NOTE: This document incorporates Codex Circular Letter 1989/49-FH.
TO: Codex Contact Points  
  Participants at the 24th Session of the Codex Committee on Food Hygiene  
  Interested International Organization

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

SUBJECT: Distribution of the Report of the 24th Session of the Codex Committee on Food Hygiene (ALINORM 91/13)

A. MATTERS OF INTEREST TO THE 19TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Guidelines at Step 8 of the Procedure

1. Guidelines for the Salvaging of Canned Foods Exposed to Adverse Conditions (ALINORM 91/13, para. 49, App. IV)


3. Draft Guidelines for the Preservation of Raw Milk by Use of the Lactoperoxidase System (ALINORM 91/13, paras 88-89, Appendix X). The Code was advanced to Step 5 for consideration at the 22nd Session of the Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products. The Committee also recommended that the Commission considers omitting Steps 6 and 7 and adopting the document at Step 8 in view of its importance for the developing countries.

Governments wishing to propose amendments and 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 Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy, before 30 January 1991.

Draft Codes and Texts at Step 5 of the Procedure


In accordance with the Codex Procedures for the Elaboration of Codex Standards and other texts, the Commission will give due consideration to any comments that may be submitted by any of its members regarding the implications which proposed draft
documents at Step 5, or any provisions thereof may have for their economic interests. Comments are therefore invited on these two documents. Comments should be sent to the Chairman of this Committee: Dr. D.L. Archer, Director, Division of Microbiology, Center for Food Safety and Applied Nutrition, Room 3828 (HFF-230), Food and Drug Administration, 200 C Street, S.W., Washington D.C. 20204, USA, with a copy to this Office, before 30 January 1991.

B. MATTERS OF INTEREST TO GOVERNMENTS AND INTERNATIONAL ORGANIZATIONS

Proposed Draft Codes and Guidelines at Steps 3 and 6 of the Procedure


Comments are invited on all these documents and should be addressed as follows:

Document 6 - Before 30 January 1991 to:

Dr. B.E. Brown
Chief, Evaluation Division
Food Directorate
Bureau of Microbial Hazards
Health Protection Branch
Health and Welfare Canada
Ottawa, Ontario K1A 0L2, Canada

Document 7 - Before 30 March 1990 to:

International Dairy Federation (IDF)
General Secretariat
Square Vergote 41
B-1040 Brussels, Belgium

In preparing the comments for this document, a close cooperation is encouraged between the National IDF Committee and the corresponding Codex Delegation.

Documents 8 and 9 - Before 30 January 1991 to:

Dr. D.L. Archer
Chairman of the CCFH
Director, Division of Microbiology
Center for Food Safety and Applied Nutrition
Room 3828 (HFF-230)
Food and Drug Administration
200 C Street, S.W.
Washington D.C. 20204, USA

Copies of all comments should be addressed to this Office.
SUMMARY AND CONCLUSIONS

The summary and conclusions of the 24th Session of the Codex Committee on Food Hygiene (Washington D.C., 16-20 October 1989) are as follows:

The Committee:

- Forwarded at Step 8 for adoption by the Commission the Guidelines for the Salvaging of Canned Foods Exposed to Adverse Conditions (para. 49, App. IV).

- Advanced to Step 5 the Guideline Procedures to Establish Microbiological Causes of Spoilage in Canned Foods. Considering the advanced stage of elaboration of the Guidelines and their importance, the Committee recommended that the Commission consider adopting the document at Step 8 with the omission of Steps 6 and 7 (para. 53, App. V).

- Advanced to Step 5 the Guidelines for the Preservation of Raw Milk by Use of the Lactoperoxidase System, for review at the 22nd Session of the Joint FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products. The Committee also recommended that the Commission consider omitting Steps 6 and 7 and adopting the document at Step 8 in view of its importance for the developing countries. (Paras 88-89 and App. X).

- Return to Step 6 the Draft Code of Hygienic Practice for Pre-Cooked and Cooked Foods in Mass Catering for more comments (para. 66, App. VII). The Committee also agreed to request France to elaborate a document addressing refrigerated packaged foods with extended shelflife for discussion at its next session.

- Advanced the Draft General Provisions related to Food Hygiene to Step 5 and recommended that these general provisions should be applied retroactively to all Codex Standards (para. 44, App. II).

- Revised and endorsed the provisions relating to food hygiene in the Draft Revised Codex Standards for Corned Beef, Luncheon Meat, Cooked Cured Ham, Cooked Cured Pork Shoulder and Cooked Cured Chopped Meat all at Step 5 (para. 46, App. III).


- Reviewed and agreed to circulate for comments at Step 3 the "Guideline Procedures for the Visual Inspection of Lots of Canned Foods" (para. 57, App. VI).

- Returned the Proposed Draft Code of Hygienic Practice for Uncured Unripened Cheese and Ripened Soft Cheese for more comments at Step 3 (para. 80, App. IX).

- Agreed to circulate the Code of Hygienic Practice for Spices and Condiments for comments at Step 3 (para. 94, App. XI).

- Agreed that Canada with the assistance of the United States should prepare a draft model of a Pictorial Manual for Objective 1 Defects by May 1990 for presentation at the 37th Session of the Executive Committee in order to consider its further elaboration (para. 61).
- Considered a proposal for core elements for a Code of hygienic practice for the preparation and sale of street foods, and agreed to recommend to the Executive Committee to ask FAO and WHO to consider reconvening an expert consultation on street food hygienic practices (para. 40).

- Agreed to establish an Ad-Hoc Working Group on HACCP with the express purpose of producing a document with general HACCP definitions and procedures for use by Codex, with a view of being distributed for comments before the next session of the Committee (paras 96, 97).

- Agreed that the Codex Secretariat should collect the relevant information and prepare for the next session a working paper summarizing recommendations on Listeria monocytogenes made by various Expert Committees (paras 102-103).

- Noted that the establishment of microbiological criteria for foods should be considered carefully, and agreed that there should be full discussion of the need for such criteria, particularly with a view of their possible implications as non-tariff trade barriers (para. 34).

- Discussed various general aspects of the work of the Committee including, terms of reference, future developments, timing of sessions, creation of Working Groups, and decided to refer these matters to the Executive Committee and/or the Codex Committee on General Principles (paras 104-111).
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRODUCTION</td>
<td>1</td>
</tr>
<tr>
<td>OPENING OF THE SESSION</td>
<td>1</td>
</tr>
<tr>
<td>- FAO World Food Day Activities</td>
<td>1</td>
</tr>
<tr>
<td>ADOPTION OF THE AGENDA</td>
<td>1</td>
</tr>
<tr>
<td>INFORMATION ON ACTIVITIES OF INTEREST TO THE COMMITTEE WITHIN FAO, WHO</td>
<td>1</td>
</tr>
<tr>
<td>AND OTHER INTERNATIONAL ORGANIZATIONS</td>
<td></td>
</tr>
<tr>
<td>- Joint FAO/WHO Activities</td>
<td>1</td>
</tr>
<tr>
<td>- FAO Activities</td>
<td>3</td>
</tr>
<tr>
<td>- WHO Activities (Global and Interregional)</td>
<td>4</td>
</tr>
<tr>
<td>- PAHO Regional Activities</td>
<td>5</td>
</tr>
<tr>
<td>- International Organization Activities</td>
<td>5</td>
</tr>
<tr>
<td>REVIEW OF MATTERS RELEVANT TO THE COMMITTEE AS DISCUSSED BY THE CODEX</td>
<td>5</td>
</tr>
<tr>
<td>ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES</td>
<td></td>
</tr>
<tr>
<td>CONSIDERATION OF A PROPOSAL FOR A DRAFT CODE OF PRACTICE FOR THE</td>
<td>5</td>
</tr>
<tr>
<td>PREPARATION AND SALE OF STREET FOODS</td>
<td></td>
</tr>
<tr>
<td>CONSIDERATION OF GENERAL HYGIENE PROVISIONS AND ENFORCEMENT OF FOOD</td>
<td>6</td>
</tr>
<tr>
<td>HYGIENE SECTIONS IN CODEX STANDARDS</td>
<td></td>
</tr>
<tr>
<td>- Draft General Provisions Relating to Hygiene</td>
<td>6</td>
</tr>
<tr>
<td>- Endorsement of Provisions Relating to Food Hygiene in Codex Standards</td>
<td>6</td>
</tr>
<tr>
<td>GUIDELINES FOR THE SALVAGING OF CANNED FOODS EXPOSED TO ADVERSE</td>
<td>6</td>
</tr>
<tr>
<td>CONDITIONS</td>
<td></td>
</tr>
<tr>
<td>GUILDINE PROCEDURES TO ESTABLISH MICROBIOLOGICAL CAUSES OF SPOILAGE IN</td>
<td>6</td>
</tr>
<tr>
<td>CANNED FOODS</td>
<td></td>
</tr>
<tr>
<td>VISUAL EXAMINATION OF LOTS OF CANNED FOODS</td>
<td>7</td>
</tr>
<tr>
<td>DEFECT CLASSIFICATION AND MANUAL</td>
<td>7</td>
</tr>
<tr>
<td>CONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR</td>
<td>8</td>
</tr>
<tr>
<td>PRE-COOKED AND COOKED FOODS IN MASS CATERING</td>
<td></td>
</tr>
<tr>
<td>PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR ASEPTIC FOOD PROCESSING</td>
<td>8</td>
</tr>
<tr>
<td>AND PACKAGING SYSTEMS</td>
<td></td>
</tr>
<tr>
<td>CONSIDERATION OF A PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED</td>
<td>9</td>
</tr>
<tr>
<td>UNRIPEPENED CHEESE AND RIPENED SOFT CHEESE</td>
<td></td>
</tr>
<tr>
<td>PROPOSED DRAFT GUIDELINES FOR THE PRESERVATION OF RAW MILK BY USE OF</td>
<td>10</td>
</tr>
<tr>
<td>THE LACTOPEROXIDASE SYSTEM</td>
<td></td>
</tr>
<tr>
<td>PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS</td>
<td>11</td>
</tr>
<tr>
<td>CONSIDERATION OF GENERAL PRINCIPLES ON THE APPLICATION OF HACCP TO CODEX</td>
<td></td>
</tr>
<tr>
<td>CODES OF HYGIENIC PRACTICE - REPORT OF THE AD-HOC WORKING GROUP</td>
<td>12</td>
</tr>
<tr>
<td>CONSIDERATION OF THE OCCURRENCE AND PREVENTION OF LISTERIA MONOCYTOGENES IN FOODS</td>
<td>13</td>
</tr>
<tr>
<td>OTHER BUSINESS AND FUTURE WORK</td>
<td>13</td>
</tr>
<tr>
<td>SUMMARY STATUS OF WORK</td>
<td>15</td>
</tr>
<tr>
<td>APPENDIX</td>
<td>DESCRIPTION</td>
</tr>
<tr>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>I</td>
<td>LIST OF PARTICIPANTS</td>
</tr>
<tr>
<td>II</td>
<td>DRAFT GENERAL PROVISIONS RELATING TO HYGIENE (At Step 5)</td>
</tr>
<tr>
<td>III</td>
<td>REVISED HYGIENIC PROVISIONS FOR FIVE DRAFT REVISED CODEX STANDARDS FOR MEAT (At Step 5)</td>
</tr>
<tr>
<td>IV</td>
<td>GUIDELINES FOR THE SALVAGE OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS (At Step 8)</td>
</tr>
<tr>
<td>V</td>
<td>GUIDELINE PROCEDURES TO ESTABLISH MICROBIOLOGICAL CAUSES OF SPOILAGE IN LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS (At Step 5)</td>
</tr>
<tr>
<td>VI</td>
<td>GUIDELINE PROCEDURES FOR THE VISUAL INSPECTION OF LOTS OF CANNED FOODS FOR OBJECTIVE DEFECTS (At Step 3)</td>
</tr>
<tr>
<td>VII</td>
<td>DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-COOKED AND COOKED FOODS IN MASS CATERING (At Step 6)</td>
</tr>
<tr>
<td>VIII</td>
<td>DRAFT CODE OF HYGIENIC PRACTICE FOR ASEPTECALLY PROCESSED AND PACKAGED LOW-ACID FOODS (At Step 5)</td>
</tr>
<tr>
<td>IX</td>
<td>PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED UNRIPENED CHEESE AND RIPENED SOFT CHEESE (At Step 3)</td>
</tr>
<tr>
<td>X</td>
<td>GUIDELINES FOR THE PRESERVATION OF RAW MILK BY USE OF THE LACTOPEROXIDASE SYSTEM (At Step 5)</td>
</tr>
<tr>
<td>XI</td>
<td>PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS (At Step 3)</td>
</tr>
</tbody>
</table>
INTRODUCTION

1. The Twenty-Fourth Session of the Codex Committee on Food Hygiene was held at the Department of State, Washington, D.C., from 16 to 20 October 1989 through the courtesy of the Government of the United States of America. Representatives and observers from 31 countries and 3 international organizations were present. The Session was presided over by Dr. Douglas Archer, Director, Division of Microbiology, United States Food and Drug Administration, and for certain items by Dr. Catherine E. Adams, Assistant to the Administrator, Food Safety and Inspection Service, United States Department of Agriculture. A list of participants is attached as Appendix I.

OPENING OF THE SESSION (Agenda Item 1)

2. Dr. Archer opened the Session and introduced Dr. Madilyn Fletcher, Center of Marine Biotechnology, University of Maryland, who addressed the participants on Biofilms and their Implication in the Food Industry. The Committee expressed its appreciation for her comprehensive overview of current issues in this area, and noted the importance of this subject in food hygiene matters.

FAO WORLD FOOD DAY ACTIVITIES

3. Mr. John Lupien, Chief, Joint FAO/WHO Food Standards Programme, provided the Committee with an overview of FAO World Food Day activities on 16 October 1989. The Committee noted that World Food Day was an annual worldwide celebration held in honour of the founding of FAO, and that this year's theme was "Food and the Environment".

4. The Committee noted that activities in the United States addressing this event included a White House ceremony with President George Bush, a Department of Agriculture ceremony with Secretary Clayton Yeutter, and a World Food Day Teleconference on Food, the Environment and Development.

5. The Committee agreed that World Food Day activities should continue to emphasize the importance of adequate food supplies as well as food quality and safety aspects, and noted that these issues had direct relevance to the Committee's proceedings. The Committee also noted the importance of developments between Codex and the General Agreement on Tariffs and Trade in the areas of food safety and quality when related to the elimination of technical barriers to international food trade.

ADOPTION OF THE AGENDA (Agenda Item 2)

6. The Committee agreed to adopt the Provisional Agenda (CX/FH 89/1) with the understanding that Agenda Item 6 would be discussed after Agenda Item 10 in order to allow adequate time for deliberations of the Working Group on Canned Food.

7. The Committee, while noting the absence of a working document for discussion under Agenda Item 13 (Occurrence and prevention of *Listeria monocytogenes* in food), decided to focus oral discussions under this item on the prevention of food contamination by *listeria* and other microorganisms.

8. The Committee also agreed to the convening of working group sessions on Mass Catering and Hazard Analysis Critical Control Points (HACCP) under the chairmanship of the United States.

INFORMATION ON ACTIVITIES OF INTEREST TO THE COMMITTEE WITHIN FAO, WHO AND OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 3)

JOINT FAO/WHO ACTIVITIES

Joint FAO/WHO Expert Committee on Food Additives, 35th Meeting

9. The Committee was informed of the 35th Meeting of the Joint FAO/WHO Expert Committee on Food Additives, which met in Rome in June 1989 to evaluate the safety of food additives and contaminants. The Expert Committee had also evaluated the safety
of the lactoperoxidase/thiocyanate/hydrogen peroxide system for the preservation of raw milk. The results of that evaluation are noted under discussion of the guidelines for this system (see para. 84).

Joint FAO/UNEP/WHO Food Contamination Monitoring Programme

10. Within the framework of this programme, several chemical contaminants relevant to food safety in a variety of foods were monitored. Of interest to CCFPH was the fact that aflatoxins are included in the monitoring activities and that, in the future, certain foodborne pathogens (e.g. Salmonella, Trichinella, Campylobacter) in certain foods (e.g. poultry, pork) may also be considered.

Book on Food Irradiation

11. The Committee noted that FAO and WHO had jointly prepared a book entitled "Food Irradiation - A Technique for Preserving and Improving the Safety of Food". An English version was published by WHO in 1988, while the French and Spanish versions were expected to appear shortly.


12. The Committee noted that the Conference, which included delegations from 57 countries and observers from 14 organizations, had adopted a Document on Food Irradiation, which included recommendations to consider the application of this technology for public health benefits, for the reduction of post-harvest losses and for the quarantine treatment of certain foods. The Conference proceedings, which included the Document on Food Irradiation, were published by IAEA on behalf of the four sponsoring organizations.

ICGFI Consultation on Microbiological Criteria for Foods to be Further Processed including by Irradiation, Geneva, 29 May to 2 June 1989

13. The Joint FAO/IAEA/WHO International Consultative Group on Food Irradiation (ICGFI) had sponsored this consultation which had been charged with the development of microbiological criteria that relate to spoilage which could be considered as indicators of good manufacturing practice (GMP)*.

14. For most of the foods discussed by this consultation there existed Codex Codes of Practice which define GMP. As many Codes did not contain end-product specifications, the Consultation considered recommending criteria where these were absent and reviewed existing criteria as they may apply to food for further processing. Microbiological guidelines were suggested for red meats (beef, pork, lamb), poultry, fish and crustaceans. For spices, herbs and vegetable seasonings only provisional guidelines were suggested, while for mechanically separated meats and frogs legs no criteria could be prepared. The consultation also reviewed the Codex specifications for cooked, peeled, frozen shrimps and prawns.

15. In summing up the conclusions and recommendations of the consultation, Dr. Käferstein of WHO proposed that the following action be undertaken by the appropriate Codex Committees:

* In adopting this paragraph several delegations noted that this information had been presented by the Representative of WHO but had not been discussed by the Committee, and stated that in their opinion the responsibility within Codex for developing microbiological criteria for foods lay with this Committee (see also para. 34).
(1) To obtain more recent data on the microbiology of cooled, peeled, frozen shrimps and prawns (produced under GMP) in order to see if a revision of the existing Codex specification would be appropriate since it might be too strict.

(2) To incorporate, by means of revising the existing codes of hygienic practice, the guidelines for meats, poultry, fish and crustaceans.

(3) To obtain through the Codex mechanism, data on the microbiology of spices, herbs and vegetable seasonings, mechanically separated meats and frogs legs (produced under GMP) in order to arrive at guideline levels for incorporation into the appropriate Codes of hygienic practice.

16. In replying to a query of the delegation of the United States, Dr. Käferstein informed the Committee that the proposed revised microbiological criteria for cooked, peeled, frozen shrimps and prawns by the ICGFI consultation were not based on a solid data base and that more information was needed, but the general opinion of the consultation was that the criteria should be revised, and new ones developed for other commodities to be considered by the consultation.

17. Considering the extent and complexity of these proposals, the Committee agreed to refer this problem for the advice of the Executive Committee.

18. At the request of the delegation of Sweden, the Secretariat informed the Committee that preparations for the Joint FAO/WHO International Conference on Food Standards, Food Additives and Food Trade were well in hand. The Conference would be held at FAO Headquarters and was tentatively scheduled for April 1991.

FAO ACTIVITIES

19. The Secretariat informed the Committee of continuing activities in FAO towards providing technical assistance on food control to many countries. Thirteen FAO-assisted projects and activities are under way in the region of Latin America and the Caribbean, 15 projects were being implemented in Africa, 20 in Asia, 6 in the Middle East, and 2 in Europe. Particular emphasis has recently focussed on food import/export control programmes. Workshops on this topic had been held in Cairo in December 1988, Costa Rica in February 1989 (with PAHO), and two more were being prepared in Indonesia and Thailand.

20. Mycotoxins have first priority in FAO-assisted food contamination control and surveillance programmes in many countries, including Argentina, Chile, Chuba, Guatemala. A training programme on methods of analysis for mycotoxins for some African countries was organized in Malawi in December 1988. In Tanzania a UNEP/UNEP/C/FAO project for improving mycotoxin control has been completed. An Asian regional FAO/UNEP training network on mycotoxin analysis was implemented in 1989 and a similar project was being considered for Latin America and the Caribbean region.

21. Street foods are another high priority area of FAO. Studies with FAO assistance have been carried out in Malaysia, Nigeria, Nepal, India, Indonesia, Colombia, Venezuela, Guatemala, Thailand. A global FAO Expert Consultation on Street Foods was held in Yogyakarta, Indonesia in December 1988 in order to summarize all outstanding issues of street-vended foods, including hygiene and sanitation.

WHO ACTIVITIES (GLOBAL AND INTERREGIONAL)

22. The Committee noted that the Consultation on Health Surveillance and Management Procedures for Food Handling Personnel, Geneva, 18 to 22 April 1988 (WHO TRS 785, 1989), had concluded that while food handlers can indeed be the cause of food contamination leading to disease outbreaks, pre-employment or routine medical and laboratory examinations were of no value in preventing foodborne diseases. Therefore, the discontinuation of this practice was recommended. Instead, the Consultation proposed, inter alia, education and training of food handlers in food safety, the use of the HACCP system within food establishments and surveillance of outbreaks of foodborne diseases. The Committee agreed to request guidance from the Executive
Committee on the implications of these conclusions, in view of provisions addressing Health Requirements for Food Handlers contained in many Codex Codes of Practice.

**Foodborne Listeriosis**

23. The Committee noted that WHO had convened two consultations on the subject of listeriosis. The more recent consultation addressing foodborne listeriosis was held in February 1988, and its report is published as document WHO/EHE/FO8/88.5. The following two documents on the subject are available from WHO's Food Safety Unit: (1) Annual list of references on listeria - 1988; (2) Literature Review on Human Listeriosis and Listeria in Food - 1988.

**Food Virology**

24. The WHO Collaborating Center on Food Virology in Madison, Wisconsin, USA had prepared two documents on the subject which are available from WHO's Food Safety Unit: (1) Literature Review - 1988; (2) 1988 List of Food Virologists.


25. This Committee had concentrated on measures to prevent the spread of animal-borne salmonella infections at the beginning of the food chain, e.g. on the farm. It had stressed the need to apply measures such as decontamination of animal feeds, vaccination of animals against salmonellosis, use of competitive intestinal flora, raising of SPF-animals, good animal husbandry and others.

WHO Consultation on Epidemiological Emergency in Poultry and Eggborne Salmonellosis

26. This Consultation had concluded that the greatest potential for effective control of human salmonellosis originating from poultry and poultry products was agricultural production free of infection, and that the strategy of microbiologically controlled poultry production must be supplemented by increasing efforts to improve hygiene in food processing and preparation and to apply preventive measures, e.g. heat, irradiation, and chemical treatment of food.

WHO Golden Rules for Safe Food Preparation

27. WHO had recently published ten golden rules for safe food preparation which were available in the form of a poster in English, French, Spanish, Chinese and German. The rules are also contained in the document "Food Safety - Examples of Health Education Materials" (document WHO/EHE/FO8.89/2).

**PAHO REGIONAL ACTIVITIES**

28. The representative of PAHO informed the Committee of various activities carried out in the region within the framework of the Regional Programme of Technical Cooperation in Food Protection. These activities covered several main areas.

