, France

Madame Catherine Vigreux
Conseiller Reglementaire, BSN
7 rue de Teheran
75008 Paris, France

Mrs. Dominique Burel
Federation Nationale des Cooperatives Laitieres
34 rue Godot de Mauroy
Paris 75009, France

GERMANY
ALLEMAGNE
ALEMANIA

Dr. Paul Teufel
Director and Professor
Federal Health Office
P.O. Box 33 00 33
D-W 1000 Berlin 33
(From 01 June 93:
P.O. Box 480447
12254 Berlin)
Germany

INDONESIA
INDONESIE

Mr. Nelson Hutabarat
Agricultural Attache
Embassy of Indonesia
2020 Massachusetts Avenue, N.W.
Washington, D.C. 2036, U.S.

Mr. Irmawan Emir Wisnandar
Third Secretary
Embassy of Indonesia
2020 Massachusetts Avenue, N.W.
Washington, D.C. 20036, U.S.

ISRAEL

Dan Halpern
Institute of Quality Control
76, Mazeh Street
Tel-Aviv 65789, Israel

JAPAN
JAPON

Mr. Satoshi Takaya
Deputy Director
Food Sanitation Division
Environmental Health Bureau
Ministry of Health and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo 100, Japan

Mr. Keiji Hayashi
Technical Adviser
Japan Food Hygiene Association
Japan

MADAGASCAR

Mr. Biclair H. G. Andriantoandro
Counselor for Economic and Commercial Affairs
Embassy of Madagascar
2374 Massachusetts Avenue, NW
Washington, D. C. 20008, U.S.

MALAYSIA
MALAISIE

Dr. Rahman bin Ismail
Health Division
Kuala Lumpur City Hall
Malaysia

MEXICO
MEXIQUE

Ms. Josephine Gomez Miranda
Km 12 1/2 Carretera Federal
Cuernavaco-Cunutla
Jiutepec, Morelos, Mexico

NETHERLANDS
PAYS-BAS
PAISES BAJOS

J. T. Jansen
Ministry of Welfare, Health and
Cultural Affairs
General Inspectorate for Health
Protection
P.O. Box 5406
2280 HK Rijswijk (Z. H.)
Netherlands

Dr. M. H. de Jong
Ministry of Agriculture, Nature
Management and Fisheries
Department for the Environment,
Quality and Nutrition
P.O. Box 20401
2500 EK The Hague
Netherlands

M. J. A. Bouwman
Netherlands Controlling Authority for
Milk and Milk Products
P.O. Box 250
3830 AG Leusden, Netherlands

Dr. Martin J. M. Michels
Unilever Research Laboratory
P.O. Box 114
3130 AC Vlaardingen, Netherlands

NEW ZEALAND
NOUVELLE ZELANDE
NUEVA ZELANDIA

Mrs. J. A. Bullians
National Assessor (Compliance)
MAF Regulatory Authority (Meat and
Seafood)
P.O. Box 10136, Te Rapa
Hamiltion, New Zealand

NEW ZELAND (Cont.d)

Mr. J. W. van den Beuken
Food Technologist
Food Administration Section
Department of Health
P.O. Box 5013
Wellington, New Zealand

NIGERIA

Mr. Patrick Taggert
Chief Fisheries Officer
Fish Inspection and Quality Assurance
Department of Fisheries, Agricultural
Cooperatives and Fertilizer
Federal Ministry of Agriculture
Victoria Island,
P.M.B. 12529 Lagos, Nigeria

NORWAY
NORVEGE
NORUEGA

Mr. Gunnar Langeland
Norwegian Food Control Authority
P.O. Box 8187 Dep
N-0034 Oslo, Norway

Mr. Per Henrik Prante
Head of Institute
NORCONSERV
Institute of Fish Processing and
Preservation Technology
P.O. Box 327, N-4001 Stavanger, Norway

POLAND
POLOGNE
POLONIA

Dr. Lucjan Szponar
Director
National Food and Nutrition Institute
Powsinska 61/63
02-903 Warsaw, Poland

SPAIN
ESPAGNE
ESPAÑA

Oscar Hernández
Ministerio de Sanidad y Consumo
Paseo Del Prado 18-20
28014 Madrid, Spain

SWEDEN
SUEDE
SUECIA

Eva Lönberg
National Food Administration
Box 622
751 26 Uppsala, Sweden

Professor Sven E. Lindgren
National Food Administration
Box 622
S75126 Uppsala, Sweden

SWITZERLAND
SUISSE
SUIZA

Andreas Baumgartner
Federal Office of Public Health
Division of Food Science
Section of Microbiology
Haslerstrasse 16, 3008 Bern
Switzerland

Mr. O. Bindschendler
Nestec SA
CH-1800 Vevey, Switzerland

THAILAND
THAILANDE
TAILANDIA

Mrs. Achara Poomchatra
Director, Division of Food-for-Export Analysis
Department of Medical Sciences,
Ministry of Public Health
693 Bumrungmaung Road, Bangkok 10100,
Thailand

Mr. Suwit Imngern
Catering Services Department,
Thai Airways International Ltd.
Bangkok, Thailand

Dr. Amonchai Hanpadungdhama
Manager, Hygiene Division (CG)
Thai Airways International Ltd.
Bangkok Airport
Bangkok 10210, Thailand

THAILAND (Cont.d)

Ms. Ranee Kumton
Standards Officer
Thai Industrial Standards Institute
Rama 6 Street
Bangkok 10400, Thailand

Mrs. Helen Arromdee
Industrial Works Department
Ministry of Industry
57 Phrasumain Road, Chanasongkarm,
Pranakorn, Bangkok, 10200
Thailand

Dr. Thanit Yingvana-Siri
Agriculture Attache, Embassy of Thailand
Washington, D.C., U.S.

UNITED KINGDOM
ROYAUME-UNI
REINO UNIDO

Dr. Roger Skinner
Principal Medical Officer
Department of Health, Health Aspects of Environment and Food Division
Skipton House, Room 539B
80 London Road
Elephant and Castle
London, SE1 6LW. U.K.

Dr. David Harper
Senior Principal Scientific Officer
Department of Health, Health Aspects of Environment and Food Division
Skipton House, Room 541B
80 London Road
Elephant and Castle
London, SE1 6LW

Mr. John F. Barnes
Principal Environmental Health Officer
Department of Health, Health Aspects of Environment and Food Division
Skipton House, Room 554C
80 London Road
Elephant and Castle
London, SE1 6LW, U.K.

UNITED KINGDOM (Cont.d)

Ms. Caroline Brock
Principal
Department of Health, Health Aspects
of Environment and Food Division
Skipton House, Room 636B
80 London Road
Elephant and Castle
London, SE1 6LW, U.K.

Dr. Robert Mitchell
Principal Scientific Officer
Ministry of Agriculture, Fisheries and
Food Microbiological Safety of Food
Division "B"
Ergon House, Room 213
c/o Nobel House
17 Smith Square
London, SW1P 3JR, U.K.

Mr. Christopher Pratt
Principal
Ministry of Agriculture, Fisheries and
Food
Microbiological Safety of Food
Division "B"
Ergon House, Room 508
c/o Nobel House, 17 Smith Square
London, SW1P 3JR, U.K.

Mr. Malcolm C. Kane
Chief Food Technologist
J. Sainsbury plc, Stamford House
Stamford Street, Blackfriars,
London SE1 9LL, U.K.

Dr. Anthony C. Baird-Parker
Head of Microbiology Division
Unilever Research
Colworth Laboratory
Colworth House
Sharnbook, Bedford, Mk44 ILQ
U.K.

UNITED STATES
ETATS UNIS
ESTADOS UNIDOS

Mr. E. Spencer Garrett
Laboratory Director
DOC/NOAA/National Marine Fisheries
Service
National Seafood Inspection Laboratory
3209 Frederic Street
Pascagoula, MS 39568-1207, U.S.

UNITED STATES (Cont.d)

Dr. Stanley S. Green, Chief
Microbiological Monitoring &
Surveillance Branch
USDA, FSIS, S&T, MD
Room 408 Annex Building
Washington, DC 20250, U.S.

Dr. George Jackson
Special Assistant
Office of Special Research Skills
(HFS-501)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, U.S.

Mr. Raymond D. Beaulieu
Retail Food Protection Branch
(HFS-627)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, U.S.

Dr. Dale D. Boyle, DVM
Lieutenant Colonel, USA
Naval Supply System Command
Crystal Mall, Building #3, Room 710
1931 Jefferson Davis Highway
Arlington, VA 22202, U.S.

Dr. George P. Hoskin
Associate Director
Office of Seafood (HFS-400)
Food and Drug Administration
200 C Street SW
Washington, DC 20204, U.S.

Dr. John E. Kvenberg
Director
Division of Cooperative Programs
(HFF-625)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, U.S.

Dr. Thomas Mulvaney
Scientific Advisor for Processing
Office of Plant and Dairy Foods
and Beverages (HFS-302)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, U.S.

UNITED STATES (Cont.d)

Mr. Johnnie G. Nichols
Chief, Milk Safety Branch
Division of Cooperative Programs
(HFS-626)
Food and Drug Administration
200 C Street SW
Washington, DC 20204, U.S

Mr. E. Jeffery Rhodehamel
Division of HACCP Programs (HFS-615)
Food and Drug Administration
200 C Street SW
Washington, DC 20204, U.S.

Mr. Robert A. Miller
Branch Chief
Thermal Processing Branch, PPID, S&T
Food Safety and Inspection Service
U.S. Department of Agriculture
Room 2155, South Building
14th and Independence Avenue SW
Washington, DC 20250, U.S.

Mr. Stephen Spinak
Food Technologist
Regulatory Food Processing and
Technology Branch (HFS-617)
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, U.S.

Mr. Dane Bernard
Senior Director, Microbiology Division
National Food Processors Assn.
Eastern Research Laboratory
1401 New York Avenue, NW
Washington, DC 20005, U.S.

Mr. Cleve Denny
6230 Valley Road
Bethesda, MD 20817, U.S.

Dr. Michael J. DiGeronimo
President and General Manager
Dover Brook Associates
P.O. Box 177
Chester, NY 10918, U.S.

Dr. Andrew G. Ebert
Technical Director
5775 Peachtree-Dunwoody Road
Suite 500-G
Atlanta, GA 30342, U.S.

UNITED STATES (Cont.d)

Dr. George Evancho
Director of Microbiology
Campbells Institute for Research and
Technology
Campbell Place
Camden, NJ 08103, U.S.

Ms. Martha Hudak-Roos
mhr Consultants
109 Keyser Street
Marietta, OH 45750, U.S.

Mr. Roy Martin
Vice President for Science and
Technology
National Fisheries Institute, Inc.
1525 Wilson Blvd., Suite 500
Arlington, VA 22209, U.S.

Ms. Jenny Scott
Associate Director, Microbiology
Division
National Food Processors Assn.
1401 New York Avenue, NW
Washington, DC 20005, U.S.

INTERNATIONAL ORGANIZATIONS
ORGANISATION INTERNATIONALES
ORGANIZACIONES INTERNACIONALES

AOAC INTERNATIONAL (AOAC)

Mr. George R. Heavner
Technical Coordinator
AOAC International
2200 Wilson Boulevard, Suite 400
Arlington, VA 222201-3301, U.S.