29. A number of workshops and meetings were devoted to foodborne diseases - two workshops, in Venezuela (June 1988) and Argentina (August 1988), a Regional Training Course on HACCP (Argentina) and a round table discussion of Food Protection (Buenos Aires). A Latin American Network on Foodborne Disease Monitoring was also established.

Assistance was provided to HACCP research projects on Salmonella and sampling plans, and PAHO provided direct technical assistance on food safety to 12 countries from Latin America and the Caribbean.

INTERNATIONAL ORGANIZATION ACTIVITIES

The Committee noted information supplied by the delegation of France on behalf of ISO about a number of microbiological standards published or being elaborated by this organization. The observer of IDF thanked the Committee for being given the opportunity to help prepare items 9 and 10 of the agenda of the session.

REVIEW OF MATTERS RELEVANT TO THE COMMITTEE AS DISCUSSED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 4a)

The Secretariat introduced working paper CX/FH 89/2. The Committee noted the decisions and texts adopted by the Commission.

The Committee expressed support for the decision of the Codex Coordinating Committee for Europe not to include microbiological criteria in the regional standard for mayonnaise (ALINORM 89/19 para 65). The Committee noted that the establishment of microbiological criteria for foods should be considered carefully, and agreed that there should be full discussion of the need for such criteria, particularly with a view of their possible implications as non-tariff trade barriers. The Chairman of the Codex Committee on Fish and Fishery Products informed the Committee of the difficulties in producing microbiological specifications for crab meat, due to a lack of the appropriate data and agreement on what specifications should be.

CONSIDERATION OF A PROPOSAL FOR A DRAFT CODE OF PRACTICE FOR THE PREPARATION AND SALE OF STREET FOODS (Agenda Item 4b)

The Secretariat introduced working paper CX/FH 89/3 which contained a proposal for core elements to be included in a code of hygiene for street foods and a proposed draft code for street vended foods considered at the 6th Session of the Codex Coordinating Committee for Latin America and the Caribbean (ALINORM 89/36 App. III). The Chairman summarized the tasks before the Committee as agreed to by the 36th Session of the Executive Committee to examine and propose a number of core elements to serve as guidance to the Regional Coordinating Committees in the elaboration of codes of hygienic practice for street vended foods. The delegations of Sweden and USA stressed the need to specify the target audience to which the documents would be addressed, i.e., national regulatory authorities.

The delegations of Canada and the United Kingdom suggested that more core elements be included such as training, and a list of most hazardous regional foods. A general modification of the structure of the code was also suggested, which would involve a gradual development of various stages of the code.

The delegation of the USA, supported by the delegation of Belgium, noted that only key points and basic elements should be considered by the Committee, and that details should be left to the regional coordinating committees, with a view towards final review by the CCFH.

The delegate of the Federal Republic of Germany and the WHO Representative noted that the basic elements, as well as the draft Code presented at the 6th Session of the Coordinating Committee for Latin America and the Caribbean, did not sufficiently address the most important issues related to food safety, e.g. factors responsible for food contamination and for the growth and survival of foodborne pathogens.

The delegations of Cuba, Brazil and Colombia stressed the importance of street-vended foods in the region and the need for a code of hygienic practice bearing the approval of FAO and WHO.

The Committee agreed to recommend to the Executive Committee to request FAO and WHO to consider convening an expert consultation on street food hygienic practices in order to produce a more detailed document for consideration by the CCFH and the Regional Coordinating Committees.
CONSIDERATION OF GENERAL HYGIENE PROVISIONS AND ENDORSEMENT OF FOOD HYGIENE SECTIONS IN CODEX STANDARDS (Agenda Item 5)

Draft General Provisions Relating to Hygiene

41. The Committee had before it document CX/FH 89/4, which summarized comments from the Governments of Thailand and the United States submitted in response to CL 1988/26-FH.

42. The Committee noted that it had, at its 23rd Session, agreed to solicit comments at Step 3 on the Draft General Provisions Relating to Hygiene (ALINORM 89/13, Appendix III), with a view towards simplifying the endorsement procedure while achieving unification in Codex standard hygiene provisions at the same time.

43. The delegation of the United States noted its written comments, which suggested the addition of the phrase "in the food" to Section 2(a) of the draft provisions (see CX/FH 89/4).

44. The Committee agreed to this proposed revision, and noted that individual Codex Committees were responsible for deciding which text of the provisions were applicable to their specific product standards. The Committee also recommended that these provisions should be applied retroactively to all Codex standards when they are revised or republished in the Revised Codex Alimentarius, and that only items deviating from these general provisions would need to be subject to future endorsement. The Committee agreed to advance the draft General Provisions Relating to Hygiene to the 19th Session of the Commission at Step 5 of the Codex Procedure (the text is attached as Appendix II).

Endorsement of Provisions Relating to Food Hygiene in Codex Standards for Processed Meat and Poultry Products

45. The Committee noted that Part C of document CX/FH 89/4 - Add.1 provided a summary of deliberations which took place at the 14th Session of the Codex Committee on Processed Meat and Poultry Products in September 1988. This document also included proposed revisions of the hygiene sections in the Codex standards for Corned Beef, Luncheon Meat, Cooked Cured Ham, Cooked Cured Pork Shoulder and Cooked Cured Chopped Meat, as forwarded by CCPMPP for endorsement. (ALINORM 89/16, Appendices V to IX).

46. The Committee agreed to have Canada revise several sections in these provisions in order to provide meaningful references to existing Codes of Hygienic Practice, with a view towards their eventual alignment with the General Provisions agreed to above (see paragraph 44). The revised sections were endorsed by the Committee, and are included as Appendix III to this document.

GUIDELINES FOR THE SALVAGING OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS (Agenda Item 6a)

47. In introducing this item the Chairman of the Canned Foods Working Group (Canada) informed the Committee that due to a lack of comments the document had not been considered at the Paris meeting of the group in November 1988.

48. The delegation of the United States presented its comments as summarized in CX/FH 89/5. These consisted of changes in, and additions to, Sections 2.11, 2.13, 3.6 and 4.6. In response to the concern expressed by the delegation of Brazil regarding the characteristics of recanned or reprocessed product, an additional paragraph was added to Section 4.6. The delegation of Spain also drew attention to an error in Section 2.10 of the Spanish version of the draft.

49. The Committee concurred with these proposed revisions, and forwarded the guidelines for adoption to the Commission at Step 8. The revised text of the Guidelines is annexed as Appendix IV to this report.
GUIDELINE PROCEDURES TO ESTABLISH MICROBIOLOGICAL CAUSES OF SPOILAGE IN CANNED FOODS (Agenda Item 6b)

50. The Committee was informed that this document was not reviewed at the Paris meeting of the Canned Food Working Group (November 1988). The comments of the United States, however, were presented to the Committee under Conference Room Document No. 8.

51. The delegation of Thailand proposed that the temperature interval of 30°C to 35°C in figures 2 and 3 of the text be changed to 30°-37°C. The upper limit was said to be more realistic for tropical countries such as Thailand. The delegation of the United States, supported by the delegation of Canada, pointed out that this proposal was acceptable provided it was accompanied by a cautionary note.

52. The delegation of the United States proposed that this document be further reviewed with a view of being extended to other types of containers and situations. The delegation of the United Kingdom pointed out that attempting to cover all new technologies and types of containers would mean an indefinite delay in producing the document. The delegation noted further that the guidelines have been on the agenda for a long time and urged the committee to speed up their elaboration.

53. The delegation of Canada summed up all proposed changes and revisions which were approved by the Committee. The Committee agreed to forward the revised guidelines for adoption by the Commission at Step 5. Taking into consideration the detailed revision of the document and its importance, the Committee agreed to recommend to the Commission to consider adopting the guidelines at Step 8 with the omission of Steps 6 and 7. The revised text is annexed as Appendix V.

VISUAL EXAMINATION OF LOTS OF CANNED FOODS (Agenda Item 6c)

54. The Chairman recalled that the 23rd Session of the CCFH had examined the above document together with the Defect Classification and Manual. The Working Group on Canned Foods (Paris, November 1988), had dealt with these items separately, and the Chairman of the group introduced the working paper CX/FH 89/7, entitled "A Guide for the Visual Inspection of Lots of Canned Foods for Objective 1 Defects".

55. The delegation of the United Kingdom noted that the document would provide useful guidance for the inspection of canned food. The delegation outlined the origin of the document as a companion text to existing codes and the pictorial manual. It also stressed that it could be elaborated on its own and suggested that the document be labelled as a guidelines.

56. The delegation of the United States noted that the Guide is an acceptable document which could be referenced in other documents. The delegation of Canada questioned the independent status of the guides in view of the undecided question of the pictorial manual.

57. The Committee agreed that the document should be circulated for comments at Step 3 of the Codex procedure under the title of "Guideline Procedures for the Visual Inspection of Lots of Canned Foods for Objective 1 Defects". The revised text is annexed as Appendix VI.

DEFECT CLASSIFICATION AND MANUAL (Agenda Item 6d)

58. The delegation of Canada presented Conference Room Document 7, which contained the report of the meeting of the Canned Food Working Group in Paris, November 1988. The group had reviewed the preparations of the Pictorial Manual for objective 1 defects and had also examined existing published manuals. The group had considered that the preparation of a complete defect manual would be a very costly exercise, and recommended that existing manuals be utilized.

59. The delegation of the United Kingdom supported this position and agreed that there were books and manuals available that could be used in conjunction with the "Guideline Procedures for the Visual Inspection of Lots of Canned Foods".
60. The delegation of the United States indicated that a manual produced as a Codex document would be available to a wide range of users for which more costly manuals were not accessible. In reply to a query from the Secretariat concerning possible costs and a time frame for the preparation of such a manual, the delegations of the United States and Canada informed the Committee that a model manual could be produced collaboratively within several months.

61. The Committee agreed to request Canada, with the assistance of the United States, to prepare a draft model pictorial manual by May 1990 in order to allow the 37th Session of the Executive Committee (July 1990) to determine the feasibility of continuing its elaboration.

CONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-COOKED AND COOKED FOODS IN MASS CATERING (Agenda Item 7)

62. In discussing the proposed Code (ALINORM 89/13, Appendix IX) the Committee had before it working paper CX/FH 89/9 and Conference Room Documents 3 and 9, which summarized comments submitted in response to CL 1988/26-PH from the governments of France, Switzerland, Thailand and the United States.

63. The Chairman provided a brief background concerning the elaboration of the proposed Code, and noted that the 18th Session of the Commission had endorsed the draft Code at Step 5 of the Codex procedure.

64. The Chairman of the Working Group on Mass Catering, Dr. Stanley Green (USA), summarized the group's deliberations concerning this issue. The Committee noted that the Working Group had revised and adopted several definitions and sections in the proposed Code while evaluating comments submitted by governments concerning this subject. The report of the Working Group was circulated to the Committee in Conference Room Document 12.

65. The Committee debated at length the various issues presented in the Working Group report, including definitions, methods of disinfection, document references, the need for medical examinations, storage of toxic materials, temperature parameters and translation difficulties (e.g. the Committee agreed that the storage temperature should be 4°C).

66. In view of the complexity of written and oral comments, and in consideration of the limited time allowed for document review by Codex delegations, the Committee agreed to return the proposed draft Code to Step 6 of the Codex Procedure in order to allow for additional debate. It was further agreed that the revised Code would be circulated for comment along with the Committee's report in order to expedite this process. The revised code is attached to this report as Appendix VII.

67. The Committee, at the suggestion of the delegation of Canada, also agreed to request France to elaborate a document addressing refrigerated packaged food with extended shelf-life for discussion at the next Committee session, with the understanding that the Executive Committee of the Codex Alimentarius Commission and/or the Commission will concur with the development of such a document at its earliest opportunity (i.e. July 1991). The Committee noted that the paper in question would be based on existing French documentation.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR ASEPTIC FOOD PROCESSING AND PACKAGING SYSTEMS (Agenda Item 8)

68. In discussing the proposed Code the Committee had before it working paper CX/FH 89/10, which summarized a comment from Thailand submitted in response to CL 1988/26-PH, as well as Appendix VII of ALINORM 89/13 (Revised), which included the Draft Code of Hygienic Practice for Aseptically Processed and Packaged Low Acid Foods as re-drafted by the Aseptic Working Group Meeting in Paris (14 to 18 November 1988). The delegation of the United States presented these documents and gave a short background to the elaboration and revision of the draft code.
The delegation of France noted that the Code referred to low acid foods, i.e. those with a pH above 4.6, and suggested that an annex be provided to cover the aseptic packaging of acid foods such as fruit juices with a pH below 4.6. It was suggested that the annex should be analogous to the Annex on Acidified Foods in the Code of Hygienic Practice for Low Acid and Acidified Low Acid Canned Foods.

The delegation of the United States pointed out that while the canning of acidified low acid foods is included as an annex to the code of low acid foods, the situation in aseptic canning is more complicated in terms of equipment and processes. The delegation suggested that the elaboration of a separate code be considered.

The Committee agreed to advance the code to Step 5 and to request the delegation of the United States to report at the next session on the need for elaborating an annex for acid foods. The document is annexed to the report as Appendix VIII.

CONSIDERATION OF A PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED UNRIPENED CHEESE AND RIPENED SOFT CHEESE (Agenda Item 9)

In discussing this agenda item, the Committee had before it working paper CX/FH 89/11, which contained the draft Code of Hygienic Practice for Uncured Unripened Cheese and Ripened Soft Cheese, as well as Conference Room Documents 5 and 10, which contained revisions to the Code adopted by the IDF at its annual session of 4 to 8 September 1989, and revisions to Sections 2.9 and 7.7.3 by the observer from the IDF, respectively. The Chairman invited comments from the floor concerning the proposed Code.

The delegation of France indicated that separate Codes needed to be developed for each category of cheese, in view of different characteristics between uncurd unripened cheeses and ripened soft cheeses. The delegation emphasized that pasteurized milk was not required for the production of many cured cheeses, and suggested the development of microbiological criteria for the category of cured cheeses made from pasteurized milk, and other criteria for the category of cured cheeses made from non-pasteurized milk. The delegation of the United States requested that pasteurization in Section 2.1 of the Uncured Unripened Cheese category remain obligatory while the delegation of Norway felt that all milk used in cheese production should be pasteurized.

The delegation of Canada, with support from the delegation of France, objected to defining pasteurization in section 2.9 of the cheese code on the basis of the definition used in powdered milk. The delegation of Canada also noted that the time/temperature combinations for pasteurization were too restrictive and should be broadened.

The delegation of the United States noted that a sample size of 5 for Listeria and Salmonella in Section IX (Microbiological Criteria) was insufficient, while the delegation of Norway indicated that the microbiological specifications for E. coli did not seem strict enough. The delegation of Canada also noted that controlling cheese microbiological quality with end product specifications was difficult.

The delegations of Denmark and Canada noted that provisions relating to the composition of floors and walls should not reference non-toxic materials, in order to correspond to definitions included in the Code of General Principles of Food Hygiene. The delegation of Spain also indicated that the ceiling definition reference to dirt should more appropriately refer to "dust".

The delegation of Canada also questioned the feasibility of controlling air as "free from odors and other contaminants" in Section 4.4.4, while the delegation of France noted that requiring air to be "free from microorganisms" was inappropriate in view of natural moulds on cheese surfaces.

And finally, the delegation of Denmark suggested that the figure of 220 lux in Section 4.4.9 should also refer to 20 foot candles. Several delegations objected to the use of the term "official agencies" in Sections 8.2 and 6.2.
79. The delegation of France stated that the three documents presented for discussion by the IDF were not consistent, and that the views of several important cheese producing countries not present at this meeting had not been considered. The delegate also noted that the document had not been sent for government comments, and that it would be premature to move it forward.

80. The Committee concluded that the continued development of a single Code for these products was warranted, but that in view of the above discussions, that it should be returned to Step 3 of the Codex Procedure. The Committee also agreed to consider the deliberations of the ad-hoc HACCP group towards its review of the hazard analysis critical control point annexes. The Committee encouraged the coordination of National IDF and Codex delegations towards the development of the Code.

81. It was agreed that the Codex Secretariat would issue a Circular Letter to solicit comments on the Code at Step 3, in order to allow time for their consideration by the Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products at its 22nd Session in June 1990. The proposed draft Code is annexed as Appendix IX.

PROPOSED DRAFT GUIDELINES FOR THE PRESERVATION OF RAW MILK BY USE OF THE LACTOPEROXIDASE SYSTEM (Agenda Item 10)

82. The Committee had before it working paper CX/FH 89/12 and Conference Room Document 4, which summarized comments submitted in response to CL 1988/22-FH/MDS from the governments of Belgium, Denmark, Federal Republic of Germany, Madagascar, Sweden and Thailand. The International Dairy Federation (IDF) provided background information and comments concerning this issue in Conference Room Document 6.

83. The Committee noted that the proposed guidelines were developed by the IDF at the request of the 21st Session of the Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products (CCMDS). The 23rd Session of the CCFH considered the draft guidelines in March 1988, and agreed that comments should be solicited at Step 3, (CL 1988/22-FH/MDS). The 35th Session of the Executive Committee (July 1988) and the Third Session of the Milk Committee Steering Group (May 1989) agreed with this procedure. The 18th Session of the Codex Alimentarius Commission (July 1989) endorsed these recommendations.

84. The Committee also noted that the 35th Session of the Joint FAO/WHO Expert Committee on Food Additives (June 1989) had evaluated the draft guidelines, and recognized that the use of the lactoperoxidase system would increase total thiocyanate exposure but that this would not pose any toxicological hazard provided that iodine intake was adequate. JECFA concluded that, when used according to the draft guidelines, the lactoperoxidase system did not present a toxicological hazard and, furthermore, the system was preferable to hydrogen peroxide alone for raw milk preservation only where absolutely necessary, i.e., in the absence of adequate refrigeration facilities.

85. The observer from the IDF reiterated that the system was referred to as a guideline instead of a code of practice, and indicated that the title of the document was revised by removing the phrase "where refrigeration is virtually impossible" as this restriction was accurately reflected in the Scope section. IDF also indicated that it supported the minor amendment to Section III (Intended Utilization of Method) as suggested in the comments of Denmark (CX/FH 89/2). The observer from IDF stressed the importance of adopting the guidelines as quickly as possible in view of the potential need in developing countries throughout the world.

86. The delegation of Canada reminded the Committee that the 23rd Session of the CCFH had added the phrase "where refrigeration is virtually impossible" to the guideline title. The delegation of Belgium supported the retention of the longer title to ensure the limited use of the guidelines. The delegation of Sweden supported the shorter text as the Scope section of the guidelines was felt to be sufficiently restrictive. The Committee supported the use of the shorter title. The Committee also noted that the Scope section clearly indicated the method was limited to preventing bacterial spoilage of raw milk during collection and transportation to a dairy processing plant.
The delegation of the USA stressed that this system was only acceptable for non-refrigerated milk, and was not applicable to products moving in international trade. The USA also noted that the system did not exclude the necessity of pasteurization of milk before human consumption, as outlined in Section 3.6, while the delegation of the Federal Republic of Germany noted that the method was not an alternative to refrigeration.

The delegation of the United Kingdom indicated that the guidelines presented useful information for countries in need of such a system and supported its rapid elaboration. The delegations of Brazil, Colombia, Cuba and the United States concurred with this view, as the method was needed for consumer protection and had been evaluated as safe by JECFA.

The Committee, while agreeing that the method was not acceptable for products intended for international trade or for other than non-refrigerated milk, decided to advance the Code to Step 5 of the Codex Procedure for review at the 22nd Session of the CCMDS (June 1990) and for consideration at the 19th Commission Session (July 1991). The Committee also recommended the omission of Steps 6 and 7 of the Codex procedure in order to allow for the rapid adoption of the guidelines by the Commission at Step 8. The guidelines are annexed to this report as Appendix X.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS (Agenda Item 11)

The Committee had before it working paper CX/FH 89/13 when discussing this agenda item, and noted that the 22nd CCFH Session (October 1986) had decided against the elaboration of a General Code of Practice at that time. The 17th Session of the Commission, while noting this decision, agreed with the CCFH proposal that the Codex Committee on Processed Meat and Poultry Products (CCPMPP) should develop a Code for its own specific needs. The 18th Session of the CCPMPP agreed to the circulation of a proposed guide limited to microbiological aspects of spices and herbs used in processed meat and poultry products for government comments at Step 3 (ALINORM 89/16, Appendix III). As several countries continued to support the elaboration of a General Code of Hygienic Practice for Spices, the 18th Session of the Commission had decided to return this matter to CCFH for consideration.

The Committee noted that the proposed Code, as contained in CX/FH 89/13, was originally prepared by a technical committee (ISO/TC 34/SP 7) of the International Organization for Standardization, and had been referred to CCFH for further elaboration. The Committee was requested to circulate the proposed Code at Step 3 of the Codex Procedure for comment, as agreed to by the Commission.

The delegation of the United Kingdom, with support from the delegations of the United States and Norway, welcomed the elaboration of such a Code. The delegation of the United Kingdom also felt that the Code was too general and needed to be more specific. The delegation of Sweden supported this opinion, and agreed with the delegation of Norway that the Code was important among other reasons because presently available methods for the disinfection of spices such as irradiation, and the use of ethylene oxide are banned in some countries. The delegation of France also suggested that additional sections such as storage (temperature) and drying controls should be added.

The delegation of the United States, while suggesting that the Code should be narrowed to enhance its effectiveness, also noted that the document should be elaborated as a guideline. The delegation of Norway, with support from the United States, requested the Secretariat to contact the FAO/WHO Legal Office in order to define exact differences between guidelines and codes of practice. The Committee agreed to this proposal, and noted that this problem was also applicable to previous discussions concerning the title of the Lactoperoxidase Guidelines (see paras 85, 86).

The Committee agreed to circulate the Code of Hygienic Practice for Spices to governments for comment at Step 3. The proposed draft Code is attached to this report as Appendix XI.
The Ad-Hoc Group considered the working paper prepared by the United States (CX/FH 89/14), which, among other issues, detailed the evolution and technical complexities of the HACCP concept in food control systems. It was indicated that when HACCP was properly applied, it could serve as an excellent system to focus scarce resources in providing increased consumer protection. The Ad-Hoc Group also considered the previous deliberations of the 22nd CCFH session, as summarized in Appendix VI of ALINORM 87/31A.

The working group reached the following conclusions:

(i) The HACCP system was thought to offer considerable potential benefits in the field of food safety, and its widespread use should be encouraged by the Codex Alimentarius Commission.

(ii) The current critical control point notes contained in many of the Codex Codes were not HACCP derived (developed through a formal HACCP process for the commodity) but rather, explain the need for the requirement.

(iii) For Codex purposes, general principles on the application of HACCP, including internationally agreed definitions for key terms such as "hazard", "critical control point", etc. must be elaborated. These general principles could be aligned with those presented in Appendix VI of ALINORM 87/13A.

(iv) The Ad-Hoc Group confirmed its view that HACCP was applicable only to a specific processing operation. Nevertheless, it was felt that generic HACCP models could be elaborated in connection with Codes of Practice which address certain processes, such as the Code for Low Acid Canned Foods – and possibly also in connection with specific product commodity codes.

(v) Because of the importance of the subject, and in consideration of the need for internationally agreed principles and definitions for use within the Codex Procedure, the Ad-Hoc Group recommended that it should begin to elaborate proposals for such principles and definitions for presentation to the next meeting of CCFH.

(vi) Although the Ad-Hoc Group did not discuss the HACCP plan in document CX/FH 89/11, (Draft Code of Hygienic Practice for Uncured Unripened Cheese and Ripened Soft Cheese) in any detail, it recognized the value of the approach and was of the opinion that should a group continue to work in this area, it should also examine this document and make appropriate recommendations.

After consideration of the Ad-Hoc working group report, the Committee concurred with its conclusions, and agreed to continue the working group for the express purpose of producing a document with agreed upon general HACCP definitions and procedures for use by Codex. The delegation of Sweden cautioned the Committee that the Codex Committee on General Principles and the Commission have discouraged the creation of working groups outside of Codex plenary sessions. In this regard, the Chairman pointed out that every effort is made to keep such meetings to a minimum and should only be considered by the Committee when necessary. The Secretariat observed that if the working group continued its work, it should produce a document far in advance of the next CCFH session in order to allow for its early distribution and solicitation of comments.

The USA agreed to continue acting as Chairman of the working group, and the countries of Canada, France, Norway, UK, Sweden, Switzerland, Federal Republic of Germany, Finland and the observer of the EEC agreed to participate.
CONSIDERATION OF THE OCCURRENCE AND PREVENTION OF LISTERIA MONOCYTOGENES IN FOODS
(Agenda Item 13)

99. The Committee noted that its 23rd Session had requested the delegations of the Federal Republic of Germany and the Netherlands to prepare a summary of existing recommendations made by various expert groups on Listeria monocytogenes in foods for review by the Committee, in order to determine the need, if any, for actions to be taken concerning this issue.

100. The delegation of the Federal Republic of Germany informed the Committee that it would have been premature to present such a paper for consideration by the CCFH for a number of reasons, including the lack of adequate methodology for the determination of Listeria and a lack of appropriate codes of practice for the prevention of Listeria formation. Other microorganisms, such as Campylobacter and Yersinia were also mentioned as causing concern. The delegate also read a written statement provided by the delegation of Belgium which drew the attention of the Committee to the increased frequency of foodborne poisoning due to Salmonella enteriditis. The Belgian note also proposed that the agenda of the next meeting of CCFH should include a paper on the deliberations and recommendations of the WHO Working Group on Salmonella Control (WHO, TRS, 774, 1988).

101. The Committee noted that IDF had been asked to prepare a working paper on listeria for the 19th Session of the Milk Committee in Rome, June 1990. The Secretariat requested the Committee to suggest a more specific topic concerning Listeria if it was to be included as a future agenda item.

102. The delegation of the Federal Republic of Germany, supported by the delegation of Norway, reiterated its proposal that the Codex Secretariat should assume a coordinating role in preparing a document which summarized recommendations of various expert groups to determine what action, if any, the Committee should take in making proposals to the Commission for possible future deliberations concerning Listeria monocytogenes. The delegation of the United States supported this proposition.

103. The Committee concluded and agreed that the Codex Secretariat would issue a circular letter to gather information on recommendations concerning Listeria monocytogenes with the intention of preparing a working paper for the next CCFH session.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 14)

104. In introducing this item the Chairman requested the Committee to propose specific tasks for future work and to comment on other matters of a more general nature.

105. The delegation of the Federal Republic of Germany strongly urged the Committee to seek clarification from the Commission regarding its terms of reference, particularly in regard to the elaboration or endorsement of codes of practice and guidelines for food products which do not move in international trade.

106. The delegation of Sweden proposed that the Committee should agree to forward the following matters of principle to the Codex Executive Committee and/or the Codex Committee on General Principles for advice:

(i) A review of the Committee's terms of reference and future coordinating role in view of the importance of general subject committees in the Codex system;

(ii) A review of the timing of the Commission sessions in view of serious delays in the receipt of comments and elaboration of documents by the Committee;

(iii) When there is a Code of general principles within a subject area, the codes on specific subjects should be limited to essential differences to avoid unnecessary repetition;
(iv) The reconsideration of appropriate justification and guidelines for the establishment of ad-hoc working groups between sessions of the Committee.

107. The delegation of Sweden also emphasized that the Committee should concentrate on general matters and should be flexible enough to respond to hygienic problems of new products and technologies. The delegations of the United States and the United Kingdom stated that the future work of the Committee should be oriented towards ideas for future work which could be collected through a Circular Letter.

108. The delegation of the United Kingdom supported the positions of the Federal Republic of Germany and Sweden concerning a review of the terms of reference and future work of the Committee, and stressed that the Committee should accurately define its future tasks.

109. The delegation of the United States agreed with the concerns of the Federal Republic of Germany regarding the elaboration or endorsement of documents for products which did not enter international markets.

110. The delegations of Brazil, Cuba and Colombia stressed the importance of their countries' participation in the work of Codex for their international trade, consumer protection, national food legislation and regulation, and at the same time requested the Committee to devote more attention to regional problems and to consider them as important as the international issues discussed within the Committee.

111. The Committee agreed to refer the above matters concerning terms of reference, timing of sessions and the creation of working groups to the Executive Committee and/or Codex Committee on General Principles for review and advice.

112. The Committee also agreed that the following items should be included in the agenda for its 25th Session:

- Draft Manual for Objective 1 defects.
- Draft Code of Hygienic Practice for Spices.
- HACCP - principles of application to Codex work.
- Review of recommendations made by expert committees concerning Listeria monocytogenes.
- Code of Hygienic Practice for refrigerated packaged foods with extended shelf-life.
- Code of Hygienic Practice for aseptic food processing and packaging systems.

113. The meeting noted that the appendices to the report, with the exception of the List of Participants, were not seen by the Committee and therefore could not be considered as adopted textually. However the Committee noted further that this does not affect the decisions as summarized in the body of the report concerning the further elaboration of these documents through the Codex procedure including their forwarding for adoption by the Commission at Step 8.

114. The Committee was informed that its Twenty Fifth Session will be held in October 1991 in Washington, D.C., USA.
### SUMMARY STATUS OF WORK

<table>
<thead>
<tr>
<th>Subject Matter</th>
<th>Step</th>
<th>Action by</th>
<th>Document Reference</th>
</tr>
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<tbody>
<tr>
<td>Guidelines for the Salvaging of Canned Foods Exposed to Adverse Conditions</td>
<td>8</td>
<td>Governments</td>
<td>ALINORM 91/13, App. IV</td>
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<td>Draft Guideline Procedures to Establish Microbiological Causes of Spoilage in Canned Foods</td>
<td>8</td>
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<td>ALINORM 91/13, App. V</td>
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<tr>
<td>Draft Guidelines for the Preservation of Raw Milk by Use of the Lactoperoxidase System</td>
<td>8</td>
<td>Governments</td>
<td>ALINORM 91/13, App. X</td>
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<tr>
<td>Draft General Provisions Relating to Hygiene in Codex Standards</td>
<td>5</td>
<td>19th CAC</td>
<td>ALINORM 91/13, App. II</td>
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<tr>
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<td>19th CAC</td>
<td>ALINORM 91/13, App. VIII</td>
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<td>Proposed Draft Guideline Procedures for the Visual Inspection of Lots of Canned Foods for Objective 1 Defects</td>
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<td>ALINORM 91/13, App. VI</td>
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<td>Governments</td>
<td>ALINORM 91/13, App. XI</td>
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<td>Food Hygiene Provisions in the Draft Revised Codex Standards for Corned Beef, Luncheon Meat, Cooked Cured Ham, Cooked Cured Pork Shoulder and Cooked Cured Chopped Meat, all at Step 5</td>
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<td>CC/PMPP</td>
<td>ALINORM 91/13, para. 46; App. III</td>
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<td>ALINORM 91/13, paras 96-97</td>
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<td>Summary of Recommendations on Listeria monocytogenes made by Expert Consultations</td>
<td>- Codex Secretariat 25th CCFH</td>
<td>ALINORM 91/13, paras 102-103</td>
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<td>Proposal for a Draft Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-life</td>
<td>- 19th CAC, France 25th CCFH</td>
<td>ALINORM 91/13, para. 67</td>
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<td>Core Elements for a Draft Code of Hygienic Practice for Street Foods</td>
<td>- 37th Executive Committee 25th CCFH</td>
<td>ALINORM 91/13, para. 40</td>
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Commodity Committees may wish to select one of the following texts according to the nature of the product subject to the standard:

1. For shelf-stable products where microbiological spoilage before or after process is unlikely to be of significance:

   - It is recommended that the product covered by the provisions of this Standard be prepared in accordance with the appropriate sections of the General Principles of Food Hygiene recommended by the Codex Alimentarius Commission (Ref. No. CAC/RCP 1-1969, Rev. 2 - 1985).

2. For shelf-stable products, heat-processed in hermetically sealed containers:

   - It is recommended that the product covered by the provision of this standard be prepared in accordance with the General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 2 - 1985) and, where appropriate, with the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. CAC/RCP 23-1979, Rev. 1 - 1989) or other Codes of Hygienic Practice as recommended by the Codex Alimentarius Commission.

   - To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

   - When tested by appropriate methods of sampling and examination, the product:

     (a) shall be free from microorganisms capable of development in the food under normal conditions of storage; and

     (b) shall not contain any substance originating from microorganisms in amounts which may represent a health hazard.

3. For all other products:

   - It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 2 - 1985), and other Codes of Practice recommended by the Codex Alimentarius Commission which are relevant to this product. (A list may follow).

   - To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

   - When tested by appropriate methods of sampling and examination, the product:

     (a) shall be free from microorganisms in amounts which may represent a hazard to health;

     (b) shall be free from parasites which may represent a hazard to health; and

     (c) shall not contain any substance originating from microorganisms in amounts which may represent a hazard to health.
1. Draft Revised Codex Standard for Corned Beef (At Step 5 of the Procedure; ALINORM 89/16, App. V)

6. HYGIENE


6.2 All meat used in the manufacture of corned beef shall have been subjected to the inspection processes prescribed in the Code of Hygienic Practice for Fresh Meat and in the Code of Practice for Ante-Mortem and Post-Mortem Judgment of Slaughter Animals and Meat. It shall have been passed by an inspector as fit for human consumption. Meat shall not, subsequent to being examined by an inspector, have been exposed to contamination or processed or handled or subjected to the addition of any harmful substance, which renders it unfit for human consumption.

6.3 Raw or semi-processed meat and corned beef shall be handled, stored or transported in an establishment in a manner that will protect the meat and the corned beef from contamination and deterioration.

6.4 Corned beef shall be packed in hermetically sealed containers in compliance with Sub-section 7.4 of the Recommended International Code of Hygienic Practice for Low Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.5 Corned beef shall be thermally processed in compliance with Sub-sections 7.5 and 7.6.1 to 7.6.7 inclusive, of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.6 The cooling of the thermally processed filled and sealed containers shall be carried out in compliance with Sub-section 4.6.8 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.7 After thermal processing the fitted, sealed containers shall be handled in compliance with Sub-section 7.7 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

2. Draft Revised Codex Standard for Luncheon Meat (At Step 5; ALINORM 89/16, App. VI)

6. HYGIENE

6.1 It is recommended that the Recommended International Code of Hygienic Practice for Processed Meat and Poultry Products (Ref. No. CAC/RCP 13-1976 (Rev. 1) (1985)), where applicable the Recommended International Code of Hygienic Practice for Poultry Processing (Ref. No. CAC/RCP 14-1976), the

6.2 All meat used in the manufacture of luncheon meat shall have been subjected to the inspection processes prescribed in the Code of Hygienic Practice for Fresh Meat and, where applicable, the Code of Hygienic Practice for Poultry Processing. Meat from mammals shall have been inspected according to the Code of Practice for Ante-Mortem and Post-Mortem Judgment of Slaughter Animals and Meat. It shall have been passed by an inspector as fit for human consumption. Meat shall not, subsequent to being examined by an inspector, have been exposed to contamination or processed or handled or subjected to the addition of any harmful substance, which renders it unfit for human consumption.

6.3 Raw or semi-processed meat and luncheon meat shall be handled, stored or transported in an establishment in a manner that will protect the meat and the luncheon meat from contamination and deterioration.

6.4 Luncheon meat shall be packed in hermetically sealed containers in compliance with Sub-section 7.4 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.5 If luncheon meat is heat treated before packaging it shall be packaged in such a way that contamination is kept to a minimum, so that the product will withstand spoilage and present no public health hazard under the conditions of handling, storage, transport and sale indicated on the label. The containers themselves shall not present any health hazard or permit contamination under normal conditions of handling. They shall be clean, and where applicable, show evidence of vacuum.

6.6 Luncheon meat shall be thermally processed in compliance with Sub-sections 7.5 and 7.6.1 to 7.6.7 inclusive, of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.7 The cooling of the thermally processed filled and sealed containers shall be carried out in compliance with Sub-section 4.6.8 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.8 After thermal processing the fitted, sealed containers shall be handled in compliance with Sub-section 7.7 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

3. Draft Revised Codex Standard for Cooked Cured Ham (At Step 5; ALINORM 89/16, App. VII)

6. HYGIENE


1/ Whenever the word "meat" is used in this section, it includes meat, edible offal and poultry meat.
6.2 All meat used in the manufacture of cooked cured ham shall have been subjected to the inspection processes prescribed in the Code of Hygienic Practice for Fresh Meat and the Code of Practice for Ante-Mortem and Post-Mortem Judgement of Slaughter Animals and Meat. It shall have been passed by an inspector as fit for human consumption. Meat shall not, subsequent to being examined by an inspector, have been exposed to contamination or processed or handled or subjected to the addition of any harmful substance, which renders it unfit for human consumption.

6.3 Raw or semi-processed meat and cooked cured ham shall be handled, stored or transported in an establishment in a manner that will protect the meat and the cooked cured ham from contamination and deterioration.

6.4 Cooked cured ham shall be packed in hermetically sealed containers in compliance with Sub-section 7.4 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.5 If cooked cured ham is heat treated before packaging it shall be packaged in such a way that contamination is kept to a minimum, so that the product will withstand spoilage and present no public health hazard under the conditions of handling, storage, transport and sale indicated on the label. The containers themselves shall not present any health hazard or permit contamination under normal conditions of handling. They shall be clean, and where applicable, show evidence of vacuum.

6.6 Cooked cured ham shall be thermally processed in compliance with Sub-sections 7.5 and 7.6.1 to 7.6.7 inclusive, of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.7 The cooling of the thermally processed filled and sealed containers shall be carried out in compliance with Sub-section 4.6.8 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.8 After thermal processing the fitted, sealed containers shall be handled in compliance with Sub-section 7.7 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

Draft Revised Codex Standard for Cooked Cured Pork Shoulder
(At Step 5; ALINORM 89/16, App. VIII)

6. HYGIENE


6.2 All meat used in the manufacture of cooked pork shoulder shall have been subjected to the inspection processes prescribed in the Code of Hygienic Practice for Fresh Meat and the Code of Practice for Ante-Mortem and Post-Mortem Judgement of Slaughter Animals and Meat. It shall have been passed by an inspector as fit for human consumption. Meat shall not, subsequent to being examined by an inspector, have been exposed to contamination or processed or handled or subjected to the addition of any harmful substance, which renders it unfit for human consumption.
6.3 Raw or semi-processed meat and cooked cured pork shoulder shall be handled, stored or transported in an establishment in a manner that will protect the meat and the cooked cured pork shoulder from contamination and deterioration.

6.4 Cooked cured pork shoulder shall be packed in hermetically sealed containers in compliance with Sub-section 7.4 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.5 If cooked cured pork shoulder is heat treated before packaging it shall be packaged in such a way that contamination is kept to a minimum, so that the product will withstand spoilage and present no public health hazard under the conditions of handling, storage, transport and sale indicated on the label. The container itself shall not present any health hazard or permit contamination under normal conditions of handling. They shall be clean and, where applicable, show evidence of vacuum.

6.6 Cooked cured pork shoulder shall be thermally processed in compliance with Sub-sections 7.5 and 7.6.1 to 7.6.7 inclusive, of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.7 The cooling of the thermally processed filled and sealed containers shall be carried out in compliance with Sub-section 4.6.8 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.8 After thermal processing the fitted, sealed containers shall be handled in compliance with Sub-section 7.7 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

5. Draft Revised Codex Standard for Cooked Cured Chopped Meat (At Step 5; ALINORM 89/16, App. IX)

6. HYGIENE


6.2 All meat 1/ used in the manufacture of cooked chopped meat shall have been subjected to the inspection processes prescribed in the Code of Hygienic Practice for Fresh Meat and, where applicable, the Code of Practice for Ante-Mortem and Post-Mortem Judgement of Slaughter Animals and Meat. It shall have been passed by an inspector as fit for human consumption. Meat shall not, subsequent to being examined by an inspector, have been exposed to contamination or processed or handled or subjected to the addition of any harmful substance, which renders it unfit for human consumption.

6.3 Raw or semi-processed meat and cooked cured chopped meat shall be handled, stored or transported in an establishment in a manner that will protect the meat and the cooked cured chopped meat from contamination and deterioration.

1/ Wherever the word "meat" is used in this section it includes meat, edible offal and poultry meat.
6.4 Cooked cured chopped meat shall be packed in hermetically sealed containers in compliance with Sub-section 7.4 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.5 If cooked cured chopped meat is heat treated before packaging it shall be packaged in such a way that contamination is kept to a minimum, so that the product will withstand spoilage and present no public health hazard under the conditions of handling, storage, transport and sale indicated on the label. The container itself shall not present any health hazard or permit contamination under normal conditions of handling. They shall be clean and, where applicable, show evidence of vacuum.

6.6 Cooked cured chopped meat shall be thermally processed in compliance with Sub-sections 7.5 and 7.6.1 to 7.6.7 inclusive, of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.7 The cooling of the thermally processed filled and sealed containers shall be carried out in compliance with Sub-section 4.6.8 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).

6.8 After thermal processing the fitted, sealed containers shall be handled in compliance with Sub-section 7.7 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. No. CAC/RCP 23-1979 (Rev. 1, 1989)).
GUIDELINES FOR THE SALVAGE OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS (At Step 8 of the Procedure)

Table of Contents

Explanatory Preface
1. Scope
2. Definitions
3. On-Site Operations
   1. Assessment of Adverse Conditions
   2. Notification
   3. Product Inventory and Identification of Product Location
   4. Feasibility of Salvage
   5. Preliminary Sorting
   6. Removal from Site and Storage
4. Treatment of Potentially Salvageable Canned Foods
   1. Evaluation and Sorting
   2. Product Not Salvageable
   3. Evaluation for Contamination
   4. Visually Unaffected Containers Not Requiring Reconditioning
   5. Containers Requiring Reconditioning
   6. Recanning or Reprocessing
   7. Coding
5. Quality Assurance
6. Storage and Transport of Salvaged Product
7. Laboratory Control Procedures
8. End Product Specifications

Appendix I - Flow Chart of Sequence of Events
EXPLANATORY PREFACE

The purpose of this document is to provide guidelines for the salvage of canned foods manufactured in compliance with the International Code of Hygienic Practice for Low-acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979 (Rev. 1, 1989)) which are suspected of having become contaminated or otherwise rendered unsuitable for human consumption as a result of being subjected to adverse conditions, for example, flood, fire or other accidents, during their storage, transportation and/or distribution. The guidelines are designed to permit the salvage of canned food unaffected by such conditions and thus reduce the loss of wholesome food whilst preventing the sale or distribution of canned foods which may have been rendered unfit for human consumption.

The salvage operations should only be carried out by trained personnel under the direct supervision of person(s) having expert knowledge of canning and container technology.

The Hazard Analysis Critical Control Point (HACCP) concept should be applied when salvaging canned foods and should include:

1. An assessment of the hazards associated with the adverse conditions which led to the food being suspect and the various salvage operations to which it may be subjected.

2. Identification of the critical control points for the salvage operations and the type or frequency of the control measures deemed necessary.

3. Guidance for the monitoring of the critical control points including maintenance of adequate records.

1. SCOPE

These guidelines concern the salvage of lots of canned foods which are suspected of having been contaminated as a result of exposure to adverse conditions, (fire, flood, freezing or other accident), during storage, transportation and distribution. It is not intended to cover canned foods which are suspect as a result of errors or omissions on the part of the processor (canner); however, it may be applied to product subjected to adverse conditions while under the direct control of the processor (canner). A flow chart showing the sequence of events in the salvage of canned foods exposed to adverse conditions is shown in Appendix 1.

2. DEFINITIONS

2.1 Adverse conditions are those conditions which may result in physical damage to and/or contamination of a container or its contents rendering the food unsuitable for human consumption.

2.2 Canned food means commercially sterile food in hermetically sealed containers.

2.3 Cleaning means the removal of soil, food residues, dirt, grease or other objectionable matter from the external surface of the container and for the purposes of this code may be extended to the removal of rust and other products of corrosion.

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

2.5 Commercial sterility of a thermally processed food means the condition achieved by application of heat, sufficient, alone or in combination with other appropriate treatments, to render the food free from microorganisms capable of growing in the food under normal non-refrigerated conditions at which the food is likely to be held during distribution and storage.

2.6 Contamination means the presence of any objectionable material on the surface of a container, or in a food.
2.7 Disinfection of a container means the reduction, without adversely affecting the container or contents, of the number of microorganisms on the container surface to a level that will not lead to harmful contamination of the food.

2.8 Disposal means an action (e.g. incineration, burial, conversion to animal feed, etc.) which will prevent a contaminated product from being sold or distributed for human consumption.

2.9 Hermetically sealed container means containers which are designed and intended to protect the contents against the entry of microorganisms during and after processing.

2.10 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 "International Standards for Drinking Water", World Health Organization.

2.11 Recanning means the transfer and sealing of a product into a new hermetically sealable container followed by a scheduled process.

2.12 Reconditioning means the cleaning of sound containers and may include disinfection.

2.13 Reprocessing means the treatment of a canned food in its original container recovered in a salvage operation followed by a scheduled process.

2.14 Salvage means any appropriate process or procedure by which food is recovered from a suspect lot of canned food and by which its safety and fitness for consumption is ensured.

2.15 Salvor means the person responsible for carrying out the salvage operations including any or all of the on-site operations.

2.16 Scheduled process means the thermal process chosen by the processor for a given product and container size to achieve at least commercial sterility.

2.17 Suspect Lot of Canned Food means a group of containers which is suspected of being contaminated as a result of exposure to adverse conditions and may include a part of, the whole of, or a number of code lots.

3. ON-SITE OPERATIONS

3.1 Assessment of Adverse Conditions

The nature and circumstances of the adverse conditions which gave rise to the canned foods being suspect should be assessed and recorded. Special attention should be given to the cause and likely consequences in terms of contamination of the container and/or its contents.

3.2 Notification

The salvor should, as soon as possible, supply the appropriate agency having jurisdiction with the results of the assessment of the adverse conditions as well as the types and quantities of food products involved.

3.3 Product Inventory and Identification of Product Location

Whenever possible prior to removal of any containers of canned food, (including the taking of samples, product segregation, disposal, etc.), a complete inventory of all product involved should be made. The inventory should record the location of all product exposed to the adverse conditions, the quantity of each product type identifying by trade name, container type and size, can and/or carton codes, etc. Before commencing with any salvage operations, the salvor should notify the owner or legal agency of all affected product and provide an inventory of the affected product to the appropriate agency having jurisdiction.
3.4 Feasibility of Salvage

All canned foods subjected to the adverse conditions should be assessed as to whether any salvage is feasible. If salvage operations are not feasible then all product should be disposed of as soon as possible in a manner described in Section 4.2.