EUROPEAN ECONOMIC COMMUNITY (EEC)

Mr. Henri Belveze
Administrateur Principal
Commission des Communautes Europeennes
Direction Generale de l'Agriculture
Rue de la Loi 200
1049 Brussels, Belgium

Mr. Alex Mossel
Commission of the European Communities
Direction Generale Marche
Interieur et Affaires Industrielles
Rue de la Loi, 200
1049 Brussels, Belgium

EEC (Cont.d)

Mr. Giuseppe Verardi
Commission of the European Communities
Direction General for Agriculture
Rue de la Loi, 200
1049 Brussels, Belgium

Mr. Bent Mejborn
EC-Council Secretariat
Rue de la Loi, 170
B-1048 Bruxelles, Belgium

INTERNATIONAL FEDERATION OF GROCERY MANUFACTURERS ASSOCIATIONS (IFGMA)

Dr. Catherine Adams
Director, Scientific Affairs
Grocery Manufacturers of America, Inc.
1010 Wisconsin Ave., NW
Washington, DC 20007, U.S.

INTERNATIONAL DAIRY FEDERATION (IDF)

Mr. Claus Heggum
Danish Dairy Board
Frederiks Alle 22
DK-8000 Aarhus C, Denmark

PAN AMERICAN HEALTH ORGANIZATION (PAHO)

Dr. Claudio Almeida
Regional Advisor in Food Protection
Veterinary Public Health Program
Pan American Health Organization
525 Twenty-Third Street, NW
Washington, DC 20037-2895, U.S.

INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS FOR FOODS (ICMSF)

Dr. M. van Schothorst
Secretary of the ICMSF
Food Safety and Environmental Affairs
Nestec Ltd.
Nestle Research Centre
P.O. Box 44
CH-1000 Lausanne 26
Switzerland

FOOD AND AGRICULTURE ORGANIZATION (FAO)

Mr. A. J. Whitehead
Consultant
Food Quality and Standards Service
Food Policy and Nutrition Division
Food and Agriculture Organization
Via delle Terme di Caracalla
00100 Rome, Italy

WORLD HEALTH ORGANIZATION (WHO)

Dr. F. K. Käferstein
Chief, Food Safety Unit
Division on Health Protection and Promotion
World Health Organization
1211 Geneva 27, Switzerland

JOINT FAO/WHO SECRETARIAT

Dr. Alan Randell
Senior Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the United Nations
Via delle Terme di Caracalla
00100 Rome, Italy

Ms. Selma H. Doyran
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the United Nations
Via delle Terme di Caracalla
00100 Rome, Italy

UNITED STATES SECRETARIAT

Ms. Rhonda S. Nally
Executive Officer for Codex Alimentarius
FSIS, Room 3175-South Building
U.S. Department of Agriculture
14th and Independence Ave., SW
Washington, DC 20250, U.S.

UNITED STATES SECRETARIAT (Cont.d)

Ms. Patty L. Woodall
Staff Assistant for Codex Alimentarius
FSIS, Room 3175-South Building
U.S. Department of Agriculture
14th and Independence Ave, SW
Washington, DC 20250, U.S.

Ms. Kathy R. LaQuay
Program Assistant
FSIS, Room 3175-South Building
U.S. Department of Agriculture
14th and Independence Ave, SW
Washington, DC 20250, U.S.

Mr. Craig Fedchock
Advisory Committee Specialist
FSIS, Room 3175-South Building
U.S. Department of Agriculture
14th and Independence Ave, SW
Washington, DC 20250, U.S.

Ms. Edna E. Poe
Program Analyst
Division of HACCP Programs (HFS-618)
Food and Drug Administration
200 C Street SW
Washington, DC 20204, U.S.

Mr. Nathaniel L. Murrell
Division of HACCP Programs (HFS-618)
Center for Food Safety and Applied
Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204, U.S.

SPECIAL PARTICIPANTS

Dr. Patricia M. Griffin
Assistant Chief, Epidemiology Section
Enteric Diseases Branch
Centers for Disease Control
Building 1, Room 4065
Atlanta, GA 30333, U.S.

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

1. Assemble the HACCP Team
2. Describe Product
3. Identify Intended Use
4. Construct Flow Diagram
5. On-Site Verification of Flow Diagram
6. List All Identified Hazards Associated With Each Step and Consider Preventative Measures to Control Hazards

Step	
Identified Hazard	Preventative Measures (PM)
Biological Chemical Physical	

7. Apply HACCP Decision Tree to Each Step With Identified Hazard(s) (Answer Questions in Sequence)

Q1 → Yes

Do Preventative Measure(s) Exist?

↓ No → Modify step, process or product

Is control at this step for safety? → YES

↓ NO → Not a CCP → STOP(*)

Q2 Is the Step Specifically Designed to Eliminate or Reduce the Likely Occurrence of a Hazard to an Acceptable Level? → Yes

↓ No

Q3 Could Contamination With Identified Hazard(s) Occur in Excess of Acceptable Level(s) or Could These Increase to Unacceptable Level(s)?

↓ Yes ↓ No → Not a CCP → STOP(*)

Q4 Will a Subsequent Step Eliminate Identified Hazard(s) or Reduce Likely Occurrence to an Acceptable Level?

↓ Yes ↓ No → Critical Control Point

↓ Not a CCP → STOP(*)

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

8. Establish Critical Limits for Each CCP
9. Establish a Monitoring System for Each CCP
10. Establish Corrective Action for Deviations that May Occur
11. Establish Verification Procedures
12. Establish Record Keeping and Documentation

Figure 2

HACCP WORKSHEET

1. Describe Product

2. Diagram process flow

3. List:

Step	Hazard(s)	Preventative Measure(s)	CCP(S)	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4. Verification

DRAFT OF HYGIENIC PRACTICE FOR ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID FOODS

(At Step 8 of the Procedure)

TABLE OF CONTENTS

DRAFT CODE OF HYGIENIC PRACTICE FOR ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID FOODS

INTRODUCTION

"Aseptic processing and packaging" means the processing and packaging of a commercially sterile product into sterilized containers followed by hermetically sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product. Aseptic processing and packaging differs from canning in that in canning the food is placed in the can, sealed and heat processed in that order.

The provisions of this code will provide guidance for identification of Critical Control Points for establishment developed HACCP plans as recommended in the Codex Food Hygiene Committee draft of Principles and Application of the Hazard Analysis Critical Control Point (HACCP) System [(Alinorm 93/13 Appendix IV) (reference to be updated when HACCP code is endorsed)]. Establishments engaged in aseptic processing and packaging are encouraged to develop and operate under a HACCP plan.

1.0 SECTION I - SCOPE

This code of practice is concerned with the aseptic processing and packaging of low-acid foods as defined in this code. It does not apply to those low-acid foods in hermetically sealed containers processed by conventional canning procedures nor to those that require refrigeration for their preservation, nor to acid and acidified low-acid products.

Acidified low-acid and conventionally canned low-acid foods are dealt with in the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods.

2.0 SECTION II - DEFINITIONS

For the purpose of this Code:

2.1 "Aseptic" means commercially sterile.

2.2 "Aseptic processing and packaging" means the processing and packaging of a commercially sterile product into sterilized containers followed by hermetic sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product.

2.3 "Aseptic zone" means the area required to be made and maintained sterile such that sterile product and containers will not be recontaminated by microorganisms. This zone is bounded by physical barriers such as structural features or sterile air flows.

2.4 "Canned food" means commercially sterile food in hermetically sealed containers.

2.5 "Cleaning" means the removal of food residues, dirt, grease or other objectionable material.

2.6 "Code lot" means all product produced during a period of time identified by a specific container code mark.

2.7 "Commercial sterility" means the absence of microorganisms capable of growing in the food at normal nonrefrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.

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

2.9 "Equilibrium pH" means the pH of a finished food once all components have attained pH uniformity.

2.10 "Flow diversion system" means product piping and valving designed to divert potentially non-sterile product from the filler or aseptic surge tank.

2.11 "Headspace" means the volume in a container not occupied by the food.

2.12 "Hermetically sealed containers" means containers which are designed and intended to protect the contents against the entry of viable microorganisms after closing.

2.12.1 "Flexible container" means that the shape or contours of the filled, sealed container are affected by the enclosed product.

2.12.2 "Semi-rigid container" means that the shape or contours of the filled, sealed container are not affected by the
enclosed product under normal atmospheric temperature and pressure but can be deformed by an external mechanical pressure of less than 0.7 kg/cm^2 (10 psi), i.e., normal finger pressure.

2.12.3 "Rigid container" means that the shape or contours of the filled and sealed container are neither affected by the enclosed product nor deformed by an external mechanical pressure of up to 0.7 kg /cm^2 (10 psi), i.e., normal finger pressure.

2.13 "Hold Section" means the section (for example, hold tube) of the food product sterilizing system in which the heated food is maintained for a time and temperature sufficient to attain commercial sterility of the food.

2.14 "Incubation tests" means tests in which the heat processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs under these conditions.

2.15 "Low-acid food" means any food, other than alcoholic beverages, where any component has a pH value greater than 4.6 and a water activity greater than 0.85.

2.16 "Potable water" means water fit for human consumption. Standards of potability should be no less strict than those contained in the latest edition of the "Guidelines for Drinking Water Quality - Volume 1", World Health Organization.

2.17 "Preproduction sterilization" means the commercial sterilization of all necessary equipment before commencement of production.

2.18 "Product-to-product regenerator" means the equipment designed to exchange heat between hot product and cold product aseptically.

2.19 "Scheduled process" means all the conditions needed to achieve and maintain commercial sterility of equipment,containers and food.

2.20 "Seals" mean those parts of a container which are formed, bonded or fused together in order to close the container.

2.21 "Steam seal" means an enclosure that utilizes steam as a barrier to entry of microorganisms.

2.22 "Sterilant" means any physical and/or chemical treatment used to achieve commercial sterility.

2.23 "Sterile" means commercially sterile.

2.24 "Sterility" means commercial sterility.

2.25 "Sterilization temperature" means the temperature of the thermal process as specified in the scheduled process.

2.26 "Sterilization time" means the time specified in the scheduled process.

3.0 SECTION III - HYGIENE REQUIREMENTS IN THE PRODUCTION/HARVESTING AREAS

3.1. Environmental Hygiene and Areas from which Raw Materials are Derived

3.1.1 Unsuitable growing or harvesting areas Food should not be grown or harvested where the presence of potentially harmful substances would lead to an unacceptable level of such substances in the food.

3.1.2 Protection from contamination by wastes

3.1.2.1 Raw food materials 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 health hazard 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

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

3.1.4 Pest and disease control

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, particularly those which may arise from residues in the food. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

3.2 Harvesting and Production

3.2.1 Techniques

Methods and procedures associated with harvesting and production should be hygienic and such as not to constitute a potential health hazard or result in contamination of the product.

3.2.2 Equipment and containers

Equipment and containers used for harvesting and production should be so constructed and maintained as not to constitute a hazard to health. Containers which are re-used should be of such material and construction as will permit easy and thorough cleaning. They should be cleaned and maintained clean and, where necessary, disinfected. Containers previously used for toxic materials should not subsequently be used for holding foods or food ingredients.

3.2.3 Removal of obviously unfit raw materials

Raw materials which are obviously unfit for human consumption should be segregated during harvesting and production. Those which cannot be made fit by further processing should be disposed of in such a place and in such a manner as to avoid contamination of the food and/or water supplies or other food materials.

3.2.4 Protection against contamination and damage

Suitable precautions should be taken to protect the raw materials from being contaminated by pests or by chemical, physical or microbiological contaminants or other objectionable substances. Precautions should be taken to avoid damage.

3.3 Storage at the Place of Production/Harvesting

Raw materials should be stored under conditions which provide protection against contamination and minimize damage and deterioration.

3.4 Transportation

3.4.1 Conveyances

Conveyances for transporting the harvested crop or raw materials from the production area or place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit easy and thorough cleaning. They should be cleaned and maintained clean, and where necessary disinfected and disinfested.

3.4.2 Handling procedures

All handling procedures should be such as will prevent raw materials from being contaminated. Care should be taken to prevent spoilage, to protect against contamination and to minimize damage. Special equipment - such as refrigeration equipment - should be used if the nature of the product or distances involved so indicate. If ice is used in contact with the product it should be of the quality required in Sub-Section 4.4.1.2 of this Code.

4.0 SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

Establishments should be located in areas which are free from objectionable odors, 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 Buildings and Facilities

4.3.1 Buildings and facilities should be of sound construction and maintained in good repair.

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 harboring 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 material at the premises to the finished product, and should provide for appropriate temperature conditions for the process and the product.

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 and should be light colored. Up to a height appropriate for the operation they 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 covered to facilitate cleaning.

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.

Windows and other openings should be so constructed as to avoid accumulation of dirt and 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, 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 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 raw materials 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 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.

4.4 Sanitary facilities

4.4.1 Water Supply

4.4.1.1 An ample supply of water, in compliance with Sub-Section 7.3 of the Recommended International Code of Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 1), 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.

4.4.1.2 Ice should be made from water, in compliance with Sub-Section 7.3 of the General Principles referred to in Sub-Section 4.4.1.1, and should be manufactured, handled and stored so as to protect it from contamination.

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

4.4.1.4 Non-potable water used for steam production, refrigeration, fire control and other similar purposes not connected with food should be carried in completely separate lines, identifiable preferably by color, and with no cross-connection with or back-siphonage into the system carrying potable water (see also Sub-Section 7.3.2).

4.4.2 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.

4.4.3 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 on to food handling areas. Hand washing facilities with potable warm or hot and cold water, a suitable hand-cleaning preparation, and 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 dispensers 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 their hands after using the toilet.

4.4.4 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. Potable 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 operable type are desirable. The facilities should be furnished with properly trapped waste pipes leading to drains.

4.4.5 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.

4.4.6 Lighting

Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colors 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 food in case of breakage.

4.4.7 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 should never be from a dirty area to a clean area. Ventilation openings should be provided with a screen or other protecting enclosure of material which will not corrode. Screens should be easily removable for cleaning.

4.4.8 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, buildings or roadways on the premises.

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 which does not transmit toxic substances, odor or taste, is non-absorbent, resistant to corrosion and 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 materials in such a way that contact corrosion can occur should be avoided.

4.5.2 Sanitary design, construction and 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. Processors should have suitable systems for transporting container materials. System design, structure and installation should ensure that container material does not become contaminated or unacceptable because of damage.

4.5.2.2 Containers for inedible material and waste should be leakproof, constructed of metal or other suitable impervious material which should be easy to clean or disposable and able to be closed securely.

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

4.5.2.4 Equipment identification

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

4.6 Steam Supply

Steam supply to the thermal processing system should be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands for steam by the plant.

4.7 Sterile Gas Supply

Air, or other appropriate gases should be filtered for removal of extraneous material (dust, oils and the like) and rendered sterile. Sterilization may be achieved by double filtration within one filter housing or two separate filter housings, or by a combination system such as incineration followed by filtration. The system used to deliver the commercially sterile air or other gas to the point of use should be capable of being sterilized prior to use and being maintained in a sterile condition during operation.

4.7.1 The filters used should have a demonstrated and verified capability to provide the degree of removal of microorganisms and extraneous material required under the conditions of use. They should be examined before installation and after removal for evidence of damage which may result in malfunction. They should not be affected by the gases in any manner which would reduce their efficacy or shorten their working life. Filters used for commercial sterilization should be installed, maintained and changed in accordance with the manufacturer's instructions. Their performance should periodically be verified using appropriate test methods and records maintained.

4.7.2 If incineration is used to provide sterile air, critical factors such as final air temperature and flow rate should be controlled and recorded.

5.0 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 good repair and in an orderly condition. As far as practicable, rooms should be kept free from steam, vapor and surplus water.

5.2 Cleaning and Disinfection

Cleaning and disinfection should meet the requirements of Appendix I of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1 of this Code.

5.2.1 To prevent contamination of food, containers, container materials and all equipment and utensils should be cleaned as frequently as necessary and disinfected whenever circumstances demand.

5.2.2 Adequate precautions should be taken to prevent food and container materials 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 into contact with food should be removed by thorough rinsing with water, in compliance with Sub-Section 7.3 of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1 before the area or equipment is again used for handling food.

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

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

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

5.3 Hygiene Control Programmer

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 material are designated for special attention. A single individual, who should preferably be a permanent member of the 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 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 should be stored in such a manner as to avoid contamination of food. They should be removed from the working areas as often as necessary and at least daily.

5.5 Storage and 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.

5.6 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 programmer 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 the use of these agents, including those hazards 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.

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

5.8 Storage of Hazardous Substances

5.8.1 Pesticides or other substances (e.g. hydrogen peroxide) which may represent a hazard to health should be suitably labeled 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 food.

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

5.9 Personal Effects and Clothing

Personal effects and clothing should not be deposited in food handling areas.

6.0 SECTION VI: PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene Training

Managers of establishments should arrange for adequate and continuing training of all food handlers in hygienic handling of food and 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 into 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, whether 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 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 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 any likelihood of such a person directly or indirectly contaminating food with pathogenic microorganisms. Any person so affected should immediately report to the management that he is ill.

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 water-proof covering which is firmly secured, and which is conspicuous in color. Adequate first-aid facilities should be provided for this purpose.

6.5 Washing of Hands

Every person, while on duty in a food handling area should wash his hands frequently and thoroughly with a suitable hand cleaning preparation under running warm potable water. 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 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, while on duty in a food handling area should maintain a high degree of personal cleanliness, and should at all times while so engaged wear suitable protective clothing including head coverings and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor. During periods where food is manipulated by hand, any jewelry that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewelry when engaged in food handling.

6.7 Personal Behavior

Any behavior which could result in contamination of food such as eating, use of tobacco, chewing e.g., gum, sticks and betel nuts, or unhygienic practices such as spitting, should be prohibited in food handling areas.

6.8 Gloves

Gloves, if used in the handling of food products, 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 prevent visitors to food handling areas from contaminating food. These may include the use of protective clothing. Visitors should observe the provisions recommended in Sub-Sections 5.9, 6.3, 6.4 and 6.7 of this code.

6.10 Supervision

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

7.0 SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

7.1.1 No raw material or ingredient should be accepted by the establishment if known to contain parasites, microorganisms or toxic, decomposed or extraneous materials which will not be reduced to acceptable levels by normal plant procedures of sorting and/or preparation of processing.

7.1.2 Raw materials or ingredients should be inspected and sorted prior to being moved into the processing line and where necessary laboratory tests should be made. Only clean, sound raw materials or ingredients should be used in further processing.

7.1.3 Raw material and 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 raw materials and ingredients should be properly rotated.

7.1.4 Blanching by heat, when required in the preparation of food for aseptic processing, should be followed by either rapidly cooling the food or subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by good design, the use of adequate operating temperatures and by routine cleaning.

7.1.5 All steps in the preparation of the food should be performed under conditions which will minimize or prevent contamination, and deterioration, and minimize the growth of microorganisms in the food.

7.2 Prevention of Contamination of Raw and Semi-Processed Product Ingredients

7.2.1 Effective measures should be taken to prevent contamination of food material by direct or indirect contact with material at an earlier stage of the process.

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 raw materials or semi-processed products which have come into direct contact with or have been soiled by raw materials or semi-processed products and they have changed into clean protective clothing.

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

7.2.4 All equipment which has been in contact with raw materials or contaminated material should be thoroughly cleaned and disinfected before use or prior to contact with food which has been further processed.

7.3 Use of Water

7.3.1 As a general principle only potable water 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 or re-used 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.

7.3.4 In systems which utilize heat alone to sterilize containers and water is necessary to cool containers before they are filled with product, the water used must be sterilized, cooled, and delivered sterile to the point of use.

7.4 Packaging

7.4.1 Storage and characteristics of container materials

7.4.1.1 All container 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 container material should be sound and should provide appropriate protection from contamination. The product containers should be sufficiently durable to withstand the mechanical, chemical and thermal stresses encountered during normal distribution. An overwrap may be necessary for flexible and semi-rigid containers. With laminates particular attention should be paid to ensure that the combination of processing requirements and product characteristics does not cause delamination, as this may result in loss of integrity.

The sealant material chosen must be compatible with the product as well as the container and closure systems. The closures for glass containers are particularly susceptible to mechanical damage which may result in a temporary or permanent loss of hermetic seal. The closures of sealed jars should therefore be contained within the glass body diameter to avoid closure to closure contact of sealed jars.

7.4.1.2 All empty containers or container material used in aseptic systems should be as clean as possible. Soiled or damaged aseptic packaging materials, may impede sterilization and proper sealing and should not be used. Aseptic container material may be affected by changes in physical parameters such as relative humidity and should be stored so as to minimize such changes. All storage and handling procedures should minimize the chance of contamination or damage of packaging material.

7.4.2 Inspection of container materials and containers

7.4.2.1 Appropriate sampling and inspection schemes should be used by both container manufacturers and food processors to ensure that containers and closures are in compliance with jointly agreed specifications and any requirements of the agency having jurisdiction that may apply. As a minimum these should include those inspections and measurements given in Sub-Section 7.4.8 of this Code.

7.4.2.2 If container or container material cleaning methods are available, they may be used providing the cleaning process does not prevent proper sterilization of container material or its barrier properties after filling and sealing. Inspection is particularly important in the case of glass containers which might possibly contain fragments of glass and glass defects which are difficult to see.

7.4.2.3 Faulty containers should not be filled. Care should be taken to avoid damage to empty containers, closures and container materials which can result from faulty handling prior to closure. If these are filled, material will be wasted and there is always a danger of damaged containers jamming a filling or sealing machine and necessitating a shutdown and resterilization. Faulty containers may leak during or after processing and storage.

7.4.2.4 The food processor should ensure that the container and closure specifications are such that the container is capable of withstanding the processing and subsequent handling strains to which the containers are normally subjected. Since such specifications may vary depending upon the aseptic operation and subsequent handling, these should be established in consultation with the container or closure manufacturer.