3.5 Preliminary Sorting

When salvage is feasible, the product should, whenever possible, be segregated into the following categories: potentially salvageable, not salvageable and unaffected product. This is a general sorting, that is by cartons, cases, pallets, etc., and not by individual containers. Sorting by individual containers is dealt with in Section 4.1. A complete inventory of the not salvageable product should be recorded and the product disposed of in a manner described in Section 4.2. Product not subjected to the adverse conditions and hence unaffected should be separated from that which was involved and can be released for distribution and sale. Such unaffected product would not be subject to the coding requirement of Section 4.7.

3.6 Removal from Site and Storage

In situations when adverse conditions may continue to prevail, all product should be removed from the site as soon as possible.

The official agency having jurisdiction and the owner of the product should be informed as soon as possible by the salvor of the movement of a suspect lot of canned food.

All product involved in the salvage operation should be stored under conditions which protect against their unauthorized removal. Potentially salvageable product should also be stored under conditions which minimize damage, deterioration and contamination and prevent mixing with other products.

A complete record of any product removed from the site in which the quantities, manner of removal and place of subsequent storage are detailed should be made and retained.

4. TREATMENT OF POTENTIALLY SALVAGEABLE CANNED FOODS

4.1 Evaluation and Sorting

Each container of canned food deemed as potentially salvageable from the preliminary sorting (Section 3.5) should be thoroughly inspected. Containers showing visible evidence that their integrity has been lost and/or the contents have become contaminated should be set aside as not salvageable and disposed of in the manner given in Section 4.2.

The remaining salvageable canned food should, by visual inspection, be segregated into the following categories: (a) visually unaffected (appearing normal) containers which do not require reconditioning (4.4), and (b) those that require reconditioning (4.5). Where possible, labels should be removed to permit visual inspection of the entire container surface. The containers which require reconditioning should be further segregated into two groups, those which can be reconditioned (4.5.2) and those which are not reconditionable (4.5.1). The nature and extent of the adverse conditions will dictate which categories may be present in the suspect lot(s).

The inspection, sorting, sampling and evaluation should be conducted by persons trained and experienced in carrying out such procedures.

An inventory of the product in each of the above categories should be recorded. Records of the inventory, inspection, sorting, sampling and subsequent evaluation shall be made and kept for a period acceptable to the agency having jurisdiction.
4.2 Product Not Salvageable

Canned food which is not salvageable should be carefully disposed of under adequate supervision of the agency having jurisdiction to assure the protection of the public health. Records should be kept detailing the manner and location of disposal and be maintained for a period acceptable to the agency having jurisdiction.

4.3 Evaluation for Contamination

Whenever loss of container integrity and/or contamination of the contents in salvageable canned foods is suspected but, not visually indicated, samples of a size in keeping with the degree of safety required should be tested and evaluated. Microbiological evaluation of the contents should be carried out according to the procedures outlined in "Guideline Procedures to Establish Microbiological Causes of Spoilage in Canned Foods", or "Official Methods of Analysis of the Association of Analytical Chemists", 14th ed., sections 46.063 - 46.070.

4.4 Visually Unaffected Containers Not Requiring Reconditioning

It should not be assumed that the contents of containers appearing normal (i.e., visually unaffected, and do not require reconditioning) are free of contamination. Unless there is evidence that the containers and/or their contents are free of contamination, such containers and their contents should be evaluated in accordance with Section 4.3 above. Where the results of such an evaluation indicate that there is virtually no possibility of the contents being contaminated, the remaining normal appearing containers can be released for distribution and sale. Where the results indicate that the product may be contaminated, the product should be classed as unsalvageable and disposed of as detailed in Section 4.2. In some instances potentially contaminated product may be salvaged by reprocessing (see Section 4.6).

4.5 Containers Requiring Reconditioning

4.5.1 Containers Not Reconditionable

Some containers by virtue of their type or condition are not capable of being reconditioned without adversely affecting their contents. The following list some examples of not reconditionable containers:

- containers with any indication of swelling, with the exception of intentionally pressurized containers and some containers which by virtue of their shape, size or type of contents are prone to overfilling and appear slightly swollen.

- glass jars with any indication of a raised lid, raised button or showing evidence of loosening of the closures.

- containers with visible evidence of leakage.

- containers with punctures, holes or fractures. (These conditions may be indicated by the accumulation of product on or around the puncture, hole or fracture in a can, under the lip of a glass jar, in the seal or on the body of a flexible pouch).

- pull-top containers with fractures or dents on the score lines or in the rivet area.

- corroded containers with severe pitting such that any cleaning and disinfection may result in perforation.

- rigid containers crushed to the point where they cannot be stacked normally on shelves or opened with wheel-type can openers.

- cans severely dented at or in the immediate vicinity of either an end or side seam.

- cuts or fractures through at least one layer of metal on the double seam of cans.

- containers with gross seam or seal defects.
Containers which are not reconditionable should be disposed of according to Section 4.2. Under certain circumstances further salvage operations may be undertaken to recover product in such containers. However, before any further action is taken, the contents should be evaluated for the possibility of contamination as stated in Section 4.3. If test results indicate that the contents may be contaminated then the containers should be classed as not salvageable and disposed of in accordance with Section 4.2. Where the test results indicate that the contents are not contaminated, the product may be recanned in accordance with Section 4.6. Since these containers do require reconditioning, special care should be taken to avoid contamination of the product during the process of recanning.

In some cases, for example, containers with external pitted corrosion only, the product may be expedited for immediate consumption as long as the contents have been shown to be free of contamination.

4.5.2 Reconditionable Containers

Prior to reconditioning, the contents of this group of containers should be evaluated for the possibility of contamination in accordance with Section 4.3. When the test results indicate that the contents may be contaminated then the containers should be disposed of in accordance with Section 4.2. However, depending upon the nature and extent of the contamination, the containers may be reconditioned followed by reprocessing (Section 4.6) and as long as that reprocessing will produce a product safe and suitable for human consumption.

All salvageable and reconditionable containers of food which have been in contact with not potable water or other deleterious substances as the result of flood, sewer backup or similar mishaps should be reconditioned by methods approved by the agency having jurisdiction. (Guidance for cleaning and disinfection is found in the "General Principles of Food Hygiene, Appendix 1, CAC/Vol. A-Ed. 1-1979"). Surface corrosion should be removed from reconditionable containers by cleaning. The containers should then be treated and stored in a manner to minimize further deterioration.

(Note: Certain types of containers which have been in contact with not potable water, foam, or other deleterious substances as a result of fire fighting efforts, flood, sewer backups or similar mishaps present special problems in reconditioning and require expert evaluation).

In those instances where salvage is confined to separation of normal appearing from mechanically damaged containers and where there is no possibility of contamination of the contents, the normal appearing containers should, if necessary, be reconditioned and then upon approval of the agency having jurisdiction be released for distribution and sale.

Where there is a possibility of contamination of the contents of normal appearing containers, appropriate testing in accordance with Section 4.3 should be carried out on both normal appearing and rejected containers. The sampling, analyses and evaluations should be carried out by persons trained and experienced in carrying out such procedures with canned foods.

In some circumstances recanning of the contents of the normal appearing containers may be necessary. In other circumstances reprocessing of the containers may be sufficient.

4.6 Recanning or Reprocessing

Recanning or reprocessing should be carried out in compliance with the "International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev. 1, 1989)". The prior history of the product should be considered in the development of an appropriate scheduled process for recanning or reprocessing. For instance, the heating characteristics of the product may be changed as a result of the heat process originally applied.
4.7 Coding

Before a salvaged canned food is released for sale or distribution in its original container, each container shall be permanently marked with a legible, visible and specific code to permit its subsequent identification as a salvaged product.

5. QUALITY ASSURANCE

It is important that all salvage operations be properly established, correctly applied, sufficiently supervised, monitored and documented.

Section 8 of the "International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev. 1, 1989)", is applicable with the following substitution for 8.2.4.

Records should be kept identifying each lot of salvaged canned foods as well as the conditions under which the original food became suspect and the means by which it was salvaged.

6. STORAGE AND TRANSPORT OF SALVAGED PRODUCT

As given in the "International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned foods, CAC/RCP 23-1979 (Rev. 1, 1989)", with the following addition:

Where such foods are released for export, the agency having jurisdiction in the importing country should be notified that the product has been salvaged.

7. LABORATORY CONTROL PROCEDURES

As given in the "International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev. 1, 1989)".

8. END PRODUCT SPECIFICATIONS

As stated in the "International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev. 1, 1989)".
FLOW CHART SHOWING THE SEQUENCE OF EVENTS IN THE SALVAGE OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS (DETAILS PROVIDED IN TEXT OF MAIN DOCUMENT)

ON SITE
1. INSPECT AND ASSESS ADVERSE CONDITIONS (3.1)
2. NOTIFY OWNER AND AGENCY HAVING JURISDICTION (3.2 & 3.3)
3. INVENTORY PRODUCT AND IDENTIFY LOCATION (3.3)
4. ASSESS FEASIBILITY OF SALVAGE (3.4)
5. PRELIMINARY SORT (3.5)

UNAFFECTED
- REMOVAL FROM SITE (3.6)
- NOTIFY AGENCY HAVING JURISDICTION (3.6)
- DISTRIBUTION AND SALE

POTENTIALLY SALVAGEABLE
- REMOVAL FROM SITE (3.6)
- NOTIFY AGENCY HAVING JURISDICTION (3.6)
- EVALUATION AND SORTING (4.1)

NOT SALVAGEABLE (4.2)
- DISPOSAL*

NO RECONDITIONING REQUIRED (4.4)
- EVALUATE FOR CONTAMINATION (4.3)
- NO EVIDENCE
- RECONDITION (4.6)
- RECAN**
- REPROCESS (4.6)
- RECONDITIONABLE (4.5.2)

RECONDITIONING REQUIRED (4.5)
- EVALUATE FOR CONTAMINATION (4.3)
- NO EVIDENCE
- RECONDITION (4.6)
- RECAN**
- REPROCESS (4.6)
- NOT RECONDITIONABLE (4.5.1)
- EVALUATE FOR CONTAMINATION (4.3)
- NO EVIDENCE
- RECONDITION (4.6)
- RECAN**
- REPROCESS (4.6)
- DISPOSAL*

(The solid lines indicate the usual courses of action. The broken lines indicate alternate actions which may be undertaken under special circumstances and should always be carried out under the direct supervision of person(s) knowledgeable and experienced in the particular aspects of salvage as well as the methods of sampling and evaluating the possibility of contamination.)

* Notify the agency having jurisdiction and product owner of removal from site and plan for disposal.

** Cleaning and/or disinfection of the containers prior to opening may be necessary.
GUIDELINE PROCEDURES TO ESTABLISH MICROBILOGICAL CAUSES OF SPOILAGE IN LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS (At Step 5 of the Procedure)

Table of Contents

1. Scope
2. Explanatory Preface
3. Introduction
4. Procedures for Determining the Cause of Spoilage in Lots of Canned Food
5. Guidelines for the Interpretation of Laboratory Data
6. Guidelines to Assist in Identifying Causes of Spoilage
7. Concluding Remarks
8. References

Table 1 - Some Visual External Defects Found in Metal Cans
Table 2 - Interpretation of Laboratory Data Concerning a Low-Acid Canned Food
Table 3 - Interpretation of Laboratory Data Concerning Acidified Low-Acid Canned Food

Figure 1 - Flow Diagram of the Procedures for the Examination of a Thermally Processed Food in a Hermetically Sealed Container
Figure 2 - Flow Sheet for the Aerobic Cultural Examination of Low-Acid Canned Foods for Spoilage and Diagnosis of Results
Figure 3 - Flow Diagram for the Anaerobic Cultural Examination of Low-Acid Canned Foods for Spoilage and Diagnosis of Results

Appendix 1 - An Example of a Product Identification and History Enquiry Form
Appendix 2 - Procedures for Microbiological Analysis of the Analytical Sample
GUIDELINE PROCEDURES TO ESTABLISH MICROBIOLOGICAL CAUSES OF SPOILAGE IN LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS
(At Step 5 of the Procedure)

Cautionary Note on the Use of these Guideline Procedures

The proper diagnosis of the causes of microbiological spoilage requires considerable training and experience. Anyone not experienced in spoilage diagnosis should use these guidelines and identified references only in consultation with canned food laboratory experts.

1. SCOPE

These guidelines summarize procedures to establish the causes of microbiological spoilage in low-acid and acidified low-acid canned foods; references to appropriate techniques are supplied. It is intended that these procedures be used in the investigation of the causes of microbiological spoilage and not to establish the total absence of viable organisms in a single container or to determine commercial sterility of a lot. These methods may also be used for the initial identification of potential safety problems. They have no role in establishing commercial sterility.

Water activity controlled foods (e.g., canned bread, cheese spread, chorizo sausage and pasta in pouches), aseptically processed and packaged foods, and perishable cured meat products require special consideration and are not covered in this text. Spoilage diagnosis should be carried out in consultation with experts in that commodity.

2. EXPLANATORY PREFACE

Microbiological End-Product Specifications

Canned foods should be commercially sterile and not contain any substances originating from microorganisms in amounts which may present a hazard to health (International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev. 1, 1989), Section XI). The key is the term "commercial sterility", which is defined in the Code of Hygienic Practice.

Strict adherence to the procedures presented in the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods will give reasonable assurance that a lot of canned food will meet this end-product specification. While sampling and analysis of the end-product is not recommended for establishing the commercial sterility of a lot, they are important procedures in the investigation of lots which may contain spoiled food.

3. INTRODUCTION

The primary reasoning behind the spoilage diagnosis procedure is to distinguish between post-process contamination (leakage) and insufficient thermal processing. The spoilage diagnosis procedure relies on the fact that vegetative cells (including yeasts) have little or no heat resistance. Bacterial spores are heat resistant, so a pure culture of spore forming organisms usually means insufficient thermal processing. A mixed flora of different vegetative organisms usually means leakage. Therefore to distinguish between thermally resistant and sensitive organisms, heat treatment of inocula for cultural examination is necessary. Heat treatment can be performed before or after cultural examination. Interpretation of results from the heat treatment step should take into consideration the possibility that all spores present may have germinated and would thus be heat sensitive. Figures 2 and 3 reflect only the heat treatment step performed after culturing. Since microbiological examination of canned foods is an integral part of any investigation of the cause of spoilage, it is important that reliable and reproducible procedures for the examination of both the container as well as its contents be employed. Such procedures can be used by a processor, an independent laboratory or a regulatory agency.
It should be remembered that spoilage can also indicate a potential hazard to the health of the consumer. If there is evidence that a search for a specific pathogen is necessary, appropriate procedures should be applied. Methods for the identification and enumeration of various pathogens associated with foods can be found in a number of texts on the subject. Various texts which have been found generally useful are referenced at the end of the document.

As spoilage of canned foods may result from poor handling of ingredients prior to processing, under-processing, or post-thermal processing leaker contamination, procedures to establish the cause of spoilage ought not to be limited solely to examination of the food contents for viable organisms. They should also include the physical examination of the container and an evaluation of its integrity, as well as, where possible, the examination of pertinent cannery records of the can seam teardown, the processing and shipping history of the product. The results of these should be taken into account, together with the microbiological results, in arriving at a final conclusion.

4. PROCEDURES FOR DETERMINING THE CAUSE OF SPOILAGE IN LOTS OF CANNED FOOD

The identification of the lot, the compilation of its history including can seam teardown and thermal processing records, together with knowledge of distribution are needed, as well as the sampling, inspection and examination of containers and contents.

4.1 Lot Identification and History

It is important to compile as much information as possible about the suspect product lots. This should not be restricted solely to the acquisition of microbiological data. It is also important that the information and data be examined for the presence of trends or patterns before arriving at any conclusions. A check list of the information required is helpful to ensure that essential data are not missed. An example of information needed in such a check list is given in Appendix 1.

A note should be made as to the source of the can (sample), e.g., from an inspector, or from a domicile or establishment where there has been an outbreak of food poisoning.

4.2 Laboratory Examination

An outline of procedures for examining a product and its container are shown in the following flow diagram (figure 1). Specific information relating to each of the stages in this procedure is contained in the following sections of the text. While certain of the procedures relate mainly to the examination of rigid metal cans, they can be adapted for all types of containers used for packaging thermally processed foods. There are sections in the report concerning the interpretation of the results of these procedures and guidance on where hygiene problems may exist so that corrective action can be taken.

4.2.1 External inspection

4.2.1.1 Each container in the sample should be examined visually before and after removal of any labels. All identifying marks and stains or signs of corrosion on the containers and labels should be carefully and accurately recorded. The label, after removal in one piece and inspection of both sides, should be identified with the same reference as the container and be retained.

4.2.1.2 The visual examination should be carried out under good illumination and preferably with the aid of a magnifying lens before opening or attempting any seam measurements. With respect to metal cans, particular attention should be paid to the examination of the seams for the defects, such as cutovers, dents (adjacent to or on the seam), droops, vees or spurs, pleats, knocked down flanges and for lap faults. Other less noticeable defects may occur, for example, faults in tin plate, score marks caused by supermarket case opening knives, small pin holes in welded side seams, rust holes, etc. Therefore, careful visual examination of the whole of the container is essential. A list of some of the visual external defects commonly found to occur in metal cans is given in Table 1.
Figure 1

FLOW DIAGRAM OF THE PROCEDURES FOR THE EXAMINATION OF A THERMALLY PROCESSED FOOD IN A HERMETICALLY SEALED CONTAINER

1. **External Visual Inspection and Physical Non-Destructive Measurements**
   (Inspect label, read code, then weigh can and contents. Mark can and label; remove label; inspect inside of label for location of stains and can for corrosion. Inspect seams for product leakage and visible defects such as knocked down flange, solder voids, etc.).

   Normal Container  Swollen, Leaking, Punctured or Holed Container

2. **Incubation** - if packed less than 2 weeks or stored cold

3. **Clean and Disinfect External Container Surfaces**

4. **Open Container Aseptically** - if swollen, test for hydrogen gas

5. **Aseptically Sample Contents for Microbiological Examination**
   take reference sample and refrigerate.

6. **Prepare Smear and Examine by Direct Microscopy**

7. **Microbiological Analysis**

8. **Measure pH of Contents**

9. **Sensory Evaluation of Contents** odour, colour, texture and appearance
   This may help to determine whether can was thermally processed. Under no circumstances should product under investigation or analysis be tasted.

10. **Empty Container, Sterilize (if putrid), Determine Net Weight**

11. **Test Container for Leaks** (e.g., vacuum, dye testing, etc.)

12. **Assess Seams and/or Seals for Correct Formation**
Table 1
Some Visual External Defects Found in Metal Cans*

<table>
<thead>
<tr>
<th>Place where fault Probably occurred</th>
<th>Position on Can</th>
<th>Type of Defect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can Manufacture</td>
<td>Can end/body</td>
<td>Cut, hole, fracture in tin plate</td>
</tr>
<tr>
<td></td>
<td>Can body</td>
<td>Side seam faults</td>
</tr>
<tr>
<td></td>
<td>Easy open strip</td>
<td>Fractured score line, excessive score line</td>
</tr>
<tr>
<td>Cannery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seamer</td>
<td>Can end</td>
<td>Deep coding, compound squeeze, damage to key fixing</td>
</tr>
<tr>
<td></td>
<td>Double seam</td>
<td>First operation roll, skidder, false seam knocked down flange, jumped seam, broken chuck Second operation roll, cutover, droop, split droop, deformed end seam, spur, knocked down curl</td>
</tr>
<tr>
<td></td>
<td>Can body</td>
<td>Perforated, pierced, cut dents</td>
</tr>
<tr>
<td>Filling</td>
<td></td>
<td>Peaked, flipper, springer</td>
</tr>
<tr>
<td>Cooling</td>
<td></td>
<td>Peaked, panelled</td>
</tr>
<tr>
<td>Can runways</td>
<td></td>
<td>Cable burn, abrasions, dents under rim of double seam</td>
</tr>
<tr>
<td>Storage</td>
<td></td>
<td>External corrosion (rust), physical damage</td>
</tr>
<tr>
<td>Transit/Retail</td>
<td></td>
<td>Cuts, dents</td>
</tr>
</tbody>
</table>

* Based on R.H. Thorpe and P.M. Baker, "Visual can defects", 1984, Campden Food Preservation Research Association, Chipping Campden, England
4.2.1.3 During examination of the container an attempt should be made to establish whether the defects are the result of damage caused by mishandling during shipment or is a result of damage within the processing establishment. All observations should be recorded.

The location of any defect on the can is important and should be marked on the can and recorded.

4.2.1.4 Non-destructive measurements of seals or seams should be carried out. For example, for cylindrical cans, measurements of double seam height and thickness, and countersink should be carried out at at least three locations approximately 120° apart around the double seam, exclusive of the juncture with the side seam. Blown, badly distorted or damaged containers are usually only suitable for visual examination since the seams are often too distorted for proper seam measurements to be made. However, they should not be discarded, for even badly distorted cans should be retained for detailed structural and possibly other, (e.g., chemical), examination and until the investigating authority and the manufacturer are quite satisfied that they need not be kept any longer. Tests or measurements, e.g., tap-test, countersink or centre depth can be used to give comparative measures of the internal vacuum with respect to a normal can.

4.2.1.5 Determination of Net Weight

The gross weight of the container and contents should be measured and recorded at this stage. The determination of the net weight is delayed.

The net or drained weight, whichever is appropriate, should be determined for each container in the sample. (A close approximation of net weight can be obtained by subtracting the average weight, if known, of empty containers plus the second cover from the gross weight of the filled, sealed container.)

4.2.1.6 Over-filling

Over-filling reduces the headspace and may adversely affect the vacuum when the container is sealed. With solid products it may cause containers to have a zero internal vacuum and even result in bulging of the container ends giving the appearance of a swollen can. Over-filling may decrease the effectiveness of a thermal treatment. This is particularly true when agitating sterilization or flexible containers are used. It causes excessive strain on seals or seams during processing. Over-filling of a container may be indicated when the net weight exceeds a reasonable tolerance of the declared or target net weight or of the average net weight determined by examination of a significant number of containers of normal appearance.

4.2.1.7 Under-filling

Under-weights may indicate that either the container was underfilled or leakage has occurred. Other evidence that leakage may be the cause of under-weight should be sought, e.g., stains or product residues on the container surface, label or surrounding containers in the same carton. Panelled cans may indicate loss of liquid during thermal processing.

4.2.2 Incubation

Swollen, punctured, or holed containers must not be incubated.

Consideration should be given as to whether the container(s) should be incubated before opening for microbiological examination of the contents. The aim of incubation is to increase the likelihood of finding viable microorganisms in subsequent microbiological examinations. Incubation results alone should not be used to decide the fate of the affected lot.

Considering the length of time involved in international shipments of canned foods, incubation may not be necessary. Containers should be incubated at, for example, 30°C for 14 days and/or 37°C for 10 to 14 days. Note that a number of
leakage spoilage organisms will not grow above 30°C. In addition, if the product is intended to be distributed in areas of the world with tropical climate or is to be maintained at elevated temperatures (vending machines for hot product), containers should also be incubated at higher temperatures, e.g., for 5 days at 55°C. Since thermophiles may die during such incubation period, it is desirable to examine containers periodically for the evidence of gas production before the end of incubation.