7.4.3 Cleaning of container materials

7.4.3.1 Container materials to be sterilized chemically as with hydrogen peroxide should be stored in accordance with 7.4.1.2 so that the necessity for cleaning is avoided.

7.4.4 Proper use of containers

Containers must never be used within the processing facility for any purpose other than packing food. They must never be used as ash trays, small waste containers, receptacles for small machine parts or for other purposes. This should

be avoided because there is a considerable risk that such containers may accidently find their way back onto the production line and result in the packing of food in the same container with very objectionable or possibly dangerous material.

7.4.5 Protection of container materials during plant cleaning

Container materials should be removed from the packing room and from the conveyors which lead to the filling machines before production lines are washed down. If not practicable they should be shielded or located so that they will not become contaminated or obstruct clean-up operations.

7.4.6 Forming of product containers

In-line formation of containers from container materials should be accomplished according to container material and/or packaging machine manufacturer's specifications and should be formed by a method which maintains container integrity and prevents aseptic zone and container contamination.

7.4.7 Filling of product containers

During filling, contamination of seal or seam areas with product should be avoided unless equipment is specifically designed to remove product from seal areas prior to sealing. (Overfilling and splashing can lead to contamination of seams or seals and adversely affect container integrity).

7.4.8 Closing operations

7.4.8.1 Particular attention should be given to the operation, maintenance, routine checking and adjustment of container closing equipment. Sealing and closing machines should be fitted and adjusted for each type of container material used. Seams and other closures should be tight and secure and meet the requirements of the container material and closing equipment manufacturers, the food processor and those of the agency having jurisdiction.

7.4.8.2 Seam or seal areas should be kept as clean and dry as necessary to obtain a satisfactory closure.

7.4.9 Inspection of closed containers

7.4.9.1 Inspection for external defects

During production runs, regular observations should be made for external container defects. At intervals of sufficient frequency to ensure proper closure, the operator, closure inspector, or other person competent to inspect containers and their closures, should examine the filled, sealed containers for product leakage or the presence of defects which may affect container integrity. Records of observations should be maintained and, where irregularities are found, corrective action should be taken. Additional visual closure inspections should be made immediately following a machine malfunction, adjustment or start-up following a prolonged shut down.

The specifications of the container materials and closing equipment manufacturers, the food processor and those of the agency having jurisdiction for examining each container should be followed exactly.

7.4.9.1.1 Inspection of glass container closures

For glass containers see 7.4.8.1 of the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods. Appropriate detailed inspections and tests should be conducted by competent personnel at intervals of sufficient frequency to ensure consistently reliable hermetic sealing. Many different designs of closures exist for glass jars, so that it is impossible to give definitive recommendations for such closures. The recommendations of the manufacturer should be carefully followed. Records of such tests and corrective actions taken should be maintained.

7.4.9.1.2 Inspection and tear-down of double seams

For metal containers, see 7.4.8.1.2 of the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods.

For plastic containers with metal ends, consult the container manufacturer.

7.4.9.1.3 Inspection of heat seals

Appropriate inspections and tests should be conducted by competent, trained and experienced personnel at intervals of sufficient frequency to ensure consistent reliable hermetic sealing. Records of such tests and corrective action required should be maintained. Inspection may include some physical testing for strength of the seals. There are several ways of checking seal integrity, for example, burst-pressure testing, and seal thickness measurements. Appropriate methods should be obtained from the container material and closing equipment manufacturers of these containers or materials.

7.4.9.1.4 Other mechanical closures

Appropriate tests should be carried out by competent, trained and experienced personnel at intervals of sufficient frequency to ensure consistent, reliable hermetic sealing. These tests should be conducted in accordance with the container material and/or equipment manufacturer's instructions; and should include at least tests to check that critical sealing components, such as seal rings and membranes, are intact and are of a number, material and location required to ensure maintenance of a hermetic seal.

7.4.9.1.5 Closure defects

If, upon routine inspection, a seam or closure defect that would result in a loss of hermetic integrity is found, all products produced between the discovery of the fault and the last satisfactory check should be identified and assessed. Corrective action should be taken and recorded.

7.4.10 Handling of containers after closure

7.4.10.1 At all times containers should be handled in a manner that protects containers and closures from damage which may cause defects and subsequent microbial contamination. Design, operation and maintenance of container handling methods should be appropriate for the types of containers and materials used. Where necessary, containers should be overwrapped. They should be kept dry and clean prior to overwrapping.

The risk of microleakage may be increased by inadequately designed, controlled and maintained container conveyor, handling, labeling and packaging equipment which may result in increased container abuse. Conveying systems and equipment should be designed to minimize abuse, and conveyor and equipment surfaces should be appropriately cleaned and disinfected and may need to be kept dry. Mechanical shock or abuse must be avoided by proper design. Careful attention to layout, operation and maintenance of conveyance systems is necessary if abuse is to be reduced to a minimum.

7.4.10.2 Semi-rigid and flexible containers may be prone to certain types of damage, (for example, snagging, tearing, cutting and flex cracking) and should be handled with special care. Containers having sharp edges should be avoided as they may cause damage.

7.4.11 Coding

7.4.11.1 Each container should be marked with an identifying alphanumeric code which is permanent, legible and does not adversely affect the container integrity. Where the container does not permit the code to be embossed or inked, the label should be legibly perforated or otherwise marked, and securely affixed to the product container.

7.4.11.2 The code mark should identify the establishment where the product was packed, the product, the year and the day of the year and preferably the period of the day when the product was packed.

7.4.11.3 The code mark permits the identification and isolation of code lots during production, distribution and sale. Food producers may find it useful to have a coding system from which the particular processing line and/or aseptic packaging machine can be identified. Such a system, supported by adequate records, can be very helpful in any investigation.

7.4.11.4 The identification of code lots on shipping cases and trays is desirable.

7.4.12 Washing and drying of filled, sealed containers

7.4.12.1 Only potable water as described in 7.6.8.1 Draft Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods should be used for washing containers.

7.4.12.2 Methods and equipment for washing and/or drying of filled sealed containers should not cause damage. The equipment should be readily accessible for cleaning and disinfection.

7.4.13 Cooling of filled, sealed containers

Where filled, sealed containers are cooled, procedures as described in 7.6.8 of the Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods should be followed.

7.5 Sterilization of equipment, containers and food

7.5.1 General considerations

7.5.1.1 Scheduled processes must be established by competent persons having expert knowledge of aseptic processing and packaging and having adequate facilities for making such determinations. It is absolutely necessary to establish the required processes using accepted scientific methods.

7.5.1.2 Low-acid foods with pH values above 4.6 may be able to support the growth of many kinds of microorganisms including heat resistant sporeforming pathogens such as Clostridium botulinum. It should be emphasized that the aseptic processing and packaging of low-acid foods is a very critical operation, involving public health risks and appreciable losses of finished product if inadequate sterilization occurs.

7.5.2 Establishing the scheduled process

7.5.2.1 The scheduled process will consider the following elements:

1. Product

2. Product contact surfaces

3. Container materials

4. Gases

5. Equipment

Complete records concerning all aspects of the establishment of the scheduled process, including any associated incubation tests, should be retained permanently.

7.5.2.2 The required thermal process to achieve commercial sterility of a food should be established on the basis of factors such as:

Microbial flora including Clostridium botulinum and spoilage microorganisms;

Product composition or formulation;

Levels and types of preservatives;

Equilibrium pH;

Water activity;

Likely storage temperature of the product.

Since for these systems, food products are thermally processed before packaging, traditional methods for deriving and verifying a thermal process used in conventional canning must be modified. The essential elements in the establishment of an adequate thermal process are the heating characteristics of the food product and the inactivation kinetics (thermal resistance) of specific target microorganisms. The product is brought to sterilization temperature and held at that temperature for a

time necessary to achieve commercial sterility. In continuous product flow systems the time for which the product must be held at the sterilization temperature to attain commercial sterility is achieved in the hold section or tube. The flow rate of each and every particle in the hold section or tube is critical. Therefore, it is essential that the rate of flow for the fastest particle or the shortest particle retention time be accurately determined for each product flow rate; length, dimension and design of the hold section; and, product type and characteristics. Methods, such as dye or salt injection, are available to determine minimum residence time. Mathematical models (formulae) have been developed which can be used to calculate the minimum residence time required by a product to achieve commercial sterility. These models incorporate the flow rate, physical dimensions and design of the hold section and the rheological properties of the product. For situations where flow characteristics of the product are unknown, verify the calculations by actual measurement. Properly designed and conducted product studies may be used in support of the establishment and validation of the thermal process. The inoculated pack test is one method commonly used to validate the calculated process.

Determination of the hold or residence time for products containing discrete particles includes consideration of the thermal properties, shape, dimension, mass, etc. of each type of particle and particle to fluid ratio.

For those systems where product is batch sterilized followed by aseptic transport and filling, the sterilization is affected by hold time and temperature in the heating vessel. In this case, sterilization time can be precisely controlled. Batch type systems are used primarily for processing of products containing discrete particles. The hold time will depend (as with hold tubes) on the time needed to sterilize every particle of food. Thus, the heating rate of each type and size of discrete particle must be determined and used in the calculation of the minimum hold time and temperature for each product.

These principles also apply to systems which utilize resistance heating, microwave heating or other forms of energy to heat the food. The amount of energy needed to heat every portion of every particle of food to a temperature adequate to achieve commercial sterility must be determined. Delivery of this energy to the product must be controlled, monitored and recorded. All product characteristics (such as conductivity, particle size, etc.) which may affect the delivery of the process must be defined, controlled, monitored and recorded.

Any changes in product composition or formulation should be evaluated as to their effect on the adequacy of the process. If the scheduled process is found to be inadequate, the thermal process must be re-established.

If steam injection or steam infusion is used, the addition of water (from the condensation of steam) increases the product volume by approximately 1% per 5.6°C (10°F) temperature increase above initial product temperature as it enters the product sterilizer. Volume increase may also be affected by thermal expansion of the food. This increase in product volume due to the addition of water and thermal expansion should be compensated in the establishment of the process. Product feed rate may be controlled by a positive displacement pump or continuously monitored and recorded using an accurate flow meter recording device. If a flow meter recording device is used to monitor and record product feed rate after steam injection or infusion, the device should be calibrated, using appropriate methods such as volumetric flow or injection tracing (e.g., salt or dye) methods, at a frequency sufficient to ensure accurate flow of the specific products being processed.

7.5.2.3 Preproduction equipment sterilization

7.5.2.3.1 Processing, holding and filling equipment

Before production begins, all piping, valves, pumps, surge tanks and product fillers and other product contact surfaces downstream from the hold section or tube must be brought to a condition of commercial sterility, and this condition must be maintained until production is completed. Clean food contact surfaces can be sterilized by exposure to high temperature water under pressure, or saturated steam, or other appropriate treatments. Temperatures reached during the sterilization cycles should be determined by accurate temperature measuring devices, e.g., calibrated thermocouples, at the critical points in the system or at least at the slowest heating (coldest point) of the system. Sufficient temperature measurements should be taken during establishment of pre-production sterilization procedures to ensure that the coldest point in the system has been identified. Valve clusters, which may be used on reservoirs and as flow diversion devices, should be evaluated when identifying the coldest point in the system. If the valve cluster is found to be the coldest point in the system, temperature should be measured and recorded at this point. If surge tanks or reservoirs and fillers are sterilized separately, appropriate temperature sensor locations should be identified using similar techniques. Sterilization of flow diversion devices is discussed in subsection 7.6.1.6 and sterilization of surge tanks or reservoirs is discussed in 7.6.1.7.