4.2.3 Cleaning, disinfection and opening of containers

4.2.3.1 Swollen containers

The external surfaces of containers should be cleaned with a suitable detergent and rinsed. Containers should be disinfected for at least 10 to 15 minutes in freshly prepared 100-300 ppm chlorinated water, buffered to approximately pH 6.8, or by flooding the end with an appropriate alcoholic iodine solution (e.g., 2.5% w/v iodine in ethanol) and leaving for 20 minutes. Alternatively the end can be decontaminated by flooding or spreading with a 2% solution of peracetic acid in an appropriate wetting agent (e.g., 0.1% polysorbitan 80) for 5 minutes. Containers should be dried immediately after disinfection, using clean sterile disposable paper tissues or towels. Appropriate safety precautions should be taken when using any of these chemical disinfectants.

All containers should be handled as if they contained botulinum toxin or pathogens. Horizontal laminar flow cabinets which blow air over the operator should not be used. A safety cabinet may be used when opening containers suspected of not being commercially sterile. Swollen containers should be opened within the cabinet while inside a sterile bag or by using the sterile inverted funnel method to contain any spraying of the contents. When not sampling the contents, cover the open end with a sterile cover (e.g., sterile half Petri dish or other suitable sterile covers).

It is usual to open the non-coded end of the metal container. For cans containing liquid or semi-liquid components, a sterile stainless steel spike with a shield can be used to pierce the container and the contents sampled using a sterile pipette or equivalent apparatus. For opening cans containing solid product a sterile disc cutter should be used, or alternatively the side may be aseptically pierced and the can opened by aseptically cutting round the body. It is essential that damage to the seams and seals be avoided when opening containers. Open plastic containers from the bottom or side to prevent damage to the seal area and/or lid. After disinfection lightly flame dry avoiding damage to the plastic container and with a small heated sterile device such as a soldering iron equipped with a sharp tip, cut a hole large enough for the aseptic removal of the samples.

If a safety cabinet is not used, it is recommended that a face shield be worn and that the side seam point away from the person opening the container. To test for hydrogen, gas may be collected in a test tube over the point of puncture and the open end of the tube immediately exposed to a flame. A loud "pop" indicates the presence of hydrogen. If the can to be used for gas analysis is also to be used for cultural analysis, precautions should be taken to prevent external contamination.

Describe and record any unusual odours from the contents which may be noticed immediately after opening. However direct sniffing must be avoided.

Unless a swollen can is suspected of containing gas-producing thermophilic anaerobes, it may be stored at 4°C before opening to reduce the internal pressure and reduce spraying of the contents. However prolonged storage at such temperatures should be avoided as it may effectively reduce the number of viable organisms and hamper attempts to isolate the causative microorganisms.

4.2.3.2 Flat (not swollen) containers

With liquid foods, stratification or sedimentation of the microorganisms may occur. To ensure mixing of any contaminating microorganisms, it is advisable to shake the container just before opening.
The end of the container which is to be opened for sampling should first be decontaminated by the methods described in 4.2.3.1 and/or by flame sterilizing the end. Open with a sterile opening device. Describe and record any unusual odours from the contents which may be noticed immediately after opening, and as for the swollen cans, direct sniffing must be avoided.

When not sampling the contents, cover the open end of the container with a sterile cover (e.g., sterile half Petri dish or other suitable sterile cover).

4.2.4 Microbiological Analysis

Appendix 2 and standard texts, e.g., Speck (1984), C.F.P.R.A. Technical Manual No. 18 (1987) and Buckle (1985) should also be consulted.

4.2.4.1 Reference sample

A reference sample of at least 20 g or ml should be aseptically removed from the contents and transferred to a sterile container, sealed and held at a temperature below 5°C until required. The reference sample may be required to permit confirmation of results at a later stage. Care should be taken to avoid freezing as this may kill a significant number of bacteria in the reference sample. If thermophilic contamination or spoilage is the concern the reference sample should not be refrigerated. The reference sample also provides material for non-microbiological tests or analyses, e.g., for analysis for tin, lead, toxins, etc., but if these are anticipated appropriate amounts must be taken. For solid, and in some instances semi-solid foods, the reference sample should be made up from samplings taken from various suspect points, e.g., the centre core, product surfaces in contact with the end or double seam (especially that in contact with the cross-over), product in contact with the side seam, (if there is one). Transfer all samplings to a sterile container and store as described above.

4.2.4.2 Analytical sample and inoculation of media

For the purpose of preparing analytical samples, canned products can be divided into two main groups, namely solid and liquid. Separate procedures may be required to prepare analytical samples of these products.

4.2.4.2.1 Liquid products

These products may be sampled using suitable sterile, plugged pipettes with wide-bore tips. (Pipetting by mouth suction should be avoided.) The sample should be inoculated into both liquid and solid media.

It is recommended that each tube of liquid medium be inoculated with at least 1 to 2 ml of the sample of the container contents. Each solid media plate should be streaked with at least one loopful (approximately 0.01 ml) of the sample of the container contents.

4.2.4.2.2 Solid and semi-solid products

For such products both core and surface samplings should be taken.

For taking a core sample, a suitable sterile device (e.g., a large bore glass tube or a cork borer) having an adequate diameter and length should be used.

In the case of spoilage resulting from underprocessing, the most likely location in which microorganisms may be expected to survive would be the geometric centre of the can contents. Thus the central portion of the core sample is of prime interest. Sufficient product should be aseptically excised from the central portion of the core to provide 1 to 2 g for each tube of liquid media to be inoculated and for the streaking of each plate of solid media. For multiple tubes and pour plates, the central portion can be chopped or blended with a suitable diluent.
Post-process contamination may give rise to localized surface contamination and growth in solid products. If this is suspected the surface should be sampled. Using a sterile scalpel, knife or other suitable device scrape product from the surface, paying particular attention to those areas which were in contact with the double or side seams and any easy opening feature. The scraped product should be put into a sterile container. As an alternative or additionally, it may be sufficient to swab those areas of the double and side seams plus any easy opening feature of the containers which had come into contact with the product. After swabbing, the swab should be placed into a suitable sterile diluent and shaken vigorously; portions should be used to inoculate the tubes and for streaking the plates.

The core sample and the surface samplings should be treated as separate analytical units.

Wherever possible identical microbiological analyses should also be done on at least one apparently normal can of the same code lot or batch for comparative purposes. Where cans from the same code lot or batch are not readily available, apparently normal cans from codes or batches as close as possible to the suspect lot or batch should be used.

A flow diagram of aerobic and anaerobic microbiological analysis of canned foods is found in figures 1 and 2, (see also Appendix 2). These may be useful in the interpretation of the microbiological examination.

4.2.4.3 Direct microscopic examination

This is a very useful test in the hands of an experienced worker.

Different techniques can be used for direct microscopic examination, e.g., stain with 1% aqueous crystal violet or 0.05% polychrome methylene blue, phase contrast technique, fluorescent stain procedure.

It may be necessary to defat some oily foodstuffs on the slide using a solvent, e.g., xylene.

There is an advantage in using both wet film and dry stain techniques. Remember when using a Gram stain that old cultures often give a variable Gram reaction. Therefore report morphology only.

A slide of the can contents should be prepared for examination. Control slides prepared from the contents of apparently normal cans of the same code lot or batch should also be prepared, particularly if the analyst is unfamiliar with the product or if numbers of cells per field are to be compared.

It is important to note the following:

It is easy to confuse particles of product with microbial cells, therefore it may be prudent to dilute the sample before preparing the smear.

Dead microbiological cells resulting from incipient (pre-process) spoilage or autosterilization may show up on smears at this stage and no growth will be evident in the inoculated culture media.

Do not assume that apparent absence of microbial cells in a single field means that none are present in the product.

The entire smear or wet mount should be carefully scanned to locate areas of microbiological interest from which at least five fields should be examined in detail. Record observations giving approximate numbers of each morphological type observed in each field.

4.2.5 Measurement of pH of contents

The pH of the contents should be measured in accordance with existing methodology (see Appendix II, Recommended International Code of Hygienic Practice for
Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev. 1, 1989)) and compared to that of normal cans. A significant change in the pH of the contents from that of normal product may indicate that there has been microbial growth. However, absence of such change does not always indicate that no growth has occurred.

4.2.6 Sensory examination

This is an important part of the examination of canned foods. During this procedure note should be taken of any evidence of product breakdown, off or unusual colour, odour or in the case of liquid components (brine) cloudiness or sedimentation. Under no circumstances should the product be tasted.

Normal changes in texture of solid products can be perceived by feeling or squeezing the product with a rubber or plastic gloved hand. For proper organoleptic evaluation, product temperature should not be less than 15°C and preferably not more than 20°C. Where possible, the results of the sensory evaluation should be compared to the same evaluation of the contents from apparently normal cans from the same or neighbouring code lots or batches.

4.2.7 Emptying and sterilization of the suspect container

The remaining contents should be emptied out into a suitable waste receptacle. It is important that cans containing spoiled product be disinfected or autoclaved prior to washing and further testing, e.g., leak testing, seam teardown etc. After washing, examine the internal surfaces for any evidence of discolouration, corrosion or other defects.

If required for the determination of the net or drained weight, the empty container should then be dried and then weighed, (see 4.2.1.5).

The empty container and any parts should be clearly identified and retained as long as there is any chance that it may be required for further examination or evidence.

4.2.8 Leak detection methods

A number of methods may be used for determining leakage in containers. The method chosen is often determined by the degree of accuracy required, the number of suitable containers available for testing and the need to simulate conditions thought to exist when the containers originally leaked. Often more than one type of test is employed in combination with microbiological testing to determine the type and cause of the spoilage being investigated. Data obtained from tests for container leaks are often used to corroborate microbiological test results obtained on product from the same containers. The information may be useful for preventing problems from the same cause.

Each leak testing method has its advantages and disadvantages. For example, air pressure testing, while usually rapid, may be criticized for not testing the can in its natural vacuum state. Helium testing may be too sensitive and indicate leakage when none actually occurred. Also, it does not indicate the point of leakage. The hydrogen sulphide test is useful for determining the location and size of the leakage as well as providing a permanent record; some find the method too slow for testing a large number of cans. Preparing the cans for testing as well as the ability of the operator to conduct the test properly and interpret the results accurately are as important as choosing the appropriate test for leakage.

It is not always possible to recreate leakage in containers that may have leaked at some time during or after processing. Product often plugs the leakage path and it may not be possible to remove it when cleaning the can prior to testing.

In these instances, many more suspect cans than were tested microbiologically may have to be tested to establish leakage in a lot. It is sometimes helpful to leak test cans from the same lot which are not suspect when leakage cannot be recreated in cans with spoiled product.
<table>
<thead>
<tr>
<th>Condition of Can</th>
<th>Odour</th>
<th>Appearance (3)</th>
<th>pH (1)</th>
<th>Smear</th>
<th>Key Points From Cultures (2)</th>
<th>Possible Interpretations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swell</td>
<td>Sour</td>
<td>Frothy, Possibly ropy</td>
<td>Below normal</td>
<td>Cocci and/or</td>
<td>Positive aerobe and/or Anaerobe; growth at 30°C and/or 37°C</td>
<td>Post-process leakage</td>
</tr>
<tr>
<td></td>
<td></td>
<td>brine</td>
<td></td>
<td>rods and/or yeasts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slightly off</td>
<td>Slightly to</td>
<td>Slightly to definitely</td>
<td>Rods (spores sometimes seen)</td>
<td>Positive; aerobe and/or Anaerobe; growth at 30°C; often pellicle formation in aerobic broths</td>
<td>Post-process leakage or gross underprocessing</td>
<td></td>
</tr>
<tr>
<td>(Sometimes</td>
<td>definitely</td>
<td>definitely abnormal may</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ammoniacal)</td>
<td>abnormal may</td>
<td>be higher</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swell</td>
<td>Sour</td>
<td>Frothy possibly ropy</td>
<td>Below normal</td>
<td>Mixed Population (often spores)</td>
<td>Positive; aerobe and/or Anaerobe; growth at 30°C &amp; 37°C and often at 55°C</td>
<td>No thermal process given</td>
</tr>
<tr>
<td></td>
<td>possibly ropy</td>
<td>brine. Food firm and un-</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>brine. Food</td>
<td>cooked</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>firm and un-</td>
<td>cooked</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>swell</td>
<td>Normal to</td>
<td>Pale colour or distinct</td>
<td>Slightly to definitely</td>
<td>Medium to long</td>
<td>Positive anaerobic growth at 55°C. No growth at 30°C, possibly growth at 37°C</td>
<td>Thermophilic anaerobe; inadequate cooling or storage at elevated temperatures</td>
</tr>
<tr>
<td></td>
<td>sour or Pale</td>
<td>colour or distinct colour</td>
<td>below normal</td>
<td>rods, often</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>colour or</td>
<td>change, frothy</td>
<td></td>
<td>granular, spores</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>distinct</td>
<td></td>
<td></td>
<td>seldom seen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>normal</td>
<td>to sour or</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>swell</td>
<td>Normal to</td>
<td>Usually frothy with</td>
<td>Slightly to definitely</td>
<td>Growth and gas in anaerobic culture at 37°C and or 30°C but no growth in aerobic cultures</td>
<td>Under-processing, mesophilic anaerobic HIGH RISK consider survival of Clostridium botulinum</td>
<td></td>
</tr>
<tr>
<td></td>
<td>cheesy to putrid</td>
<td>disintegration of solid</td>
<td>below normal</td>
<td>Rods (spores may be seen)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>particles</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swell</td>
<td>Normal to</td>
<td>Normal to</td>
<td>Normal</td>
<td>Normal</td>
<td>Negative</td>
<td>Low filling temperature; insufficient exhausting of can before seaming; overfill or hydrogen swell**</td>
</tr>
<tr>
<td></td>
<td>metallic</td>
<td>normal to slightly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>elevated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swell or flat</td>
<td>Little or no</td>
<td>normal</td>
<td>Normal to below normal</td>
<td>Large numbers</td>
<td>Negative</td>
<td>Pre-process (incipient) spoilage</td>
</tr>
<tr>
<td></td>
<td>gas on opening;</td>
<td></td>
<td></td>
<td>of evenly</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>fruity odour</td>
<td></td>
<td></td>
<td>stained cocci</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swell</td>
<td>Sour to cheesy</td>
<td>Frothy</td>
<td>Often below Normal</td>
<td>Poorly stained</td>
<td>Negative</td>
<td>Leaker spoilage followed by auto-sterilization</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>cocci and/or</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>rods</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*(Table 2)*

*Interpretation of Laboratory Data Concerning a Low-Acid Canned Food*
### Table 2 (Cont.'d)

Interpretation of Laboratory Data Concerning a Low-Acid Canned Food*

<table>
<thead>
<tr>
<th>Condition of can</th>
<th>Odour</th>
<th>Appearance (3)</th>
<th>pH (1)</th>
<th>Smear</th>
<th>Key Points from Cultures (2)</th>
<th>Possible Interpretations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apparently sound</td>
<td>Sulphurous</td>
<td>Contents blackened</td>
<td>Normal to below normal</td>
<td>Rods</td>
<td>Anaerobic growth without gas at 55°C only</td>
<td>Thermophilic sulphur stinker; inadequate cooling</td>
</tr>
<tr>
<td>Apparently sound</td>
<td>Normal to sour</td>
<td>Normal to cloudy brine</td>
<td>Normal to below normal</td>
<td>C cocci and/or rods</td>
<td>Positive; aerobic and/or anaerobic; growth at 30°C, and usually at 37°C</td>
<td>Post-process leakage</td>
</tr>
<tr>
<td>Apparently sound</td>
<td>Normal to sour</td>
<td>Normal to cloudy</td>
<td>Below normal</td>
<td>Rods (often granular)</td>
<td>No growth below 37°C. Aerobic growth without gas at 55°C; may get no growth if samples old or incubated for long period</td>
<td>Thermophilic aerobes (flat sour) Bacillus spp. Inadequate cooling or storage at elevated temperatures</td>
</tr>
<tr>
<td>Apparently sound</td>
<td>Normal to sour</td>
<td>Normal to cloudy</td>
<td>Below normal</td>
<td>Rods, (spores may be seen)</td>
<td>Positive; aerobic growth at 37°C and 30°C</td>
<td>Under-processing or leakage Mesophilic aerobic spore-formers. (Bacillus spp)</td>
</tr>
<tr>
<td>Apparently sound</td>
<td>Normal to sour</td>
<td>Normal to cloudy brine</td>
<td>Below normal</td>
<td>Granular rods</td>
<td>Negative</td>
<td>Under-processing or auto-sterilization; thermophilic spores</td>
</tr>
<tr>
<td>Apparently sound</td>
<td>Normal to sour</td>
<td>Normal to below normal</td>
<td>Large numbers of evenly stained cocci and/or rods per field</td>
<td>Negative</td>
<td>Negative</td>
<td>Pre-process spoilage</td>
</tr>
<tr>
<td>Apparently sound</td>
<td>Normal</td>
<td>Normal</td>
<td>Normal</td>
<td>Negative or occasional rods and/or cocci, i.e., normal</td>
<td>Negative</td>
<td>No microbiological problem</td>
</tr>
</tbody>
</table>

(1) The pH may rise particularly with microbial growth in meat or protein rich food.
(2) There may be difficulty in isolating Flavobacterium spp from milk or milk-based products at 25°C as they may not grow in aerobic broths.
(3) These refer principally to brined product. For other products, abnormal colour, texture and appearance may also indicate defects but are product-related and therefore cannot be tabulated.

* Based upon M.L. Speck, Compendium of Methods for the Microbiological Examination of Foods, 1984, American Public Health Assoc.
** Nitrite detinning can result in swollen containers.
**Table 3**

Interpretation of Laboratory Data Concerning Acidified Low-Acid Canned Food

<table>
<thead>
<tr>
<th>Condition of can</th>
<th>Odour</th>
<th>Appearance*</th>
<th>Normal ph Group</th>
<th>Smear</th>
<th>Key Points from Cultures</th>
<th>Possible Interpretations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swell</td>
<td>Normal to metallic</td>
<td>Normal to frothy</td>
<td>4.6 and below</td>
<td>Normal</td>
<td>Negative</td>
<td>Hydrogen swell</td>
</tr>
<tr>
<td>Swell</td>
<td>Sour</td>
<td>Frothy Possibly ropy brine</td>
<td>4.6 and below</td>
<td>Rods and/or cocci and/or yeasts</td>
<td>Positive aerobic and/or anaerobic growth at 30°C</td>
<td>No process given or post-process leakage</td>
</tr>
<tr>
<td>Swell</td>
<td>Sour</td>
<td>Normal to frothy</td>
<td>4.6 and below</td>
<td>Rods</td>
<td>Growth and/or gas aerobically and/or anaerobically at 30°C</td>
<td>Lactobacilli; grossly insufficient processing or post-process leakage</td>
</tr>
<tr>
<td>Swell</td>
<td>Butyric</td>
<td>Normal to frothy</td>
<td>4.6 to 3.7</td>
<td>Rods (spores may be seen)</td>
<td>Growth and gas in anaerobic culture at 30°C</td>
<td>Under processing; mesophilic aerobe</td>
</tr>
<tr>
<td>Apparently Sound</td>
<td>Sour</td>
<td>Normal to cloudy juice</td>
<td>4.6 to 3.7</td>
<td>Rods (often granular)</td>
<td>Aerobic Growth without gas at 37°C and/or 55°C</td>
<td>Thermophilic/mesophilic aerobe. Aciduric flat sour (B. coagulans)</td>
</tr>
<tr>
<td>Apparently sound</td>
<td>Normal to sour</td>
<td>Normal cloudy juice possibly mouldy</td>
<td>4.6 and below</td>
<td>Rods and/or cocci and/or moulds</td>
<td>Positive aerobe and/or anaerobe growth at 30°C</td>
<td>Leakage, under-processing</td>
</tr>
<tr>
<td>Apparently sound</td>
<td>Normal</td>
<td>Normal</td>
<td>4.6 and below</td>
<td>Normal</td>
<td>Negative</td>
<td>No microbiological problem</td>
</tr>
</tbody>
</table>

*These refer principally to brined products. For other products, abnormal colour, texture, and appearance may also indicate defects but are product-related and therefore cannot be tabulated.*

4.2.9 Seam tear-down

The procedures for examining and assessing double seams of canned foods subject to investigation for cause of spoilage are the same as those given in Section 7.4.8.1.2 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev. 1, 1989).

However, the interpretation of results from such seam examinations may be different for spoilage investigation than for process control. When microbiological results indicate recontamination spoilage, the presence of obvious seam abnormalities often confirms leakage. On the other hand, recontamination may occur in the absence of obvious seam defects. Examples of other sources of recontamination are: seam damage after closure, temporary leakage, sealing compound effects, and plate pinholes and fractures. In such instances the additional procedures given under leak testing as well as the microbiological results are necessary.

For these reasons, results from seam tear-down as part of spoilage investigation must be considered only in context with all other spoilage investigation efforts and require expert interpretation.

5. GUIDELINES FOR THE INTERPRETATION OF LABORATORY DATA

The interpretation of the laboratory data in Tables 2 and 3 as well as figures 2 and 3 (Appendix 2) should be considered together with the overall pattern of the particular spoilage incident being investigated and the product history.

6. GUIDELINES TO ASSIST IN IDENTIFYING CAUSES OF SPOILAGE

It is important that all available data be used in identifying causes of spoilage. It is essential that a complete assessment be made for each incident of spoilage. Data must be gathered (see Appendix 1) from the processing plant and the laboratory analyses and other sources by the appropriate expert(s). A careful and comprehensive analysis of such data is imperative in the accurate identification of the cause of spoilage. The following guidelines, though not all inclusive, should assist this identification.

6.1 Number of spoiled containers

   a) Isolated container - usually a random leaker and rarely the result of under-processing.

   b) Several containers - mixed microflora, probably due to post-process contamination and leakage.

Leaker spoilage may occur with or without defective seams or visible dents and may be related to over-cooling, inadequate chlorination, contaminated cooling water and/or dirty, wet post-processing equipment. Handling cans while warm and wet or excessive rough can handling practices may increase likelihood of leaker spoilage. If there is a high proportion of spoiled containers and only sporeformers are present, under-processing is usually indicated. However, leakage should not be ruled out.

6.2 Age of product and storage

   a) Excessive age and/or excessively high temperature may give rise to hydrogen swells. This is more likely to occur with canned vegetables e.g., artichoke hearts, celery, pumpkin and cauliflower.

   b) Corrosion or damage causing perforations of container may lead to leaker spoilage and secondary damage to other cans.
6.3 Location of spoilage

a) Spoilage in centre of container stacks, or near ceiling, may indicate insufficient cooling resulting in thermophilic spoilage.

b) Spoilage scattered throughout the stacks or cases may indicate post-processing leakage or under-processing.

c) Thermophilic spoilage may result from storage at high temperatures, e.g., 37°C (99°F) and above.

6.4 Processing records

a) Records showing poor control of thermal processing may correlate with spoilage from under-processing.

b) Adequate processing records may eliminate under-processing spoilage and indicate post-processing leaker contamination.

c) Incorrect retort operation, i.e., leaking air or cooling water valves, broken thermometers and incorrect reel speed of rotary cookers may lead to underprocessing.

d) Delays coupled with unhygienic pre-process conditions may result in incipient or pre-process spoilage.

e) High thermophilic counts in blanchers may correlate with thermophilic spoilage.

f) Changes in product formulation without reevaluation of process parameters may lead to under-processing.

g) Inadequate sanitation may lead to a build-up of microorganisms, which either result in pre-process spoilage or render the scheduled process inadequate. Post-process leaker contamination may also be caused by inadequate sanitation.