7.5.2.3.2 Packaging equipment

The aseptic zone of filling and packaging equipment must be cleaned and brought to a condition of sterility prior to the initiation of product filling and must be maintained in a condition of sterility throughout production. The aseptic zone should be re-sterilized when conditions occur which may result in loss of sterility.

The aseptic zone may be sterilized by heat such as in those systems which utilize superheated steam, or by physical or chemical means such as in those systems which employ hydrogen peroxide or other agents. Superheated steam is steam for which the temperature is above that of dry saturated steam at the same pressure. For those systems using heat, the time and temperature at the coldest locations within the aseptic zone will be the critical factors and should be monitored and recorded. For hydrogen peroxide or other physical or chemical systems, the quantity or level used, concentration, temperature, contact time, method of delivery and other factors may be critical and, therefore, should be monitored and recorded.

The presterilization procedure for aseptic zones within packaging equipment should be sufficient to ensure that sterility of the finished product is maintained. Establishing this portion of the scheduled process should involve adequate challenge testing using appropriate test organisms and methods. Equipment modifications should be evaluated to determine the need to perform additional challenge tests.

7.5.2.3.3 Monitoring sterilization and maintenance

Appropriate inspection and tests should be carried out to monitor the sterilization and its maintenance and records kept as specified in 8.1.4, 8.1.6, 8.1.7 and 8.1.8 of this code.

7.5.2.4 Package sterilization

7.5.2.4.1 The sterilization process applied to the packaging material should achieve sterility. Establishing this process should involve adequate challenge testing using appropriate test organisms and methods. Packaging material and procedural modifications should be evaluated to determine the need to perform additional challenge tests.

Packaging material, preformed containers and their closures are typically sterilized either inside the packaging machine or sterilized externally and introduced aseptically into the aseptic zone of the packaging machine. If the process is performed or completed inside the packaging machine, it is usually accomplished by heat or through use of a combination of chemical and physical treatments such as hydrogen peroxide and heat or U.V. radiation. If the sterilization of packaging material is done completely or partially off-site, it may be sterilized using the heat of extrusion for packaging material or use of a physical treatment such as steam sterilization or irradiation.

7.5.2.4.2 Appropriate inspections and tests should be carried out to monitor the sterilization of packaging materials and maintenance of sterility of the aseptic zone of the packaging machine. Records should be kept as specified in sub-section 8.1.4, 8.1.6, 8.1.7, and 8.1.8 of this code.

7.5.3 Processing and packaging room operations

7.5.3.1 Scheduled processes should be readily available to the system operator, and to the agency having jurisdiction.

7.5.3.2 It is extremely important that the operators are under the supervision of personnel who understand and are trained in the principles of aseptic processing.

7.6 Equipment and Procedures for Processing Systems

7.6.1 Equipment design

7.6.1.1 All equipment to be used for aseptic purposes must be designed for adequate cleaning. Equipment which is not cleaned adequately is more difficult to sterilize.

7.6.1.2 Processing equipment should be constructed of suitable materials for food contact.

7.6.1.3 If the scheduled process is controlled by the outlet temperature of a hold tube, it should be designed so that no portion of the tube between the product inlet and the product outlet from the tube can be heated. Hold tubes must slope upwards at least 2.0 cm/m. (0.25 inch per foot) of piping. The heating characteristics of product in the hold tube must be sufficiently understood with respect to product flow and temperature variations, and to environmental control around the section, to ensure that any appropriate temperature controls are installed to guarantee the scheduled process.

7.6.1.4 For continuous flow systems, product feed rate should be constant, reproducible and quantifiable. A means of preventing unauthorized changes in product feed rate must be provided (for example, an alarm, lock or seal). The product feed rate should be checked with sufficient frequency to ensure that it is as specified in the scheduled process.

7.6.1.5 Any equipment downstream from the hold section with rotating or reciprocating shafts such as pumps or valve stems are potential points of product contamination by microorganisms. Such points within the system should be equipped with steam seals or other appropriate barriers and the operator should be able to monitor the proper function of such barriers, for example, by observing steam discharge from properly located and oriented bleeder ports or observation of leak detection ports.

7.6.1.6 If the system is equipped with a flow-diversion device, it should be installed in the product piping located before the product filler or aseptic surge tank and should be designed to automatically divert flow away from the product filler or surge tank in the event that critical factors such as sterilizing temperature in the hold section and/or proper pressure differential in regenerative heat exchangers drops below specified limits. This device must be designed such that the valve seat which separates the diverted product flow pattern from the forward flow route is sterilized on all sides simultaneously, and all sides of the valve must be maintained in an aseptic condition during production. Gravity drain type flow diversion valves should never be used in aseptic systems, as microorganisms will grow through, or be drawn through, the valve seat from the non-sterile side and contaminate sterile product. If the system is designed such that product in an aseptic surge tank is to be packaged while the processing system is in a divert mode, the flow diversion system must separate sterile product from potentially non-sterile product by more than one valve seat with a sterile zone between sterile product and potentially non-sterile product. This is usually accomplished by establishing a steam barrier between sterile product and the potentially non-sterile area of the processing system.

7.6.1.7 Proper removal of gas (air) from the tank is essential in achieving sterilization. The tank should be instrumented to document proper delivery of the sterilization cycle. At the completion of the sterilization cycle, the flow of sterile gas (see section 4.7 of this code) should be initiated to prevent the tank from experiencing a negative pressure during cooling or production. If an aseptic surge (hold) tank is used in the system, the tank must be maintained under a positive pressure at all times following the initiation of the sterilization cycle until production is completed.

7.6.1.8 In aseptic systems, commercial sterility of the food is accomplished by raising the temperature of the product and maintaining this specific temperature for an exact period of time. Both time and temperature are critical factors in satisfying the scheduled process. In those systems using a hold tube, it is necessary to apply a back pressure sufficient to prevent product boiling (flashing). Product flashing can adversely affect the time and temperature relationship of the scheduled process and subsequent attainment of commercial sterility. Back pressure is commonly maintained with use of a valve, orifice or other device which restricts flow through the tube downstream from the heater and at the exit of the hold tube.

7.6.1.9 Product-to-product regenerators

Where a product-to-product regenerator (see definition 2.21) is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it should be designed, operated and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product. This reduces the chance that any leakage in the regenerator will be from the unsterilized product into the sterilized product.

7.6.2 Instruments and controls for aseptic systems

7.6.2.1 Temperature indicating devices

Each product sterilizer should be equipped with a sufficient number of accurate, calibrated, reliable temperature indicating devices and suitably located. Devices should respond to temperature changes to sufficiently ensure that the scheduled process is delivered. Devices may be subject to the approval of the official agency having jurisdiction. Such devices should have divisions that are easily readable to 0.5°C (1°F) and if, an analog type, have a graduated scale containing not more than 4.0°C per cm. (17°F per inch). Temperature indicating devices including associated instrumentation (for example, potentiometers) should be tested for accuracy against a known accurate standard thermometer. This should be done in steam or water as appropriate and in a similar position or aspect to that which it is installed in the product sterilizer. Such tests should be performed prior to installation, and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. A dated record of such tests should be kept. A device that deviates more than 0.5°C (1°F) from the standard should be replaced if it cannot be readjusted. A daily inspection of temperature indicating devices should be made to detect and replace defective devices.

7.6.2.2 Temperature/time recording devices

Each product sterilizer should be equipped with a sufficient number of accurate, calibrated, reliable temperature/time recording devices which are used in conjunction with the reference temperature indicating devices. Recording devices may becombined with the controllers and may be a recording-controlling instrument. Devices should be sufficiently sensitive to respond to temperature changes in a manner which will ensure that the delivery of the scheduled process is accurately recorded. It is important that the correct chart is used for each device. For analog devices, each chart should have a working scale of not more than 12°C per cm (55°F per inch) within a range of 10°C (20°F) of the sterilizing temperature. The recorder accuracy should be equal to or better than + 0.5°C (1°F) at the sterilizing temperature. The recorder(s) should agree as closely as possible [preferably within 0.5°C (1°F)] and should not be higher than the temperature indicating device(s) during sterilization. A means of preventing unauthorized changes in the adjustment should be provided. It is important that the chart should also be used to provide a permanent record of the sterilization temperature in relation to time. The chart timing device should be accurate and checked as often as necessary to maintain accuracy.

7.6.2.3 Location of temperature indicating sensing elements

For continuous flow type aseptic systems the sensing element(s) of the temperature indicating device should be installed in the product hold section outlet in such a way that it does not alter product flow and result in the improper delivery of the scheduled process.

For batch systems, a sufficient number of sensing elements should be so located as to ensure that the scheduled process is delivered to the entire batch.

7.6.2.4 Location of temperature recording sensing elements

The sensor(s) should be located in the hold section in such a way that it does not alter product flow and result in the improper delivery of the scheduled process. In addition, a separate temperature indicating device sensing element should be located in close proximity to the temperature sensing device probe. The probes for hold tubes must be located so that (a) the conductivity of the piping structure does not interfere with the accurate determination of product temperature, (b) the internal obstruction created by the probes is minimized, and (c) for hold tubes, the probe should be located at or after the point where the upward slope of the tube falls to less than 2 cm per meter (0.25 inch per foot) of piping as described in 7.6.1.3.

7.6.2.5 Location of controller sensing elements

Controller sensing elements should be located in such a way as not to alter product flow and result in improper delivery of the scheduled process. It should be capable of ensuring that the desired product sterilization temperature is maintained.

7.6.2.6 Pressure recorder

Where pressure is a critical factor in the scheduled process, the product zone should be equipped with an accurate, calibrated, reliable pressure recording device. The pressure recording device should be checked for accuracy against a standard at least once a year. The pressure recording device should have a range from 0 kg per cm^2 (lbs. per square inch) such that the safe working pressure is about two-thirds of the full scale and, if an analog type, be graduated in divisions not greater than 0.14 kg per cm^2 (2 lbs. per square inch).

7.6.2.7 Differential pressure recorder

Where a product-to-product regenerator is used, there should be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions should be easily readable and should not exceed 0.14 kg per cm^2 (2 lbs per square inch) on a working scale of not more than 1.4 kg/cm^2/cm (20 lbs per square inch per inch). The controller should be tested for accuracy against a known accurate standard pressure indicator, prior to use and at a frequency sufficient to ensure its accuracy but not to exceed one year and in accordance with the requirements of the agency having jurisdiction. One pressure sensor should be installed at the sterilized product regenerator outlet, and the other pressure sensor should be installed at the unsterilized product regenerator inlet.