6.5 Laboratory data

a) See Tables 2 and 3 and Figures 2 and 3 which correlate with the verification of positive tubes as discussed in Appendix 1.

7. CONCLUDING REMARKS

The foregoing is concerned with the cause of spoilage in canned foods. Such determinations are, of necessity, different from those required to establish that commercial sterility has been achieved within a given code lot of product.

It is not within the scope of this procedure to give any guidance as to the disposal of lots which have been demonstrated to be not commercially sterile.

The reasons for spoilage are many and varied. Therefore, a decision as to the disposal of such lots needs to be made on a case-by-case basis, utilizing much of the information obtained in assessing the status of the lot from which the container was obtained. Whether or not a lot can be salvaged will depend, for example, on factors such as the reason for spoilage, the ability and reliability of physically separating satisfactory from unsatisfactory products, etc. These factors will of course, vary widely. Therefore, the general principles outlined in the "Guidelines for the Salvage of Canned Foods Exposed to Adverse Conditions" apply and in some cases may be used for lots in which spoilage has been identified.
Figure 2

Flow sheet for the Aerobic Cultural Examination of Low-acid Canned foods for Spoilage and Diagnosis of Results

Sample
→ Aerobic Media Tubes

30 to 37°C** (Up to 4 days)

If + growth, mixed flora containing some cocci, yeasts or molds, indicates post-process contamination

If only rods present

NAMn*35°C (Up to 10 days)

If spores present by microscopic exam, heat 10 min at 100°C

If no spores, indication of post-process contamination

35°C (Up to 4 days) 55°C (Up to 4 days)

If + growth, probable insufficient thermal process

If + growth, probable insufficient thermal process

55°C (Up to 4 days)

If + growth, rods

NAMn*55°C (Up to 4 days)

If spores prevent by microscopic exam, heat to 10 min at 100°C

NAMn*35°C (Up to 4 days) 55°C

If + growth, mesophilic aerobic Bacillus spp

If + growth, thermophilic aerobic Bacillus spp

Probable insufficient thermal process

Normal thermophilic flora unless product was stored at high temperature

(* NAMn = Nutrient agar plus manganese)

(** Conditions for microbial growth are optimal at 30 to 35°C. However incubation temperatures of 36°C or 37°C may be used depending upon regional environmental conditions.)
Figure 3
Flow Diagram For
The Anaerobic Cultural Examination of Low-Acid Canned Foods For Spoilage
and
Diagnosis of Results

Sample
↓
Anaerobic Media Tubes

30 to 37°C* (Up to 10 days) 55°C (Up to 4 days)

If + growth
microscopic exam

Mixed flora of cocci, yeasts, molds indicates possible post-
process contamination

If positive growth, microscopic exam

If long thin rods that stain poorly, probable thermophilic
anaerobes. Indicates *Clostridia* sp., or if insufficient cooling,
high temperature storage, or that thermal process above
118°C (245°F) should be used on this product. Not an indication of insufficient
thermal process.

If shorter rods are present, these could be facultative
anaerobes. Indicates *Bacillus* spp., or if product is dark,
sulphide spoilage sporeformer. Either could indicate insufficient
cooling or high temperature storage. Not an indication
of insufficient thermal process.

rods with spores
Indicates possible inadequate thermal process. If spores are *Clostridia*,
check culture for botulinum toxin.

rods without spores
Try other anaerobic media, if no spores, indicates possible post-process contam-
nination.

Also heat spores 10 min at 100°C in anaerobic media tubes
(14 days at 35°C)

Save spores for thermal death-time work

(Termophilic anaerobic spores are only rarely seen or found in microscopic examin-
ation of product on first subculture therefore no heating is suggested, but optionally
can be used at this point followed by anaerobic media subculture at 55°C).

(* Conditions for microbial growth are optimal at 30 to 35°C. However, incubation
temperatures of 36°C or 37°C may be used depending upon regional environmental conditions.)
8. REFERENCES


10. de Man, Rogosa and Sharpe, 1960?
Appendix 1
An Example of
A PRODUCT IDENTIFICATION AND HISTORY ENQUIRY FORM*

Date: .................. Enquiry No. .................
Compiled by: ......................

1. REASONS FOR INVESTIGATION

1. Spoilage
   1. How detected (consumer complaint, warehouse inspection, incubation study etc.)
   2. Date when problem first became known
   3. Nature of problem
   4. Extent of the problem (incidence of affected and non-affected containers)
   5. Number of burst, swollen or leaking containers observed.

2. Illness
   1. Number of persons affected
   2. Symptoms
   3. Time of last meal or snack
   4. Time elapsed before onset of symptoms
   5. What other foods and beverages were also ingested for up to 4 days before onset of symptoms?
   6. Number of containers of canned food involved
   7. Identity of product, including codes
   8. Complainant product and/or container available for analysis
   9. Were other samples of product having same code taken?
   10. How and where were samples sent for analysis?

2. PRODUCT DESCRIPTION AND IDENTIFICATION

1. Product name and type
2. Container type and size
3. Identification of code lot(s) involved
4. Date of thermal processing
5. Processing establishment
6. Supplier/Importer – if imported, date of entry into country
7. Size(s) of implicated lot(s)
8. Location of lot(s)

3. PRODUCT HISTORY RELATING TO SUSPECT CODE LOT(S)

1. Product composition
2. Container supplier and specifications

* This form is only intended to be an example and may require modification for a specific investigation. For instance, the data to be collected and Section 1.2 (illness) should be expanded if food poisoning is suspected.
3. Production data (scheduled process) and records  
   a. Product preparation  
   b. Filling  
   c. Sealing  

4. Equipment used in thermal processing  
   a. Thermal processing  
   b. Cooling  
   c. Additional quality control and assurance records  

5. Storage and transportation  

6. Current status of lot(s) under examination - if product not under direct control, describe area of distribution  

4. **SAMPLE DESCRIPTION AND HISTORY**  

1. Where, when and how was sample obtained  
2. Sample size - number of containers  
3. Total number of containers at the sample site  
4. Number of containers having defects in the sample  
5. List defects for each container  
6. Describe conditions of storage and transportation  
7. Sample identification (laboratory number assigned)
Appendix 2

PROCEDURES FOR MICROBIOLOGICAL ANALYSIS OF THE ANALYTICAL SAMPLE

A. Mesophiles

1. Media and Incubation Conditions

<table>
<thead>
<tr>
<th>Low-Acid Foods (pH &gt; 4.6)</th>
<th>Acidified Low-Acid Foods (pH ≤ 4.6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Incubation Conditions</td>
<td>Aerobic</td>
</tr>
<tr>
<td>2. Media (2)</td>
<td>Liquid</td>
</tr>
<tr>
<td></td>
<td>DTB</td>
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<tr>
<td></td>
<td>PE2</td>
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<td></td>
<td>NAMn</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3. Quantity of medium</td>
<td>15 ml/tube</td>
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<td></td>
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</tr>
<tr>
<td>4. Replication</td>
<td>≈ 2 tubes</td>
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<td></td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>5. Incubation Temperature (3)</td>
<td>30°C</td>
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<tr>
<td>6. Incubation Time (4)</td>
<td>to 14 days</td>
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</tr>
</tbody>
</table>

Use at least one medium for each series of solid and liquid media incubated aerobically and anaerobically.

Notes

(1) Lower temperatures, i.e., 20°C or 25°C may be appropriate in some instances, for example, for yeasts.

(2) Abbreviations used for media:

- PCA - Plate count agar
- CMM - Cooked meat medium
- LB - Liver broth
- RCM - Reinforced clostridial broth
- LVA - Liver veal agar
- PIA - Pork infusion agar
- PE2 - Peptone, yeast extract medium, Folinazzo (1954)

(3) Abbreviations used for broth:

- DTB - Dextrose tryptone broth
- DTA - Dextrose tryptone agar
- NAMn - Nutrient agar plus manganese
- RCA - Reinforced clostridial agar
- PIA - Pork infusion agar
- TJA - Tomato juice agar

(4) A temperature of 35°C or 37°C may be used in addition or when ambient (room) temperature is near to or greater than 30°C or when specific organisms of concern have higher optimal growth temperatures.

(5) Examine tubes and plates periodically, e.g., at least every two days. Incubation is terminated when positive growth is observed.
2. Verification of suspect positive tubes

All suspect positive tubes should be examined as follows:

1. Carry out direct microscopic examination of suitably prepared and stained smears.

2. Inoculate at least duplicate plates or slants, and incubate aerobically and anaerobically for up to 5 days. For suitable media see above.

(Note: If only one tube of each series of tubes inoculated is positive it is recommended that the above procedure be repeated using analytical units drawn from the reference sample. Further information with respect to interpretation of single tube results is discussed in the section on interpretation.)

3. Identification of isolates

Facultative thermophiles can grow in cultures at 30°C to 37°C and hence be mistaken for mesophiles. Positive isolates from cultures grown at these temperatures must always be confirmed as true mesophiles by demonstrating that they will not grow at thermophilic temperatures, 55°C.

To assist in identifying the cause of spoilage it is useful to identify isolates. For this purpose standard microbiological procedures should be used (See Speck, (1984); ICMSF, (1980); US FDA BAM, (1984)).

B. Thermophiles

If circumstances suggest thermophilic spoilage, e.g., history of problem, lowered pH of product, no growth occurring below 37°C (product liquified or not obviously spoiled), culturing at 55°C on the following media is suggested.

Incubate for up to 10 days.

Thermophilic aerobes (flat sour) - Dextrose tryptone broth

B. coagulans (thermoacidurans) - Proteose peptone acid medium* at pH 5.0 (may grow at 37°C)

Anaerobes not producing H₂S - Corn liver medium*

C. thermosaccharolyticum - Liver broth*

Anaerobes producing H₂S - Sulphite agar* + reduced iron or iron citrate

*(Hersom and Holland, 1980)

C. Acid tolerant

It is preferable that all media used should be buffered to a pH value between 4.2 and 4.5.

1. Liquid
   a) Acid broth (AB) - (See US FDA BAM, 1984)
   b) MRS broth, (de Man, Rogosa and Sharp, 1960)

2. Incubation
   30°C for up to 14 days.
GUIDELINE PROCEDURES FOR THE VISUAL INSPECTION OF LOTS OF CANNED FOODS FOR OBJECTIVE* DEFECTS
(At Step 3 of the Procedure)

Table of Contents

Explanatory Preface
1. Introduction
2. Objective
3. Inspector
   1. Training
   2. Powers
4. Inspection
   1. Preparation for Inspection
   2. Overview Inspection
5. Sampling Inspection
   1. Examination of Sample
6. Action When Defects Are Found

Appendix 1 - Lot Inspection Record
Appendix 2 - Objective 1 Defects

* Objective 1 defects are those which show visual evidence that a metal container is without hermetic seal or that microbial growth has occurred in the container's contents (see Appendix 2).
The safety of canned foods is assured primarily by the application of Good Manufacturing Practices (GMP's) in the manufacture of the containers, processing and handling the container in the processing establishment, and storage and distribution of the finished product. When the safety or acceptability of a lot of canned food is in question the first action should be the verification that GMP's were followed. However, there are instances e.g., international trade, when safety or acceptability of a lot may be in question and no evidence is available which would give assurance that GMP's had been followed. In such situations it would be appropriate for a canning expert to assess the acceptability or safety by both inspection and reference to any pertinent documentation relating to processing, shipping, etc. of the lot which may be available. The type of examination carried out under such circumstances will vary and be dictated by the particular problem or situation. The examination may be expected to reflect the experiences of the particular expert engaged.

Some container defects can increase the potential for microbiological contamination of canned foods resulting in spoilage and in some instances in foodborne illness. While some of these defects are hidden, many are visible on the container surfaces permitting their detection without destructive analysis. Control of such defects, that is preventing their occurrence, is exercised in a number of critical control points in the GMP's to assure that the risk of post-process microbial contamination which may result in spoilage and food poisoning is minimized. It is in this sense that inspection of lots of canned foods for visual defects can be a viable means to determine their acceptability. Since such inspection is non-destructive it permits the inspection of larger numbers of containers at minimal cost. However, when such inspections are carried out, only statistical based sampling plans should be used.

It is important to recognize that sampling inspection for defects alone cannot give the same level of assurance to GMP's because:

1. not all defects are apparent by visual inspection; and
2. there are limitations on resources available for the application of statistically based sampling plans.

Control of visual defects is just one of the GMP's relevant to assuring that the risk of contamination with microorganisms which may result in spoilage and food poisoning are minimized. From this, it is clear that sampling plans need to be considered in relation to their intended purpose and to the acceptable and unacceptable limits of Objective 1 defects.

End-product examination for visual defects should not be over emphasized as it may divert attention away from those GMP's which cannot be monitored by end-product examination (see Codex Alimentarius Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev.1, 1989)).

Sorting may be appropriate to remove defective cans but this should be decided at the "retention" stage by a canning expert.

IT IS MOST IMPORTANT THAT SAMPLING INSPECTION OF LOTS OF CANNED FOOD FOR THE PRESENCE OF VISUAL DEFECTS IS NOT THE ONLY BASIS FOR JUDGING PRODUCT TO BE FIT FOR HUMAN CONSUMPTION.

1. INTRODUCTION

The container defects named and illustrated in the manual and listed in Appendix 2, should be obvious and render the container or its contents defective, that is not suitable for distribution and sale. Anyone with a minimum of training should be able to recognize and intercept containers with these defects and to remove them from the food distribution chain.
The external defects listed in Appendix 2 and illustrated in the manual as Objective 1 defects, are those which show visual evidence that a metal container is without a hermetic seal or that microbial growth has occurred in the containers contents. These represent only one extreme of a whole range of visual defects which may be found in metallic containers. Provisions should be made to ensure that an inspector can differentiate between those shown in the manual as Objective 1 defects and other defects that may be found in the course of an inspection.

The safety of canned foods is most properly assured through strict adherence to Good Manufacturing Practices as detailed in the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979 (Rev.1, 1989), at the time of can manufacture, canning, storage and shipping. The inspection of a sample from a lot of finished product can provide only limited assurance of safety, since its main goal is to obtain a measure of the lot quality with respect to defectives and is not suited to the examination of shipments of unknown history. What action, if any, that should be taken would depend upon the quantity and type of defectives found and/or upon prevailing requirements of the regulatory agency having jurisdiction.

2. OBJECTIVE

This guide is intended for use by those charged with the responsibility for the visual inspection of lots of canned foods for Objective 1 defects which are depicted in the pictorial manual and listed in Appendix 2. This guide is not intended to be used to determine the disposition of a lot of canned food.

3. INSPECTOR

The term inspector applies to anyone who is charged with the responsibility to inspect a lot of canned foods for container defects and is not confined to those from regulatory agencies.

3.1 Training

Inspectors should be trained in the techniques required for the inspection of canned foods for container defects, with particular reference to the detection and identification of Objective 1 defects as depicted in the manual and listed in Appendix 2.

3.2 Powers

Inspectors should have the authority to exercise control over a lot until inspection, including evaluation of the results, is complete. Inspectors should also have the authority to control the disposal of defective cans and the entire lot if it is deemed unacceptable for sale.

4. INSPECTION

4.1 Preparation for Inspection

The inspector should be given all pertinent information on the lot(s) designated for and prior to the sampling for inspection, for example:

- Location of the lot(s);
- lot size (number of cartons and number of containers/carton);
- food type (peas, beans, luncheon meat, etc.);
- type and size of can;
- list of codes in the lot(s) and number of cartons in each;
- processor, country of origin, legal agent, etc.;
- sampling plan.

In order to properly sample an inspection lot and examine cans, all cans in the lot should be accessible. Adequate space and illumination should be available at the site of the inspection. As some defects are difficult to observe with the naked eye a magnifying glass (3x to 5x) and a high intensity light source are useful for the
examination of the container surface and the label. The reference defect manual should be available for consultation to ensure that defects are correctly identified. Adequate assistance should be available to the inspector so that he may have access to the entire lot for sampling.

The inspector should be informed as to the information, observations and sampling plan that are required for the inspection. A specific form or check list which details the information required and with sufficient space to record observations is an excellent means to ensure that the necessary information and observations are acquired and recorded. An example of a check list is given in Appendix 1.

4.2 Overview Inspection

The lot(s) should be examined visually for the presence of damaged, wetted or stained cartons. To properly conduct this overview inspection, as many of the cartons as possible should be exposed to view. It is not possible to conduct a proper overview when the lot(s) are contained in a truck, boxcar or shipping container as only those cartons facing the doors are exposed for examination.

Any damaged, wetted or stained cartons should be separated from the lot for a more detailed inspection. It should be kept in mind that the wetting or staining of cartons can often be the result of leakage of cartons immediately above which may not show any visible signs of leakage.

The number of damaged, wetted or stained cartons which are separated from the lot should be recorded as well as the location to which they have been removed. Precautions should be taken to prevent their inadvertent removal until they have been satisfactorily inspected and their fate determined. When there is obvious forklift or transportation damage, the inspector may permit removal of the damaged containers without prejudicing the evaluation of the remainder of the lot, provided the damage is not a prevailing condition throughout the lot. This would also apply to lots not selected for examination where similar conditions prevail. If can damage is not due to handling, refer to actions in Section 6.

Any damaged, wetted or stained cartons previously separated from the lot during the overview inspection may be sorted separately and given a 100% inspection to identify the Objective 1 defects present.

5. SAMPLING INSPECTION

The lot(s) should be sampled in accordance with a designated sampling plan. The sampling plan(s) used should be recorded.

Statistically based sampling plans call for a random selection of the sample units in the sample. For inspections, all items in the lot should be accessible and every effort should be made to ensure that the sample obtained is representative of the lot. It is important that the method used to obtain the sample is recorded as it may have an impact on the evaluation of the results. Where the lot has very limited access, the inspector would well be advised to seek guidance.

Frequently lots of canned foods can contain more than one code lot. In such cases and prior to sampling it should be determined whether each code lot will be sampled separately and what sampling plan will be used for each.

Each sample unit should be identified so that any defects found can be related to a particular unit. The number of sample units taken should be recorded.

5.1 Examination of Sample

When the required number of cans has been selected they should be carefully examined for defects. The first step is to carefully observe the overall external appearance of the cans, paying particular attention for any signs of swelling or leakage. The latter may be evidenced by the presence of product on the can or
staining of the label. The label should be removed from a suspect can after its position has been marked. This allows for easier location of a defect on the can. All parts of the can should be carefully examined with particular attention being paid to seams, areas of embossing and tear away strips, if present.

Each sample unit found to have any of the Objective 1 defects as shown in the manual should be recorded. All defects observed for each sample unit should be recorded. In the event that an inspector is uncertain of a defect, he should seek a second opinion from an expert.

6. **ACTION WHEN DEFECTS ARE FOUND**

When an inspector finds any defect shown in the manual he should either notify his superior or follow previously established procedures which set out criteria regarding the action to be taken. It may be appropriate to retain the lot and send defective cans to a laboratory for further investigation. It is important to remember that the individual cans which have Objective 1 defects may represent a health hazard and proper care should be exercised in handling, shipping or disposing of such cans. All defective cans should remain under control until destroyed.
Appendix 1

LOT INSPECTION RECORD

Information on Lot

1. Owner or consignee (name and address)
2. Location of lot
3. Manufactured by/for (name, address and establishment No., if appropriate)
4. Transportation (type and duration)
5. Date of arrival
6. Number of cartons
7. Number of containers per carton
8. Product: brand name; and common name (include style if appropriate)
9. Secondary packaging
10. Type and size of container
11. Code lots present (include cartons per code if available)
12. Code interpretation (if available)
13. Details of any accompanying documentation
14. Has lot been salvaged?
15. Is lot part of a larger lot or consignment?
16. If yes, where is remainder of lot or consignment located?

Information on Inspection

1. Date of inspection
2. Inspector's name, address and agency or affiliation
3. Sampling plan used
4. Method by which sample was taken
5. Was it possible to sample freely?
6. Number of containers (sample units) in the sample taken
7. How were sample units identified?
8. List all defects found for each container and note which are Objective 1 defects
9. List containers sent to laboratory for further examination
10. Results of laboratory analysis
11. Other comments or observations related to the inspection

Information on Disposition

1. Lot accepted or detained
2. How were defective (Objective 1) containers disposed of?
3. If lot retained, what further action is recommended or has been taken?
Appendix 2

OBJECTIVE 1 DEFECTS

The following defects are considered to comply with the definition given for Objective 1 defects:

1. Perforated external corrosion
2. Severe body denting (plate fracture with leakage evident)
3. Severe double seam denting (fracture evident)
4. Defective side seam weld (wild burn through)
5. Defective side seam weld (wild blow out)
6. Incomplete side seam weld
7. Incomplete open side seam weld (leakage evident)
8. Mislocked side seam
9. Body puncture
10. Body perforated
11. Hard swell or buckle swell or blown
12. Cable-cut (end plate cut through, leakage evident)
13. Sharp embossed code (end plate fractured)
14. Deadhead or skidder
15. Incomplete double seam (2nd operation incomplete)
16. Cut-over or cut-through (plate fractured)
17. Torn flange (visible hole)
18. Knocked down curl
19. Knocked down flange
20. Torn back curl
21. Score line fracture
DRAFT CODE OF HYGIENIC PRACTICE
FOR PRE-COOKED AND COOKED FOODS IN MASS CATERING
(At Step 6 of the Procedure)

Table of Contents

Explanatory Preface
Section I - Scope
Section II - Definitions
Section III - Hygiene Requirements in Production/Harvesting Area
Section IV - A. Production or Preparation Establishment: Design and Facilities
- B. Serving Rooms: Design and Facilities
Section V - Establishment: Hygiene Requirements
Section VI - Personnel Hygiene and Health Requirements
Section VII - Establishment: Hygienic Processing Requirements
EXPLANATORY PREFACE

A. The Code has, as far as possible, been made consistent with the format and content of the General Principles of Food Hygiene.

B. The need for this Code is based on the following considerations:

1. Epidemiological data show that many outbreaks of food poisoning are caused by food produced in mass catering.

2. Large-scale catering operations are particularly hazardous because of the way the food is stored and handled.

3. Outbreaks can involve large numbers of people.

4. Persons fed by mass catering are often especially vulnerable — for instance children, the elderly and hospital patients, especially those who are immuno-compromised.

C. The Hazard Analysis Critical Control Point (HACCP) system has been applied to the Code.

The HACCP System consists of:

1. An assessment of hazards associated with growing, harvesting, processing/manufacturing, marketing, preparation and/or use of a given raw material or food product.

2. Determination of critical control points required to control any identified hazard(s).

3. Establishment of procedures to monitor critical control points.

The critical control points have been identified in the Code and explanatory notes describing the risk and giving the type and frequency of controls to be applied, have been inserted in connection with the relevant paragraphs. (CCP - Notes) WHO/ICMSF 1982. Report of the WHO/ICMSF Meeting on Hazard Analysis, Critical Control Point System in Food Hygiene. World Health Organization VPH 82/37, Geneva, and also the ICMSF handbook on the principles and application of HACCP).