7.6.2.8 Product process timing methods and recording

A method (for example, monitoring metering pump speeds) should be used to control the product feed rate as specified in the scheduled process.

7.6.3 Startup

Operators should check to see that the following conditions are met before beginning production on an aseptic system.

(a) All steam seals are functioning properly (for example, emitting steam);

(b) Proper preproduction sterilization with water and/or other medium has been conducted;

(c) Temperatures are correct in the hold tube;

(d) The pressure is greater on the sterile side of product-to-product regenerators, if used;

(e) There is at least 0.07 kg/cm^2 (one psi) pressure of sterile air in the aseptic surge tank;

(f) Monitor the speed of the variable speed product-metering pump to verify that the product feed rate does not exceed that specified in the scheduled process;

(g) Attention should be paid to belt speeds, sterilant bath levels, sterilant concentration, sterilant temperature, temperatures of incinerators, zone temperatures, fogging times and all other factors identified as critical to the production of a commercially sterile product;

(h) That records of these and any other critical factors are properly maintained;

(i) Container material storage, handling and closing are conducted as described in 7.4.

7.6.4 Product container sterilization, filling and closing operations

7.6.4.1 Recording devices

The systems for container and closure sterilization, as well as filling and closing should be instrumented to show that the scheduled conditions are achieved and maintained. During presterilization, as well as production, automatic recording devices should be used to record, where applicable, the sterilization media flow rates and/or temperatures. Where a batch system is used for container sterilization, the sterilization conditions should be recorded.

7.7 Deviations in Aseptic Operations

7.7.1 Loss of sterility

In the event of loss of sterility, the system(s) should be returned to a condition of commercial sterility before resuming operations.

7.7.2 Procedures for handling deviations

Failure to meet any factor identified by the process authority, the processor, or the regulatory agency as being critical to the production of a commercially sterile food product should be interpreted as a deviation to the scheduled process. Whenever the in-process monitoring, records review, processor check or other means disclose that a low-acid food container system, or production equipment has received a thermal or sterilization treatment less than that stipulated in the scheduled process, the processor should:

(a) identify, isolate and immediately reprocess to commercial sterility that part of the code lot or lots involved. Complete reprocessing records should be retained; or

(b) isolate and retain that part of the code lot or lots involved to permit further detailed evaluation of heat processing records. Such evaluation should be made by competent processing experts in accordance with procedures recognized as being adequate to detect any hazard to public health. If this evaluation of the processing records demonstrates that the product has not been given a safe thermal treatment, the product isolated and retained shall be either fully reprocessed to render it commercially sterile or suitably disposed of under adequate and proper supervision to assure the protection of the public health. A record should be made of the evaluation procedures used, the results obtained and the actions taken on the product involved.

7.7.3 Temperature drop in product hold section

When product temperature in the hold tube drops below the temperature specified in the scheduled process, the potentially non-sterile product should be diverted to waste or recirculation. If the flow diversion system is designed as in 7.6.1.6, the processing system may be cleaned and resterilized followed by a resumption of the forward flow pattern without affecting packaging operations.

7.7.4 Loss of proper pressures in the regenerator

Where a regenerative heat exchanger is used the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 0.07 kg/cm^2 (1 lb per square inch) greater than the pressure of unsterilized product. Product flow should be directed either to waste or recirculated until the cause of the improper pressure relationship has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

8.0 SECTION VIII - QUALITY ASSURANCE

It is important that scheduled processes be properly established, correctly applied, sufficiently supervised and documented to provide positive assurance that the requirements have been met. These assurances apply also to the seaming and sealing operations. For practical and statistical reasons, an end-product analysis by itself is not sufficient to monitor the adequacy of the scheduled process.

8.1 Processing and Production Records

8.1.1 Commercial sterility processing of foods

Readings should be made and legible records maintained for the following:

(a) Temperature indicating device(s) at the hold section or tube outlet;

(b) Temperature recorder at hold section or tube outlet;

(c) Temperature recorder at the final heater outlet (entering the hold section or tube);

(d) Differential pressure recorder, if a product-to-product regenerator is used;

(e) Back pressure recording, if a back pressure monitoring system is used;

(f) Product flow rate (in liters or gallons per minute, cans per minute, etc,);

(g) Aseptic surge tank sterile air overpressure;

(h) Proper performance of steam seals (check to see that steam is being emitted);

(i) Proper seals at clamps downstream from hold tube (check for leakage);

(j) The sterilization of equipment during the "presterilization" cycle;

(k) The product formulation, pH, water activity or other factors of each batch of product (if critical to the process);

(l) Production date and code mark of the containers;

(m) Records of each diversion;

(n) Cleaning and resterilization records for the system following diversion;

(o) Other conditions or factors critical to the adequacy of the scheduled process.

8.1.2 Commercial sterility processing of foods containing discrete particles

If the product contains visible particulates in its formulation and the maximum size of the particles of each ingredient was listed in the scheduled process as a critical factor, records of the maximum size used should be listed, or how size was controlled for each batch. Records to show that pasta or similar product was completely rehydrated during the time period equal to the time the product reaches the final heater outlet should be retained. In addition to the above, the record keeping requirements contained in section 8.1.1 will also apply to particulate containing products.

8.1.3 Container examinations

Records of container examinations should be kept with accordance with 7.4.9.

8.1.4 Container sterilization systems employing superheated steam

Packaging systems which utilize superheated steam to sterilize equipment surfaces and packaging material must be instrumented or equipped to monitor those factors which are critical to the delivery of the sterilization treatment. As discussed in 7.5.2.3.2, the critical parameters will be established on the results of microbiological testing.

The coolest temperature in the sterilizer should be recorded along with the time the containers are in the sterilizer. The temperature of the lid sterilizer should be recorded along with the time the lids are in the sterilizer. The record of the sterilization of the water and its delivery tube should be recorded, if used to cool the containers prior to closing. Presterilization of the filling and closing areas should be documented along with the records to show that the scheduled temperature is maintained in this area during filling and closing.

8.1.5 Sterilization using chemical sterilants

Packaging systems which utilize chemical sterilants to sterilize equipment surfaces and packaging material must be instrumented or equipped to monitor those factors which are critical to the delivery of the sterilization treatment. As discussed in 7.5.2.3.2, the critical parameters will be established based on the results of microbiological testing.

Examples of critical factors which may need to be monitored include:

Sterilant concentration;
Consumption or application rate;
Drying air temperature;
Sterilant temperature;
Contact time;
Other conditions or factors identified critical to the adequacy of the scheduled process.

Proper functioning of atomizers, nozzles, etc., should be verified. If hydrogen peroxide or other chemical sterilants are used, the processor should assure that the sterilant is approved for contact with the container material, and that any maximum or minimum concentration and residual limits imposed by regulatory agencies are adhered to.

If sterile air or other sterile gas is necessary for the maintenance of aseptic zone integrity within the packaging machine, the presence of a positive pressure should be documented from the presterilization cycle until the end of packaging.

8.1.6 Hydrogen peroxide and ultra-violet sterilization systems

In addition to the records in 8.1.3 and 8.1.5, records should be kept of the control and strength of the ultraviolet treatment for container sterilization. Specifications of the service life of wave length emitting devices should be kept on file.

8.1.7 Containers or container material sterilized prior to arrival at the processors facility

Records of sterilization processes, such as irradiation, heat of extrusion, etc. which are delivered by packaging vendors, should be maintained by the vendor and supplied to the user. Records should be kept by the user such that code lots and sterilization records of packaging material can be traced to finished lots of food product. Sterilization processes for the packaging material should be established by individuals having expert knowledge regarding aseptic processing in accordance with the provisions contained in 7.5.2.3.

8.2 Record Review and Maintenance

8.2.1 General

The records described in Section 8.1 including recording charts should be identified by date, code lot and other data as necessary, so that they can be correlated with any given lot processed. Each entry on the record should be made and initialed by the processing system operator, or other designated person, at the time the specific condition or operation occurs. Prior to shipment or release for distribution, but not later than one working day after the actual process, a knowledgeable representative of plant management should review and ensure that all records suggested in 8.1 are complete and that the product should be commercially sterile based on these records. The records should be signed or initialed by the person conducting the review.

8.2.2 Container closure records

Written records of all container closure examinations should specify the code lot, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records should be signed or initialed by the container closure inspector and should be reviewed by a competent representative of plant management with sufficient frequency to ensure that the records are complete and that the operation has been properly controlled.

8.2.3 Water quality records

Records should be kept of the results of all tests of microbiological quality and cooling water treatment.

8.2.4 Distribution of product

Records identifying initial distribution of finished product should be maintained to facilitate, if necessary, the segregation of specific food lots that may have been contaminated or are otherwise unfit for their intended use.

8.3 Retention of Records

The records specified in 7.4.9, 7.6, 7.7, 8.1 and 8.2 should be retained for a period of not less than 3 years to assist in the investigation of problems when they arise. They should be held in a manner which will permit ready reference.

9.0 SECTION IX - STORAGE AND TRANSPORTATION OF FINISHED PRODUCT

Conditions of storage and transport should be such that the integrity of the product container and the safety and quality of the product are not adversely affected. Processors should recognize that materials and containers used for aseptic packaging may not have the mechanical strength or rigidity of other containers. This may require special handling during such procedures as palletizing (e.g., stacking height, shrink wrapping, pallet overwrapping, etc.) to avoid damage to finished containers which would lead to contamination. Attention is drawn to common forms of damage such as that caused by improper use of fork lift trucks.

9.1 Warm containers should not be stacked so as to form incubation conditions for the growth of thermophilic organisms.

9.2 Containers should not be kept at high humidities or at temperatures above 32.2°C (90°F) for a long period. Metals are subject to corrosion and films may become delaminated. Freezing should be avoided.

9.3 Labels or label adhesives which are hygroscopic and therefore liable to promote rusting of tinplate should be avoided as should pastes and adhesives that contain acids or mineral salts.

Cases and cartons should be thoroughly dry. If they are made of wood it should be well seasoned. They should be of the proper size so that the containers fit snugly and are not subject to damage from movement within the case. They should be strong enough to withstand normal transport.

Metal containers should be kept dry during storage and transportation to prevent their corrosion.

9.4 The mechanical properties of outer cartons etc. are adversely affected by moisture and the protection of the containers against transport damage may become insufficient.

9.5 The storage conditions, including temperature, should be such as to prevent deterioration or contamination of the product (see 5.7 Pest Control). Rapid temperature changes during storage should be avoided as this may cause the condensation of moist air on the containers and thus lead to corrosion of metal containers.

10.0 SECTION X - LABORATORY CONTROL PROCEDURES

10.1 It is desirable that each establishment should have access to laboratory control of the processes used as well as the products packed. The amount and type of such control will vary with the food product as well as the needs of management. Such control should reject all food that is unfit for human consumption.

10.2 Where appropriate, representative samples of the production should be taken to assess the safety and quality of the product.

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

10.4 Laboratories checking for pathogenic microorganisms should be well separated from food processing areas.

10.5 Incubation tests, for example, 10 days at 35°C $\pm$ 3.0°C (95°F $\pm$ 5°F) should be conducted on a representative sample of containers of product from each code; records of the test results on each code lot should be maintained, initialed, and passed to management for final signature. These records should be retained and appropriate action taken. Other time/temperature combinations may be chosen by the processor.