D. Properly trained inspectors and personnel and an adequate sanitary infrastructure are necessary in order to implement the Code satisfactorily.
SECTION I - SCOPE

1. This Code deals with the hygienic requirements for cooking raw foods and handling cooked and pre-cooked foods intended for feeding large groups of people, such as children in schools, the elderly either in old peoples' homes or by means of "meals on wheels", patients in nursing homes and hospitals and prisoners. These categories of people are supplied as groups with the same types of foods. In this social type of mass catering the consumer has limited choice in the food, he or she eats. This Code is not intended for industrial production of complete meals, but may give guidance on specific points to those who are involved. For reasons of simplicity, foods served raw to the consumer, are not included. This does not necessarily mean that these foods will not constitute a hazard to health.

SECTION II - DEFINITIONS

2. For the purposes of this Code the following expressions have the meaning stated:

2.1 Catering - the preparation, storage and, where appropriate, delivery of food for consumption by the consumer at the place of preparation or at a satellite unit.

2.2 Catering Establishment - a kitchen where food is prepared or reheated for catering.

2.3 Chilled Food - product maintained at temperatures not exceeding 4°C in any part of the product and stored for no longer than five days.

2.4 Cleaning - the removal of soil, food residues, dust, grease or other objectionable matter.

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

2.6 a) Cooked Food - foods cooked and kept hot or reheated and kept hot for serving to the consumer.

b) Precooked Foods - foods cooked, rapidly chilled and kept refrigerated or frozen.

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

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

2.9 Food Handling - any operation in the preparation, processing, cooking, packaging, storage, transport, distribution and service of food.

2.10 Food Handler - every person handling or coming into contact with food, or with any equipment or utensil used in food handling.

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

2.12 Frozen Food - product maintained at a temperature equal to or below -18°C in any part of the product.

2.13 Lot - a definitive quantity of a cooked or pre-cooked food produced under essentially the same conditions at the same time.

2.14 Mass Catering - the preparation, storage and/or delivery and serving of food to a large number of people.
2.15 Packaging Material - any containers such as cans, bottles, cartons, boxes, cases and sacks, or wrapping and covering material such as foil, film, metal, paper, wax-paper and cloth.

2.16 Pests - any animals capable of directly or indirectly contaminating food.

2.17 Meal Assembly - composing or placing food for one person in or on a suitable container, where it will be kept until delivery to the consumer.

2.18 Portioning - division of food immediately after cooking into single or multiple portions.

2.19 Potentially Hazardous Food - food capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms.

SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA

Are not covered in this Code.

For raw material Requirements: See Section VII.

SECTION IV - A. PRODUCTION OR PREPARATION ESTABLISHMENT: DESIGN AND FACILITIES

This section covers the areas where the food is prepared, cooked, chilled, frozen and stored.

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 - 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. All construction materials should be such that they do not transmit any undesirable substances to the food.

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

4.3.3 Buildings and facilities should be designed to permit easy and adequate cleaning and to facilitate proper supervision of food hygiene.

4.3.4 Building 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.

Note: Cross-contamination is an important factor that contributes to foodborne outbreaks. Food can be contaminated with harmful organisms after cooking sometimes from a food handler, and often directly or indirectly from raw food. Operations such as the cleaning and washing of vegetables, the washing up of equipment, utensils, crockery and cutlery, and the unpacking, storage or refrigeration of raw materials should be performed in separate rooms or locations especially designed for that purpose. Managers and food inspectors should regularly check that the separation principle is properly applied. (See also CCP-Note in 4.4.1)
4.3.6 Buildings and facilities should be designed to facilitate hygienic operations by means of a controlled and 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 for the process and product.

4.3.7 In food handling areas:

- **Floors**, where appropriate, should be of waterproof, non-absorbent, washable, and non-slip 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 waterproof, non-absorbent and washable materials sealed and free of insects and should be light coloured. 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 coved to facilitate cleaning.

- **ceilings** should be so designed, constructed and finished as to prevent 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 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.

- **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 to 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 designed so that access can be controlled.

4.3.11 The use of material 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

4.3.12.1 An ample supply of water, in compliance with the WHO "Guidelines for Drinking Water Quality", 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.

Note: Samples should be taken regularly, but the frequency should depend upon the origin and the usage of the water, e.g. more frequent from private supplies than from public supplies. Chlorine or other suitable disinfectants may be used. If chlorination has been employed checks should be made daily by chemical tests for available chlorine. The point of sampling should preferably be at the point of usage, but occasionally it would be useful to sample at the point of entry of the water to the establishment.
4.3.12.2 There should be a system to ensure an adequate supply of hot potable water.

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

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

4.3.12.5 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 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. All waste pipes should be properly trapped and lead to a drain.

4.3.14 Refrigeration

4.3.14.1 Establishments should have refrigerating and/or freezing cabinets large enough to accommodate raw materials at adequate temperature in order to comply with the requirements of Section 7.1.4 and 7.1.5.

Note: Cross contamination of pathogens from raw commodities to prepared foods frequently occurs in the refrigerator. Therefore, raw foods, particularly meat, poultry, liquid egg products, fish and shellfish, must be strictly separated from prepared foods, preferably by the use of different refrigerators.

4.3.14.2 Establishments should have refrigerating and/or freezing cabinets or equipment (freeze tunnel) for chilling and/or freezing in order to comply with requirements of Sections 7.7 and 7.8.

Note: A specially designed rapid chilling system is desirable. Rapid chilling or freezing of large quantities of food requires proper equipment capable of extracting the heat rapidly from the largest quantity of food likely to be produced.

4.3.14.3 Establishments should also have refrigerating and/or freezing cabinets or equipment for chilled and/or frozen storage of prepared food corresponding to the maximum daily activity of the establishment and in order to comply with requirements of Sections 7.7 and 7.8.

4.3.14.4 All refrigerated spaces should be equipped with temperature measurement or recording devices. They should be clearly visible and should be placed in such a way as to record the maximum temperature of the refrigerated space as accurately as possible. If possible cabinets for chilled and/or frozen storage of food should be equipped with temperature alarms.

Note: The accuracy of the temperature-recording devices should be checked at regular intervals and tested for accuracy against a known accurate standard thermometer. Such tests should be performed prior to installation, and at least once a year thereafter or more frequently as may be necessary to assure their accuracy. A dated record of such tests should be kept.

4.3.15 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 appropriately heated and should not open directly on to food handling areas. Hand
wasting facilities with 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 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.

4.3.16 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 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 preferable. The facilities should be furnished with properly trapped waste pipes leading to drains.

4.3.17 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.

4.3.18 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 food in case of breakage.

4.3.19 Ventilation

Adequate ventilation should be provided to prevent excessive build-up of 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. Ventilation openings should be provided with a screen or other protecting enclosure of non-corrodible material. Screens should be easily removable for cleaning.

A device for effectively removing cooking steam and vapors should be installed above cooking units.

In rooms where food is being handled after chilling the temperature should not exceed 15°C. Ideally, the temperature in the kitchen should not exceed 26°C.

4.3.20 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, building 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 material which does not transmit toxic substance, 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. Suitable materials include stainless steel, synthetic wood and rubber substitutes. 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 source of contamination. The use of different metals in such a way that contact corrosion can occur should be avoided.

CCP Note: Equipment and utensils constitute a source of potential cross-contamination. In addition to regular routine cleaning, it is essential that all equipment and utensils used for raw foods be thoroughly disinfected before they are used for cooked and precooked foods. If at all possible, separate utensils should be used for raw and cooked products. If this is not possible, thorough cleaning and disinfection is necessary.

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.

Note: Only properly designed equipment is satisfactory for bulk cooking. Mass-catering cannot be performed safely merely by increasing size or quantity of the type of equipment traditionally used in conventional kitchens for preparation of individual dishes. The capacity of the equipment used should be adequate to permit the hygienic production of food.

4.4.2.2 Containers for inedible material 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.

4.4.3 Equipment identification

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

4.4.4 Equipment and utensil storage

Portable equipment such as spoons, beaters, pots and pans, etc., should be protected from contamination.

SECTION IV - B. SERVING ROOMS: DESIGN AND FACILITIES

This section covers the area where food is served which may include re-heating and storage.

In principle, the requirements mentioned in Section IV - A. apply also to serving rooms.

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, vapour and surplus water.
5.2 Cleaning and Disinfection - Washing up

5.2.1 Cleaning and disinfection should meet the requirements of this Code.

For further information on cleaning and disinfection procedures, see Annex I of the General Principles of Food Hygiene (CAC/VOL. A-Ed. 2, 2nd Rev. (1985)).

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

Note: Equipment, utensils etc. in contact with food, particularly raw food, (Fish, meat, vegetables) will be contaminated with micro-organisms. This may adversely affect products handled subsequently. Therefore, cleaning including dismantling is necessary at frequent intervals during the day, at least after every break and when changing from one food product to another. The purpose of dismantling cleaning and disinfection at the end of each working day is to hinder build-up of possibly pathogenic microflora. Monitoring should be done by regular inspection.

5.2.3 Adequate precautions should be taken during cleaning or disinfection of rooms, equipment or utensils to prevent food from being contaminated by wash water, detergents and disinfectants. Cleaning solutions should be stored in adequately marked non-food containers. 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 food should be removed by thorough rinsing with potable water before the area or equipment is again used for handling food.

Note: High pressure hoses produce aerosols and therefore should not be used during production. Care should be taken when using high pressure hoses not to contaminate food contact surfaces with organisms from floors, drains, etc. Presence of moisture may promote the growth of Listeria monocytogenes and other pathogenic microorganisms and, therefore, equipment and floors should be kept as dry as possible.

5.2.4 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.

5.2.5 Maintenance, cleaning tools and cleaning chemicals such as brooms, mops, vacuum cleaners, detergents, etc. should be maintained and stored in a way that does not contaminate food, utensils, equipment or linens.

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

5.2.7 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 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 Storage and Disposal of Wastes

In kitchen and food preparation rooms, by-products and waste products should be collected in single-use leak-proof bags or in properly labelled re-usable containers. These should be sealed or lidded and taken from the working area as soon as they are full or after each working period and placed (single-use bags) or emptied (re-usable
containers) in covered waste bins which must never be introduced into the kitchen. Re-usable containers should be cleaned and disinfected each time they are taken back into the kitchen.

Waste bins should be kept in a closed area reserved for the purpose separate from the food storage rooms. The area should be kept at as low a temperature as possible, well ventilated, protected from insects and rodents and should be easy to clean, wash and disinfect. The waste bins should be cleaned and disinfected each time after use.

Cartons and wrappers should, as soon as they are empty, be removed under the same conditions as waste materials. Waste compressing equipment should be separated from any food handling area.

If a system of ducted waste disposal is in use, it is imperative that offal, scraps and waste be placed in closed single-use bags. The duct opening should be cleaned and disinfected daily.

5.5 Exclusion of Domestic Animals

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

5.6 Pest Control

5.6.1 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.

Note: Insects and rodents are known carriers of pathogenic bacteria from areas of contamination to prepared foods and food contact surfaces therefore their presence in food preparation areas should be prevented.

5.6.2 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 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. Appropriate records of pesticide usage should be maintained.

5.6.3 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, equipment and utensils from contamination. After application, contaminated equipment and utensils should be thoroughly cleaned to remove residues prior to being used again.

CCP Note: Records of pesticide usage should be kept and periodically checked by a responsible supervisor.

5.7 Storage of Hazardous Substances

5.7.1 Pesticides or other non-food 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 disposed and handled only by authorized and properly trained personnel. Extreme care should be taken to avoid contamination of food. Food containers or containers which are used to handle food, should not be used to measure, dilute, dispense or store pesticides or other substances.

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 Personnel Effects and Clothing

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

SECTION VI - PERSONNEL HYGIENE AND 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 in 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, whether because of epidemiological considerations, the nature of food prepared in a particular establishment of 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 diarrhoea, 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 persons so affected should immediately report to the management that he/she is ill.

CCP Note: If an employee is restricted from working in a food handling area because of a communicable disease, he/she should receive clearance from a competent medical professional before returning 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 hands frequently and thoroughly with a suitable cleaning preparation under running warm, potable water 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 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 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 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 jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in food handling.

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, 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 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.

Note: Gloves may be useful in protecting the food handler from the product and also may improve the sanitary handling of food. Torn or punctured gloves should be discarded to avoid leakage of any accumulated perspiration, which will contaminate food with high numbers of micro-organisms. Chain mail gloves are particularly difficult to clean and disinfect because of their construction: careful cleaning followed by heating or prolonged immersion in disinfectant is necessary. Gloves must be made from materials suitable for food contact. Some gloves made from reprocessed fibers may not be suitable when handling food.

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 paragraphs 5.8, 6.3, 6.4 and 6.7.

6.10 Supervision

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

SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

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

7.1.2 Raw materials or ingredients should be inspected and sorted prior to the cooking process and where necessary laboratory tests should be made. Only clean sound raw materials or ingredients should be used in preparation of food.

7.1.3 Raw materials 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 supplied frequently and regularly, and excessive quantities should not be stored.

7.1.4 Chill stored raw foods of animal origin between 1 and 4°C. Other raw foods which require refrigeration, such as certain vegetables, should be stored at as low a temperature as quality permits.

Note: First in - first out is a good general principle. But age alone may be an imperfect indication of quality. The history of raw materials in terms of intrinsic quality and temperature history also needs to be taken into account so that different batches can be used in proper sequence. For chilled raw
materials the colder the storage temperature, without freezing, the better. Some common human pathogens can grow, albeit slowly, at chill temperatures. 

Yersinia enterocolitica can grow very slowly at 0°C, Clostridium botulinum type E and non-proteolytic types B and F at 3.3°C and Listeria monocytogenes at 0°C.

7.1.5 Frozen raw materials which are not immediately used should be maintained or stored at or below −18°C.

7.2 Prevention of Cross-Contamination

7.2.1 Effective measures should be taken to prevent contamination of cooked and pre-cooked foods by direct or indirect contact with material at an earlier stage of the process. Raw food should be effectively separated from cooked and pre-cooked foods. (See also 4.4.1).

Note: Raw meat, poultry, eggs, fish and shellfish and rice are frequently contaminated with food-borne pathogens when they reach food service establishments. Poultry, for example, frequently harbours salmonellae which may be spread to surfaces of equipment, to the hands of workers and to other materials. The possibility of cross-contamination should always be considered.

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 have changed into clean protective clothing.

7.2.3 Hands should be washed thoroughly between handling products at different stages of processing.

Note: Food handlers can be a source of contamination. For example, cooked Ingredients in potato salad can become contaminated by food handlers during mixing and preparation. Hazard analysis should therefore include observations of food handling and hand-washing practices of the kitchen staff.

7.2.4 Potentially hazardous raw products should be processed in separate rooms, or in areas that are separated by a barrier, from areas used for preparing ready to eat foods.

7.2.5 All equipment which has been in contact with raw materials or contaminated material should be thoroughly cleaned and disinfected prior to being used for contact with cooked or pre-cooked foods. It is preferable to have separate equipment for handling of raw materials and cooked pre-cooked foods, in particular apparatus for slicing and mincing.

7.3 Use of Water in the Food Process

Raw fruits and vegetables to be used in meals should be thoroughly washed in potable water before addition to the meals.

7.4 Thawing

7.4.1 Frozen products, especially frozen vegetables can be cooked without thawing. However, large pieces of meat or large poultry carcasses often do need to be thawed before cooking.

7.4.2 When thawing is carried out as an operation separated from cooking this should be performed only in:

a) a refrigerator or purpose-built thawing cabinet maintained at a temperature of 4°C or below.

or

b) running potable water maintained at a temperature not above 21°C for a period not exceeding 4 hours.
or

c) a commercial microwave oven only when the food will be immediately transferred to conventional cooking units as part of a continuous cooking process or when the entire, uninterrupted cooking process takes place in the microwave oven.

CCP Note: Hazards associated with thawing include cross-contamination from drip and growth of micro-organisms on the outside before the inside has thawed. Thawed meat and poultry products should be checked frequently to make sure the thawing process is complete before further processing or the processing time should be increased to take into account the temperature of the meat.

7.5 Cooking Process

Note: The cooking process should be designed to maintain as far as possible the nutritional value of the food.

Note: Use only fats or oils destined for this purpose. Frying fats and oils should not be overheated. The temperature is dependent on the nature of the oil or fat used. Follow the instructions of the supplier or the jurisdictional requirements if they exist, but frying fats or oils should not be heated above 180°C.

Fats and oils should be filtered before each frying operation to remove particles of food with a filter especially adapted for this purpose. (Deep-fryer should be equipped with a tap to allow for evacuation of oil from the bottom). The quality of oil or fat should regularly be checked for odour, taste and smoking colour, and if necessary, changed. If the quality is suspect, the frying oil can be checked by commercial test kit. If the result of this test is positive, a sample can be further examined for smoke point, free fatty acids and especially for polar compounds.

CCP Note: Frying fats or oils can become dangerous for consumer’s health. Quality of frying fats or oils should be strictly controlled.

Note: Frying fats and oils should not be over-heated. Fats and oils should be changed immediately as soon as any changes in colour, flavour or odour are evident.

7.5.1 The time and temperature of cooking should be sufficient to ensure the destruction of non-sporing pathogenic micro-organisms.

Note: Boned rolled joints of meat are convenient for cooking, but the operation of removing the bone and rolling the meat will transfer microbes from the surface to the centre, where they are better protected from the heat of cooking. For the safe production of rare cooked beef, the centre of joints must reach a minimum of 63°C in order to eliminate contaminating salmonellae. The proper use of other time/temperature combinations which would ensure safety is acceptable.

For large poultry carcasses, where salmonellae are also a hazard, and which are not normally eaten rare, salmonellae will be killed if a temperature of 74°C is achieved in the deep thigh muscle. It is not advisable to stuff the body cavity of large poultry carcasses because (a) the stuffing can be contaminated with salmonellae and may not achieve a temperature high enough to kill them, and (b) spores of Clostridium perfringens will survive cooking. Other techniques are available to allow for safe preparation of stuffed carcasses, such as limiting volume, establishing geometric center time/temperature controls and immediate removal of stuffing for service or to facilitate cooling. Stuffed birds cool very slowly and Clostridium perfringens will germinate and multiply during this time. The effectiveness of the cooking process should be checked regularly by measuring the temperature in the relevant parts of the foods.
7.5.2 When grilled, roasted, braised, fried, blanched, poached, boiled, or cooked products are not intended for consumption on the day they are prepared, the cooking process should be followed by cooling as quickly as possible.

7.6 Portioning Process

7.6.1 Strict conditions of hygiene should apply at this stage in the process. The portioning process should be completed within the minimum practicable period of time which should not exceed 30 minutes for any chilled product.

7.6.2 Only well cleaned and disinfected containers should be used.

7.6.3 Containers with lids are preferred so that the food is protected against contamination.

7.6.4 In large scale systems where the portioning process of cook-chilled foods can not be performed in 30 minutes, this portioning should take place in a separate area in which the ambient temperature should be 12°C. The temperature of the food should be monitored by temperature probes. The product should be served immediately or placed in cold storage at 4°C.

7.7 Chilling Process and Storage Conditions of Chilled Food

7.7.1 Immediately after preparation chilling should be carried out as quickly and efficiently as possible.

7.7.2 The performance required of the rapid chiller is to reduce the temperature in the centre of the food from 60°C to +4°C or below within two hours.

Note: Epidemiological information indicates that the most important factors contributing to the occurrence of food-borne disease outbreaks are related to operations that follow cooking; for instance, if cooling is far too slow, so that any part of the food stays for a dangerously long time in the temperature range between 60°C and 10°C where harmful microorganisms may grow; therefore, the product should not be maintained in this temperature range for more than 4 hours. Hazard analysis must assess conditions of chilling.

7.7.3 As soon as the chilling is complete the products should be put into a refrigerator. The temperature should not exceed +4°C in any part of the product and should be maintained until final use. Regular monitoring of the storage temperature is necessary.

7.7.4 The storage period between the preparation of chilled food and consumption should not be longer than five days including both the day of cooking and the day of consumption.

Note: The storage period of five days is directly related to the storage temperature of +4°C.

7.8 Freezing Process and Storage Conditions of Frozen Food

7.8.1 Immediately after preparation freezing should be carried out as quickly and efficiently as possible.

7.8.2 Cooked-frozen foods should be kept at or below -18°C. Regular monitoring of the storage temperature is necessary.

7.8.3 Cooked-frozen foods can be stored at or below 4°C but for not more than five days and should not be frozen.

7.9 Transport

7.9.1 Hygienic requirements inside vehicles transporting cooked and precooked foods are also applicable.
7.9.2 During transport the food should be protected against dust and other pollution.

7.9.3 Vehicles intended for transporting heated food should be designed to maintain food at at least 60°C.

7.9.4 Vehicles intended for transporting cooked-chilled food should be appropriate for this transport. The transport vehicle is designed to maintain the temperature of the already chilled food and not to chill the food. The temperature of the cooked-chilled foods should be maintained at 4°C but may rise to 7°C for a short period during transport.

7.9.5 Vehicles intended for transporting cooked-frozen food should be appropriate for this transport. The temperature of the cooked-frozen food should be maintained at or below -18°C, but may rise to -12°C for a short period of time during transport.

7.10 Reheating and Service

7.10.1 Reheating the food should be carried out rapidly. The reheating process must be adequate: a temperature of at least 75°C should be reached in the centre of the food within one hour of removing the food from refrigeration. Lower temperatures may be used for reheating providing the time/temperature combinations used are equivalent in terms of destruction of microorganisms to heating to a temperature of 75°C.

Note: Reheating must also be rapid so that the food passes quickly through the hazardous temperature range between 10°C and 60°C. This will usually require the use of forced air ovens, infrared or microwave reheaters. The temperature of the heated food should regularly be checked.

7.10.2 The reheated food should reach the consumer as soon as possible and at a temperature of at least 60°C.

Note: To minimize the loss of the organoleptic properties of the food it should be kept at or above 60°C for as short a time as possible.

7.10.3 Any food not consumed should be discarded and neither reheated nor returned to chilled or frozen storage.

7.10.4 In self-service establishments the serving system should be such that the foods offered are protected from direct contamination which could result from the proximity or the action of the consumer. The temperature of the food should be either below 4°C or above 60°C.

7.11 Identification and Quality Control System

7.11.1 Each container of food should be labelled with the date of production, type of food, establishment name and lot number.

Note: Lot identification is essential for implementing any product recall which may be required. It is also required to enable the "First-in/First-out Principle" to be implemented.

7.11.2 Quality control procedures should be carried out by technically competent personnel who possess an understanding of the principles and practice of food hygiene, a knowledge of the provisions of this code and who employ the HACCP approach in the control of hygienic practice.

Note: The control of temperature and time at critical control points is the key to producing a sound product. Access to a food microbiology laboratory is useful in establishing the validity of the procedures instituted. Occasional checking at critical control points serves to monitor the continuing efficacy of the management systems.
7.11.3 A sample of at least 150 g of each item of food taken from each lot should be kept in a sterile container at 4°C or below until at least three days after that whole lot has been consumed. Some organisms do not tolerate freezing and thus refrigeration of samples is recommended in lieu of freezing. The sample should be obtained from the lot at the end of the portioning period. These samples should be available for investigation in the event of any suspected food-borne disease or food poisoning.