11.0 SECTION XI - END-PRODUCT SPECIFICATIONS

Microbiological, chemical, physical or extraneous material specifications may be required depending on the nature of the food. Such specifications should include sampling procedures, analytical methodologies and limits for acceptance.

11.1 To the extent possible in good manufacturing practice, the products should be free from objectionable matter.

11.2 The products should be commercially sterile, and not contain any substances originating from microorganisms in amounts which may represent a hazard to health.

11.3 The products should be free from chemical pollutants in amounts which may represent a hazard to health.

11.4 The products should comply with the requirements set forth by the Codex Alimentarius Commission on pesticide residues and food additives as contained in permitted lists or Codex Commodity Standards, and should comply with the requirements on pesticide residues and food additives of the country in which the products will be sold.

12.0 SECTION XII - REFERENCES

12.1 Codex Alimentarius, 1992. Recommended International Code of Hygienic Practice for Low-acid and Acidified Low-acid Canned Foods (Section 7.1). Volume 1 - General Requirements (Second Edition), FAO/WHO, Codex Alimentarius, Rome, Italy.

12.2 Codex Alimentarius, 1992. References for the Tear-Down Evaluation of a Double Seam (Appendix III, Section 7.1), Volume 1 - General Requirements (Second Edition), FAO/WHO, Codex Alimentarius, Rome, Italy.

12.3 Codex Alimentarius, 1992. Guidelines for the Salvage of Canned Foods Exposed to Adverse Conditions (Appendix IV, Section 7.1), Volume 1 - General Requirements (Second Edition), FAO/WHO, Codex Alimentarius, Rome, Italy.

12.4 Codex Alimentarius, 1992. Guideline Procedures to Establish Microbiological Causes of Spoilage in Low-acid and Acidified Canned Foods (Appendix IV, Section 7.1), Volume 1 - General Requirements (Second Edition), FAO/WHO, Codex Alimentarius, Rome, Italy.

12.5 Additional information on aseptic processing and packaging may be found in the following publications:

12.5.1 Bernard, D.T., et.al., 1990. Validation of Aseptic Processing and Packaging. Food Technology 44 (12):119-122.

12.5.2 Campden Food and Drink Research Association (CFDRA), 1987, Good Manufacturing Practice Guidelines for the Processing and Aseptic Packaging of Low-Acid Foods (Part I and Part II), CFDRA, Chipping Campden, Gloucestershire, UK.

12.5.3 Elliott, P.H., Evancho, G.M. and Zink, D.C., 1992. Microbiological Evaluation of Low-acid Aseptic Fillers. Food Technology 46 (5):116-122.

12.5.4 Association of Official Analytical Chemists (AOAC), 1989 Flexible Packaging Defects, AOAC, Arlington, Virginia, USA.

12.5.5 Flexible Packaging Integrity Committee. 1989. Flexible Package Integrity Bulletin (41-L), National Food Processors Association, Washington DC, USA.

12.5.6 National Food Processors Association (NFPA), 1990. Automatic Control Guidelines for Aseptic Systems Manufacturers and Companies Using Aseptic Processing and Packaging for Preserving Foods, NFPA, Washington DC, USA.

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

(At Step 3 of the Procedure)

TABLE OF CONTENTS

DRAFT CODE OF HYGIENIC PRACTICE FOR THE MANUFACTURE OF UNCURED/UNRIPENED AND RIPENED SOFT CHEESES

(At Step 3 of the Procedure)

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 cheeses

Ripened soft cheese are cheeses which comply with the definition in Section II 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 Desinfection

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: Themal 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 establisment 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 materialflow 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, mold 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(draft) of "Guidelines for Drinking-Water Quality" (1992).

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 undesirabele 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 receptables 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 receptables 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 color 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 metals 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 color 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]).

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[1]).

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

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.

---

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

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 Annex 1 to the Recommended International Code of Practice - General Principles & Food Hygiene, Second revision.

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 a sheduled 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, receptables 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 transmissible diseases, 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 jewelry 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 throughly 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 may include the use of protective clothing. Such persons should observe the provisions recommended in Sections 5.8 and 6.7, 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 transport tankers 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 transport tankers 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 in preparation: 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[2]).

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[3]).

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)[2].

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 "Guidelines for Drinking Water Quality" (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.

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

---

[2] Requirements only for fresh and soft cheese made from pasteurized milk.

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 background 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;
- phosphatase 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 might be 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 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.

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.

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 riks 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 micro-organisms 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 of 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- 7th 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 setled monitoring criteria are surpassed, action should results 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 (endproduct 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[4]

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

Criteria for **Salmonella** and **Listeria mocytogenes** 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.

---

[4] Requirements only for fresh and soft cheese made from pasteurized milk.

APPENDIX I

AN OUTLINE OF THE HACCP SYSTEM AND OF ITS APPLICATION

[Abstracted mainly from the Recommendations for the Hygienic Manufacture of Milk and Milk based Products (International Dairy Federation 1992, Chapter 2).]

1. INTRODUCTION

- Good Manufacturing Practices are essential for the manufacture and distribution of refrigerated foods that are safe from microbiological hazards. A refrigerated foods manufacturer should use a comprehensive program that evaluates, identifies, and then controls potential hazards at every step in the product development, processing, packaging, storage and distribution, and record keeping.

- The hazard analysis critical control point (HACCP) system is such a preventive approach to the control of food manufacture and distribution to ensure food safety. In this way, the risk of foodborne infection or intoxication is kept to a minimum. The system may also be applied to the control of microbiological quality of products in order to minimise spoilage.

- The system has found widespread interest and has been described by the ICMSF in 1989 as a comprehensive and authoritative treatment of the subject : "THE APPLICATION OF THE HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM TO ENSURE MICROBIOLOGICAL SAFETY AND QUALITY"

- The current chapter gives an outline of the HACCP system and its implementation. For more background information, the reader is guided to the above publication, and to the IAMFES publication "PROCEDURES TO IMPLEMENT THE HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM" (1991).

2. DEFINITIONS

- The terms used and their definitions are:

Hazard:

A hazard is the potential to cause harm to the consumer (the safety aspect) or to the product (the spoilage aspect). A hazard is present at any stage in the manufacture and distribution of a product where:

- unacceptable micriobiological contamination, or

- growth and/or survival of unwanted microorganisms may occur.

Risk:

Risk is the probability that a hazard will, in fact, happen. Risk should be ranked as low, medium or high based on judgement or experience.

Concern:

Concern is the seriousness resulting from any failure to achieve control of the process. It is based on the knowledge of the effect of a hazard not being controlled. Concern can be rated as low, medium or high depending on the severity of the hazard, and its risk of occurrence.

Critical Control Points (CCP):

These are points identified in the location, process, or product formulation which, if controlled, prevents hazards adequately.

3. APPLICATION OF THE HACCP SYSTEM

In practice, the HACCP system is implemented in the six sequential steps outlined in 4. below. However, before the HACCP is carried out, there are a number of preliminary actions that should be taken to ensure its effectiveness:

- HACCP is best carried out as a team exercise to ensure that the appropriate expertise is available. Core members of the team should include a microbiologist, an engineer and a production manager, with other areas of expertise represented as necessary, e.g. product development, purchasing, packaging, cleaning, distribution.

- The HACCP should be applied to a particular product line at a particular site, rather than as a general approach. The product line includes all processing and packaging operations, including the distribution system, and each stage in it should be studied on its own and as part of the overall process.

- A manufacturing site will probably house a number of product lines and these should be prioritised to focus resource where the application of HACCP is expected to give the best improvement.

- When a particular product line has been selected for the application of HACCP, the following information should be obtained:

- specifications for the product, packaging materials, ingredients and the manufacturing process itself.

- a flow chart identifying fully all aspects of the process in as much detail as possible, including all inputs (even air) and outputs and all unit operations.

- details of any particular hygiene problems in the factory itself. This usually requires a thorough "walk through" of the product line in the factory itself.

- The HACCP should be reviewed before any change in ingredients, process conditions, packaging, product formulations is agreed. All new products should have a HACCP carried out before commercial introduction.

4. THE SEQUENTIAL STEPS OF THE SYSTEM

The two important aspects of the HACCP system, i.e. hazard analysis of the process or product and identification of the critical control points are achieved by the following sequential steps:

i) **Identification of the hazard and assessment of risk**

- Each step or action on the process flow chart should be considered to identify potential for failure in process or hygiene that could adversely affect the microbiological stability of the product.

ii) **Determining the critical control points at which the identified hazards may be controlled**

- A critical control point can either be a location, practice, procedure or process where control may be exercised. A control point is an operation at which preventive measures are taken because of good manufacture practices, regulations, e.a.or an operation which by design does not need to be monitored to check that the hazard is under control (iii/iv).

- With dairy products the major critical control points are the pasteurisation of the raw materials and the prevention of post heat-treatment contamination. The CCP is unique to the HACCP system in that the user can focus preventive and control measures on identified problems rather than to know everything about hygiene with the hope that something will work to prevent a problem.

iii) **Specification of criteria that show that an operation is under control at a given critical control point**

- Criteria specify the limits applied to physical (for instance time or temperature), chemical (for instance salt or acid), or microbiological factors which are associated with a process or product and which must be achieved to ensure safety or stability. For example, if heat treatment is the control then the exact time and temperature of heating must be specified, together with acceptable tolerances.

- Criteria may also be more general and refer to control of the factory environment, e.g. barrier hygiene, water management, etc.

(iv) **Establishing and implementing the procedures used to monitor each critical control point to check that it is under control**

(v) **Taking appropriate action when the monitoring results show that a critical control point is not under control**

(vi) **Verifying, by use of supplementary information, that the control is working.** This will usually involve microbiological examination of product to confirm the effectiveness of the HACCP controls.

The outcome of the HACCP review should be a formal report, prepared by the team, including:

i) the scope of the review

ii) the people involved

iii) the flow diagram highlighting the CCPs in the process

iv) a summary of the detail of the hazards at each CCP and the control options considered

v) agreed future action, including budgetary considerations.

5. IMPLEMENTATION OF THE PROGRAM

- The HACCP review will only be useful if implemented in practice and if it becomes part of the way the factory operates.

- To ensure the results of the HACCP review are used in practice, it is important to:

- produce documentation to provide information for process operations and a place to record the results of monitoring the CCPs. Such control documentation should include:

  - the control point
  - a description of the control point
  - the hazard
  - the control option
  - the control limits
  - monitoring method, frequency and responsibility
  - action when limits are exceeded

- train the management and operators in the use of the HACCP system in general and the control documentation in particular.

- identify improvements required in facilities, instrumentation, etc so that expenditure can be planned for in budgets.

- regularly review the HACCP report to ensure that development in technology and knowledge are considered and to consider any proposed changes in the ingredients, product formulation, packaging and processing.

APPENDIX II

EXAMPLE OF AN APPLICATION

- The application of the main sequentional steps of the HACCP for the production of fresh cheese is given below. This is an example for illustrating the preventive approach of the system. It must be emphasized that only can be dealt within general terms because the specifications of preventive measures and their control requirements should be tailored to each particular process.

- Step 4 and the following should not be dealt with this example because they are strongly related to the organizational aspects of the Quality Department of the company.

Outline of application for the manufacture of fresh cheese

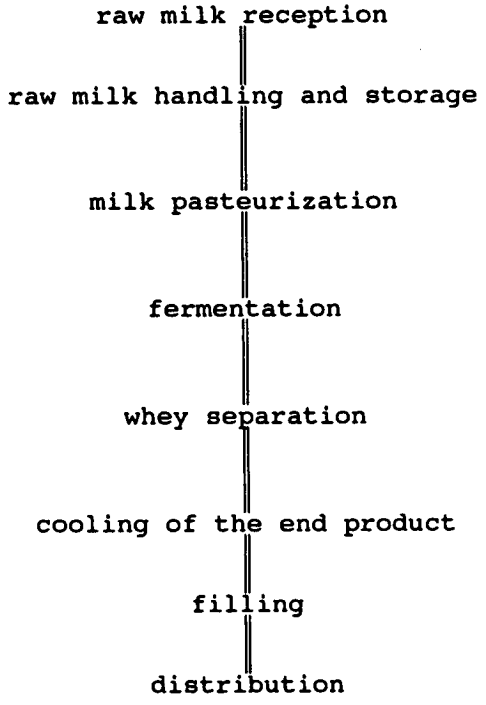
The microbiological **hazards** are:

- survival of pathogens in the milk by underpasteurization.

- recontamination with pathogens and/or spoilage micro-organisms at different stages.

- growth during processing, distribution and storage of the product, including the raw milk storage and handling.

A simplified **flow diagram** which sets up the processing stages is as follows:



The application of the HACCP steps to this process results to the following.

- Raw Milk Reception

  The hazard associated with this stage is that raw milk may contain pathogenic bacteria. The processing site should therefore be protected by the design of the plant, which should ensure that contamination from the raw milk site does not occur.

This preventive measure is not really a CCP but is taken because of good manufacturing practice and defined as a **control point.**

Monitoring is not relevant.

- Raw Milk Handling

It is important to have separate CIP systems for the raw and pasteurized stages to eliminate cross-contamination with pathogenic bacteria originating from the raw milk.This **control point** is a preventive measure to be dealt in designing of installations.

- Pasteurization

The hazard is that pathogenic bacteria survive the heat treatment of the pasteurizatio step designed to kill pathogens from the raw material.This can happen by underpasteurization or by recontamination of the product in the regenerative or cooling section of the pasteurizer and will be eliminated by correct design and running of the pasteurising plant.

A flow diversion valve ensure that raw milk which has not reached the right temperature will be returned.

A positive pressure difference between the outgoing and the incoming regenerative must prevent recontamination after the heat treatment.

Monitoring and documentation of the criteria, temperature for heat treatment and pressure difference for recontaminations, are considered in 7.5.2.

Test of residual phosphatase activity in the pasteurized milk should be applied for verification of adherence to the control of the pasteurization process.

- Fermentation

Fermentation is a CCP because the control of the acidification for curdling reduces the multiplication of potential pathogens as **S. aureus.** Criteria that should be monitored are:

* the activity of the starter

* the fermentation temperature

* the curdling time

* the level of antibiotic residues in the raw milk (optional).

- Refrigerated storage and distribution

Storage temperature of the refrigerated product should be maintained at 7°C or lower to maximize shelf life and minimize any potential microbiological hazard.

Distribution practices should enable the maintenance of product temperature at 7°C or lower as appropriate for the food.

Time/temperature recorders should be used to monitor the temperature history of the food during storage and distribution from the producer to the retailer. Microbiological criteria at the best before date should be used for verification of adherence to temperature control and to the "best before date".

ANNEX I

SPECIAL PROVISIONS FOR SOFT CHEESE MADE WITH RAW MILK

SECTION I - SCOPE

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

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[5]

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:

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 keep a permanent record of the animals in which all individual sanitary information is recorded, besides specific information pertaining to each animal;

---

[5] 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.

- 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.

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. 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.

SECTION V - 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 remises 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 - 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, m = 5, c = 0 (25g: 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.

8.2 Microbiological specifications

a) Bacteria indicating poor hygiene

Staphylococcus aureus/g	$m = 10^3$, $M = 10^4$, $m = 5$, $c = 2$
Escherichia coli/g	$m = 10^4$, $M = 10^5$, $m = 5$, $c = 2$

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.

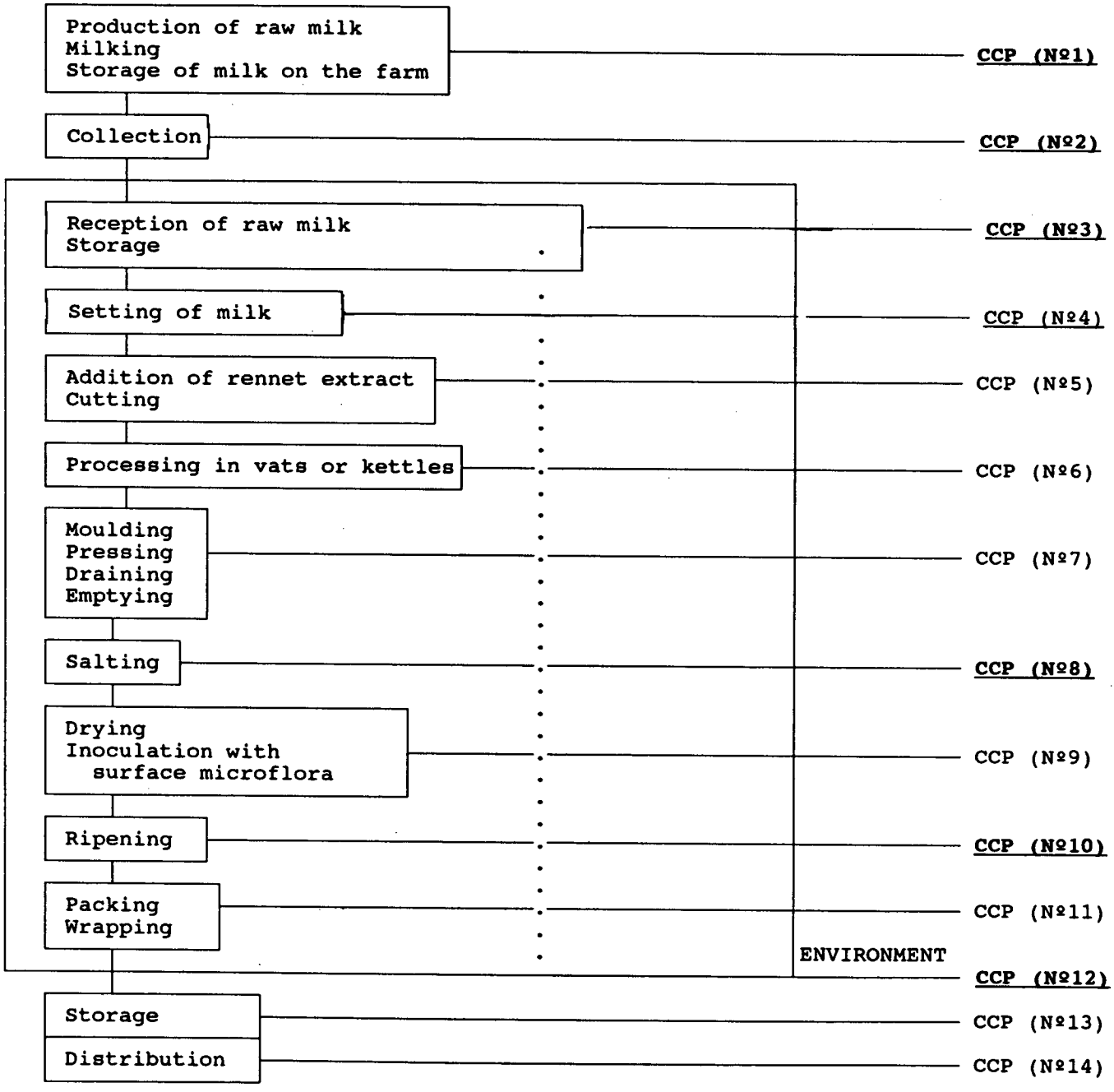
1. Production diagram (cf. table).

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 • *St. aureus* < 500 • *E. Coli* < 100 • Leucocytes < $2,5.10^5$ • pH ofensilage	• 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
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

STEP	HAZARD	PREVENTION	CCP	TARGET LEVELS	MONITORING	CORRECTIVE ACTION
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
Setting of milk Rennetting	Proliferation of undesirable microorganisms	• Control of acidification • Checking of the absence of inhibitors • Cleaning procedures	Nº4	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	Nº8	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	N°10	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
Environment	• Contamination • Proliferation and resistance of undesirable micro-organisms	• 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°12		• 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 nº1: 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 micro-organisms.

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.

ALINORM 93/13A
Appendix V

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS
(At Step 5 of the Procedure)

TABLE OF CONTENTS

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS
(At Step 5 of the Procedure)

Section I - SCOPE

This Code of Hygienic Practice applies to spices and condiments, whole, broken or ground or spice blends. 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 Condiments

The term spices and condiments relates to the natural dried aromatic plant component or mixture thereof, used for flavouring, seasoning and imparting aroma or flavour to food. The term applies equally to the 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 and condiments.

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 official agency having jurisdiction.

3.2 Drying (Curing)

Plants of parts of plants used for the preparation of spices and condiments may be dried naturally or artificially, provided adequate measures are taken to prevent contamination or alteration of the raw material during the process.

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, of a safe moisture level so as to prevent the growth of microorganisms, specially mycotoxin producing mould, etc.

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 and condiments 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 and condiments 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 and condiments 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 disinfested 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 disinfested before loading. In addition, bulk transport such as ship or rail car should be cleaned and well ventilated with dry air to remove moisture resulting from the respiration of spices and condiments 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 and condiments 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 spices 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. Ventilators 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 spices handling areas.

5.9 Personal effects and clothing

Personal effects and clothing should not be left in spices 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 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 spices 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 are coming in 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.

Plant, 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 mycotoxins 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 pests infestation, appropriate methods of treatment, may be used in accordance with the regulations set by the official agency having jurisdiction. Whenever irradiation is used, reference should be made to 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.

Area 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" of 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 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 where spices are stored. 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 spices by direct or indirect contact with material at earlier stages of the process.

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 the said products and have changed into clean protective clothing.

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.

---

[6] 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)

7.2.4 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 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 such conditions as will 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 so as to protect 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 which may require 1-3 days. Spices that have been spilled are vulnerable to contamination and should not be used for edible purposes.

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 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 which may represent a hazard to health; and

(b) should not contain any substances originating from micro-organisms, particularly aflatoxins, in amounts which exceed the tolerances or criteria established by the official agency having jurisdiction.

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

8.2 The products should comply with the provisions for food additives, contaminants and with maximum levels for pesticide residues recommended by the concerned official agency.

8.3 Microbiological Criteria

(to be elaborated for treated spices and condiments if appropriate; see para. 70.)