7.11.4 The health authority will need for its own purposes a record of the catering establishments for which it is responsible and a registration scheme seems most appropriate.
DRAFT CODE OF HYGIENIC PRACTICE
FOR ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID FOODS
(At Step 5 of the Procedure)

Table of Contents

1. Section I - Scope
2. Section II - Definitions
3. Sections III - Hygiene Requirements in the Production/Harvesting Areas
4. Section IV - Establishment: Design & Facilities
5. Section V - Establishment: Hygiene Requirements
6. Section VI - Personnel Hygiene and Health Requirements
7. Section VII - Establishment: Hygienic Processing Requirements
8. Section VIII - Quality Assurance
9. Section IX - Storage and Transportation of Finished Products
10. Section X - Laboratory Control Procedures
11. Section XI - End-Product Specifications
SECTION I - SCOPE

This Code of practice is concerned with the aseptic processing and packaging of low-acid foods. "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 an atmosphere free from microorganisms 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. It does not apply to foods in hermetically sealed containers that require refrigeration or to acid or acidified low-acid foods.

SECTION II - DEFINITIONS

For the purpose of this Code:

2.1. "Acid Food" means a food that has a natural pH of 4.6 or below.

2.2. "Acidified low-acid food" means a food which has been treated so as to attain an equilibrium pH of 4.6 or lower after heat processing.

2.3. "Aseptic" means the condition in which contamination with viable microorganisms, including viable spores, which are capable of growing in the commercially sterile food at temperatures at which the food is likely to be held during manufacture, distribution and storage, is prevented.

2.4. "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 an atmosphere free from microorganisms in a manner which prevents viable microbiological recontamination of the sterile product.

2.5. "Aseptic zone" means the area required to be made and maintained commercially sterile.

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

2.7. "Cleaning" means the removal of food residues, dirt, grease or other objectional material.

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

2.9. "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.

2.10. "Critical factor" means any physical, chemical or other factor which is determined by the process authority, the processor or regulatory agency to be critical to the production of a commercially sterile food product. Examples of critical factors
include but are not limited to product formulation, viscosity, particle size, temperature, product feed rate, strained and concentration.

2.11 "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.

2.12 "Equilibrium pH" means the pH of a finished food once all components have attained pH uniformity as determined by measuring pH of the heat processed food.

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

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

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

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

2.15.2 "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/cm² (10 psig), i.e., normal finger pressure.

2.15.3 "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/cm² (10 psig), i.e., normal finger pressure.

2.16 "Hold Section" means the section in which the heated food is maintained for a time sufficient to attain commercial sterility of the food.

2.17 "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.

2.18 "Low-acid food" means any food, other than alcoholic beverages, where any component has a pH value greater than 4.6 after heat processing.


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

2.21 "Product-to-product regenerator" means the equipment designed to exchange heat from product-to-product aseptically.

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

2.23 "Seals" mean those parts of a container which are formed, bonded or fused together in order to close the container.
2.24 "Steam seal" means an enclosure that utilizes steam as a barrier to entry of microorganisms at susceptible points in the aseptic zone downstream from the holding section (e.g., rotating or reciprocating shafts, valve stems, etc.).

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

2.26 "Sterile" means commercially sterile.

2.27 "Sterility" means commercially sterility.

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

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

3. 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. SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

Establishments should 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 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 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 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 coloured. 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.
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. 2 (1985)), 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 colour, 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 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 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, odour 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 brought to a condition of commercial sterility and being maintained in that condition during operation. 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.

5. 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, vapour 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.

5.2.2 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.

5.2.3 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.

5.2.4 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.

5.2.5 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 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 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 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 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 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. **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 diarrhoea, 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 colour. 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 Behaviour

Any behaviour 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. 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 canning, 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 superheated steam to sterilize containers, sterile water may be used to cool containers before they are filled with product. Water to be used for this purpose must be sterilized, cooled, and delivered sterile to the point of use and should be produced from potable water.

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.

7.4.2 Inspection of container materials

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. (Empty containers are particularly subject to damage by faulty operation of container handling equipment.)

7.4.3 Cleaning of container materials

7.4.3.1 When it is necessary to clean container materials, it is imperative that no contaminating cleaning materials remain which might affect container material sterilization.

7.4.3.2 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.

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. The instructions should be followed meticulously.

7.4.8.2  Seam or seal areas should be kept as clean and dry as necessary to obtain a satisfactory closure. (Overfilling and splashing can lead to contamination of seams or seals and adversely affect container integrity).

7.4.9  **Inspection of closed containers**

7.4.9.1  **Inspection of external defects**

During production runs, regular observations should be made for external container defects. Appropriate detailed inspections for defects or product leakage should be conducted by competent personnel at intervals of sufficient frequency. 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 Draft Code of Hygienic Practice for Low 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 Draft Code of Hygienic Practice for Low 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.

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 except for systems which require container surfaces to be wet prior to overwrapping.

The risk of microleakage may be increased by inadequately designed, controlled and maintained container conveyor, handling, labelling 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 cases and trays is desirable.

7.4.12 Washing and drying

7.4.12.1 Only potable water as described in 7.6.8.1 Recommended International Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods CAC/RCP 23-1979 Rev.1 (1989) 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

Where aseptic containers are cooled, procedures as described in 7.6.8 of the Recommended International Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods CAC/RCP 23-1979 Rev.1 (1989) should be followed.

7.5 Sterilization of equipment, containers and food

7.5.1 General considerations

7.5.1.1 Scheduled processes for low-acid aseptically processed foods must be established only by competent persons having expert knowledge of aseptic processing 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 while in use and if discontinued, maintained for three years.

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;

- Time to reach equilibrium pH;
- pH of the product;
- Product composition or formulation;
- Levels and types of preservatives;
- Water activity;
- Likely storage temperature of the product;
- Thermal processing system

Since for these systems, the food products are thermally processed before packaging, traditional methods for deriving and verifying a thermal process used in conventional canning cannot be employed. The essential elements in the establishment of an adequate thermal process involve a marriage of the heating characteristics of the food product with inhibition and/or the bacterial thermal resistance of specific target microorganisms i.e., *Clostridium botulinum*. The product is brought to the process temperature and held at that temperature for a time necessary to achieve at least commercial sterility. In continuous systems the time for which the product must be held at the process temperature to attain commercial sterility is achieved in the holding tube or section. The flow rate of each and every particle in the holding section is critical. Thereafter, 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 holding section, 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 incorporate the flow rate, physical dimensions and design of the holding section and the rheological properties of the product. These can be used to calculate the minimum residence time. It is wise to verify the calculations by actual measurement. Properly designed and conducted inoculated product studies may be used in support of the establishment and validation of the thermal process.

The holding or residence time for products containing particulate matter is more complicated with the thermal diffusivity, shape, dimension, mass, etc. of each type of particle being critical.

Any changes in product composition or formulation should be evaluated as to their effect on the adequacy of the process. If, for any reason, the scheduled thermal process is found to be inadequate, corrective action should be taken and the thermal process be re-established.

### 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 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 commercially sterilized by exposure to superheated water or saturated steam or other appropriate treatments. Aseptic holding tanks and fillers may be commercially sterilized separately from the rest of the equipment in the system, however, these commercial sterilization cycles preferably should be conducted simultaneously. Temperatures reached during the commercial 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 part) of the system. While for most systems, especially when superheated water is used, the coldest part is generally found to be in the piping just beyond the valve which interfaces with the filler. Sufficient tests and
temperature measurements should be taken during pre-production commercial sterilization at all critical points to ensure that the coldest part has been located if that is the only point at which temperature records will be obtained for this procedure. If surge tanks or reservoirs and fillers are commercially sterilized separately, ideal sensor locations must be found. Special attention should be paid to complex valves which are used in reservoirs and flow diversion devices. Commercial sterilization of surge tanks or reservoirs is discussed in subsection 7.6.1.7 and of flow diversion devices in 7.6.1.6.

7.5.2.3.2 Packaging equipment

The "aseptic zone" of filling and sealing equipment must be cleaned and brought to a condition of commercial sterility prior to the initiation of product filling and must be maintained in a condition of commercial sterility for production. It is recommended that this aseptic zone be sterilized as often as is necessary in order not to compromise the sterility of the product being filled.

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. 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 cycle for aseptic zones within packaging equipment should be sufficient to ensure that commercial sterility of the finished product is maintained. Establishing this process should involve adequate challenge testing using appropriate test organisms and methods.

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 Packaging material to be used in aseptic processing is typically sterilized either inside the packaging machine or is sterilized off site and brought and connected or inserted aseptically into the packaging machine or a combination of these. 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 forces such as hydrogen peroxide and heat or U.V. radiation. If the sterilization of packaging material is done completely or partially off site, it is usually done using the heat of extrusion for packaging material or use of some physical treatment such as steam sterilization or irradiation. Whatever method is used, the sterilization process applied to the packaging material should achieve commercial sterility. Establishing this process should involve adequate challenge testing using appropriate test organisms and methods.

1 Advisory section
7.5.2.4.2 Appropriate inspections and tests should be carried out to monitor the sterilization and its maintenance, and records 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 and properly supported.

7.6.1.3 If the scheduled process is controlled by the outlet temperature of a holding section, it should be designed so that no portion of the section between the product inlet and the product outlet from the section can be heated, and 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 section 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 Product feed rate to the system should be constant, reproducible and quantifiable. A means of preventing unauthorized changes in product feed rate must be provided. 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 tube 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 by observing steam discharge of properly located and oriented bleeder ports.

7.6.1.6 If the system is equipped with a flow-diversion device, it should be installed in the product piping located between the product cooler and 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 If aseptic holding tanks are 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 unless designed to operate safely under vacuum. 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.

7.6.1.8 In aseptic systems, product sterilization is typically delivered by maintenance of a temperature generally greater than 110°C (230°F) for a controlled time. Both time and temperature are critical for the scheduled process. In those systems using a holding tube, it is necessary to apply a pressure sufficient to prevent product boiling in the tube in order that both residence time and temperature can be maintained for proper sterilization. It is common practice to maintain this overpressure with a valve, orifice or other device which restricts flow through the 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. 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. (1°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. Recording devices may be combined with the controllers and may be a recording-controlling instrument. Devices should respond to temperature changes to sufficiently ensure that the delivery
of the scheduled process temperature 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 $12^\circ C$ per cm ($55^\circ F$ per inch) within a range of $10^\circ C$ ($20^\circ F$) of the sterilizing temperature. The recorder accuracy should be equal to or better than $\pm 0.5^\circ C$ ($1^\circ F$) at the sterilizing temperature. The recorder(s) should agree as closely as possible (preferably within $0.5^\circ C$ ($1^\circ F$)) 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 holding 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 holding 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 holding 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 holding tubes, no probe should be located past the point where the upward slope of the tube falls to less than $2$ cm per meter ($0.25$ inch per foot) of piping.

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 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 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, upon installation and at least once every three months of
operation thereafter or more frequently as may be necessary to ensure its accuracy. 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(s) should be used either to give the retention time of containers, and closures, if applicable, as specified in the scheduled process, or to control the sterilization cycle at the rate as specified in the scheduled process. A means of preventing unauthorized speed changes should be provided.

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 emitting steam;
(b) Proper preproduction sterilization with water and/or other medium has been conducted;
(c) Temperatures are correct in the holding 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/cm² (one psig) 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, strained bath levels, strained concentration, strained 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 and closing.

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

7.7.2 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 then 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 holding section

When product temperature in the holding 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/cm² (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. 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 containing no particulates

Permanent and legibly dated records of each formulation should be retained, as well as pH, consistency and any other factor that might influence the thermal processing of the product. 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. This increase in product volume should be compensated for by the process authority in the establishment of the process.

The following required readings should be recorded:

(a) Temperature indicating device(s) at the hold tube outlet;
(b) Temperature recorder at holding tube outlet;
(c) Temperature recorder at the final heater outlet (entering the hold tube);
(d) Differential pressure recorder, if a product-to-product regeneration is used;
(e) Back pressure recording, if a back pressure monitoring system is used;
(f) Product flow rate (in litres 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 pH, water activity or other factors of each batch of product (if critical to the process)
(l) The code mark of the containers;
(m) Records of each diversion;
(n) Cleaning and resterilization records for the system following diversion.

8.1.2 Commercial sterility processing of particulate foods

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

Container closure examination records not to exceed 30 minute intervals should be kept. Destructive testing of containers should be done immediately following a jam in a closure machine, after adjustment of closure machines or after starting machines following a prolonged shutdown. All seals and seams should be visually examined for product leakage. All pertinent observations should be recorded. Teardown and inspection of cans should be conducted as in 7.4.8.1.2 of the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods CAC/RCP 23-1979: Rev.1 (1989).
8.1.4 Metal cans or rigid container/sterilization systems employing superheated steam

The coolest temperature in the superheated steam tunnel should be recorded along with the time the cans are in the tunnel. 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 cans 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. In addition, the records in Sub-section 7.4.9.1 should be kept.

8.1.5 Plastic can systems

If round plastic cans are used with double seamed metal ends, records of the amount of chemical strained and concentration or other sterilization medium used should be kept, along with the temperature and retention time for presterilization, of both the plastic cans and metal lids. The records in Sub-Section 7.4.9.1 should also be kept.

8.1.6 Hydrogen peroxide sterilization

Packaging systems which utilize hydrogen peroxide 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 factors identified by the process authority as critical.

Proper functioning of atomizers, nozzles, etc., should be verified. If hydrogen peroxide or other chemical sterilants are used, the processor should assure that the strained 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.

8.1.7 Combination Hydrogen peroxide and ultra-violet sterilization systems

In addition to the records in 8.1.3 and 8.1.6, records should be kept of the control and strength of the ultraviolet treatment for container sterilization.

8.1.8 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, shall be maintained by the vendor and supplied to the user to become part of the processors records to be maintained with that batch. Lots of packaging material must be coded such that the
sterilization process delivered to a specific lot of packaging material can be traced
to a finished lot of food product. Processes established for sterilization of 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 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 initialled 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 initialled 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 initialled 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 should be maintained identifying initial distribution of finished product to facilitate, if necessary, the segregation of specific food lots that may have been contaminated or otherwise unfit for their intended use.

8.3 Retention of Records

The records specified in 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. 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. 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 container corrosion.

10. **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 of 10 days at 35°C ± 2.8°C (95°F ± 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, initialled, and passed to management for final signature. These records should be retained.

11. **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.
PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED UNRIPENED CHEESE AND RIPENED SOFT CHEESE
(At Step 3 of the Procedure)

Table of Contents

1. Scope
2. Definitions
3. Hygiene Requirements in the Milk Production Area
4. Establishment: Design and Facilities
5. Establishment: Hygiene Requirements
6. Personnel: Hygiene and Health Requirements
7. Establishment: Hygienic Processing Requirements
8. End-Product (Fresh and Soft Cheeses) Specifications
9. Microbiological Criteria for Fresh and Soft Cheeses

Appendix - HACCP: An Outline of the System and its Application
PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR UNCURED UNRIpenED CHEESE AND RIPENED SOFT CHEESE
(At Step 3 of the Procedure)

This Code of Hygienic Practice is of an advisory nature. The microbiological specifications attached to it are also of an advisory nature in accordance with the General Principles for the Establishment and Application of Microbiological Criteria for Foods (Ref. Codex Alimentarius Vol. I). The specifications should not be regarded as mandatory but are intended to enhance assurance that the provisions related to hygienic practice and food safety have been met.

1. SCOPE

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

It recommends general hygiene and technological practices to ensure safe and wholesome products (incorporating production, curing or ripening, processing, packaging, storage, transport and distribution).

It is strongly recommended that the Hazard Analysis Critical Control Point (HACCP) principles are applied to the food handling. A brief explanation and an example are given in Appendix.

It should be emphasized that is by way of an example only.

It is emphasized too, that, for successful application of the HACCP principles in the implementation of 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.

2. DEFINITIONS

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

2.1 Uncured Unripened Cheeses

Uncured unripened cheeses are cheeses which comply with the definition in Section 2 of Standard A6 and which are ready for consumption shortly after manufacture. For milk or milk ingredients used for the manufacture of "fresh" cheeses, pasteurization at minimum 72°C for 15 s. or equivalent (2.10 - Pasteurization) is obligatory.

2.2 Ripened Soft Cheeses

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

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.

2.6 Disinfection

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

2.7 Establishment

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

2.8 Food Handling

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

2.9 Pasteurization and Pasteurized Product

2.9.1 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 harmful microorganisms to a level at which they do not constitute a significant health hazard. Pasteurization also extends the keeping quality of some products by reducing the number of spoilage microorganisms in the product.

2.9.2 Pasteurized product

A pasteurized product is milk or a fluid milk product in accordance with Article 2 of the Code of Principles, which has been subjected to pasteurization, which, if retailed as such, has been cooled without delay and has then been packaged with minimum delay under conditions which minimize contamination. The product must give a negative phosphatase test immediately after heat treatment.

NOTE:

(a) A pasteurized product as defined is one which has been pasteurized as such as distinct from a product manufactured from milk, skimmed milk and/or cream which has been pasteurized.

(b) A negative phosphatase test is considered to be equivalent to less than 2.2 microgrammes of phenol liberated by 1 ml of sample (IDF Standard 63: 1971) or less than 10 microgrammes of p. nitrophenol liberated by 1 ml of sample (IDF Provisional Standard 82: 1978).

2.10 End-Product

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

2.11 Pests

Insects, rodents and birds.
3. HYGIENE REQUIREMENTS IN THE MILK PRODUCTION AREA

Hygienic considerations concerning milk production are not covered in this Code. For raw milk and milk products requirements see Section 7 of this Code.

4. ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

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

4.2 Roadways and Yards

Roadways and yards serving the establishment and 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. Pest harbourage should be minimized.

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 effective supervision of food hygiene.

4.3.4 The buildings and 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 and facilities should be designed to provide separation, by partition, location or other effective means, between operations in which cross-contamination should be avoided.

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

4.3.7 In food handling areas:

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

- Walls, where appropriate, should be of water-proof, non-absorbent, washable and non-toxic materials and should be light coloured. Up to a height appropriate for the operation they should be smooth and without crevices, and should be easy to clean and disinfect.

- Ceilings, should be so design, 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. 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.

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

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

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

4.3.11 The use of material which cannot be adequately cleaned and disinfected, such as wood, should be avoided.

4.4 Sanitary Facilities

4.4.1 Water supply

4.4.1.1 An ample supply of water in compliance with Section 7.3 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 the latest edition of "International Standards of Drinking Water" (WHO).

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 backspihonage 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 substances 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. Adequate refrigeration of these 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, microorganisms, insects, odours and all other contamination. Circulation of air in areas in which raw milk or ingredients are handled should be maintained separately from air circulated in areas in which fresh or soft cheese is produced, ripened or cured, processed or packaged. No water must condense in the air pressure lines.

4.4.5 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. Dispersion of droplets during effluent disposal should be avoided.

4.4.6 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. They should not open directly on to food handling areas. Hand washing facilities with 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 hands after using the toilet.

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 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 non-hand operable type are desirable. The facilities should be furnished with properly trapped waste pipes leading to drains.

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 (30 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 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, building or roadways. Containers used for waste or inedible materials should be used exclusively for that purpose and should be clearly marked or colour coded.

4.5 Equipment and Utensils

4.5.1 Materials

All equipment and utensils used in food handling areas and which may contact food should be made of material which does 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. 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.

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

4.5.2.3 The equipment for heat treating or pasteurizing milk and 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.

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 on the completion of the holding section of the heating or pasteurizing process.

4.5.2.5 Facilities for the convenient withdrawal of samples for the purpose of control of effective pasteurizing of heat-treatment should be provided where necessary.

4.5.2.6 All refrigerated spaces including curing rooms should be equipped with temperature measurement or recording devices.
4.5.3 Thermometers and 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 adequate intervals to ensure effective operation.

4.5.4 Equipment identification

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

5. 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, vapour and needless water. Storage rooms should be kept dry.

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

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 Annex 1 to the Recommended Code of Practice - Revised General Principles and Food Hygiene.

5.2.2 To prevent contamination of food, all equipment and utensils should be cleaned as frequently as necessary 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 first 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 normally be disinfected immediately before use, by physical or chemical agents as appropriate to the equipment and the nature of the food. Where chemical agents are used, the equipment should be drained and then rinsed with water that is in compliance with Section 7.3 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 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 food should be removed by thorough rinsing with water in compliance with Section 7.3 of this Code before the area or equipment is again used for handling foods.

5.2.7 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.

5.2.8 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. 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 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.

5.5 **Exclusion of Domestic Animals**

Animals should be excluded from establishments.

5.6 **Pest Control**

5.6.1 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. Records of pest control programmes should be maintained.

5.6.2 Should pests gain entrance to the establishment, eradication measures 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 have a thorough understanding of the potential hazards to health resulting from the use of these agents, particularly 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.

5.6.3 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, equipment and utensils from contamination. After application, contaminated equipment and utensils should be thoroughly cleaned to remove residues prior to being used again.

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, 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.

5.7.2 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 and Clothing**

Personal effects and clothing should not be deposited in processing areas. Appropriate storage facilities should be provided.
6. PERSONNEL: HYGIENE AND 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 food handler 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 with a suitable hand cleaning preparation under running warm water in compliance with Section 7.3 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 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 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 nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor. During periods when food is manipulated by hand, any jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in food handling.

6.7 Personal Behaviour

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

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

6.9 Visitors

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 Sections 5.8, 6.7 and 6.8 of this Code.

6.10 Supervision

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

7. ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

7.1.1 All milk and 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.

7.1.2 No milk or milk products which have been contaminated should be accepted for processing.

7.1.3 No milk or milk products should be accepted by an establishment unless they have 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.

7.1.4 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.

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

7.1.6 Raw milk and 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 properly rotated.

7.2 Prevention of Cross-Contamination

7.2.1 Effective measures should be taken to prevent contamination of pasteurized milk and milk constituents or other ingredients by direct or indirect contact with contaminants at an earlier stage of the process. Particular attention should be paid to contamination via air circulation.

7.2.2 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.

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

7.2.4 All equipment which has been in contact with raw milk or milk products or contaminants should be thoroughly cleaned and disinfected before reuse.
7.2.5 Packaging materials should be stored and handled to prevent contamination.

7.3 Use of Water

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

7.3.2 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.

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

7.4 Processing

7.4.1 Processing should be supervised by technically competent personnel.

7.4.2 All processing steps should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination or deterioration.

7.4.3 After inspection and testing, incoming milk or liquid milk products should be pasteurized directly or, if this is not possible, cooled to and held until pasteurized at a temperature sufficiently low (5°C or less) to prevent significant microbial growth. Milk which is in cans should be transferred to bulk holding tanks and cooled without delay.

7.4.4 A continuous chart recording should be made of all heat treatment of pasteurization steps, and these charts should be dated, marked to indicate the ingredient pasteurized and kept available for inspection for a period that exceeds the shelf-life of the cheese, but unless a specific need exists they need not be kept for more than 2 years.

7.4.5 Cheese making operations shall be conducted by personnel skilled in the science and art of cheese making. Appropriate tests should be conducted to affirm that the lactic acid fermentation process is normal and all key product characteristics are within specification. Adequate records should be compiled for each vat or lot which include times, temperatures, ingredients used, pH or acidity determinations, etc.

7.4.6 Cheese being cured or ripened should be examined and tested appropriately to affirm that the cheese is free from abnormal characteristics and that the environment is free from contamination.

7.4.7 When breakdowns or unplanned discontinuities in processing occur which disrupt the normal flow of the food, the food implicated should not be released for human consumption unless it is of acceptable hygienic quality. Re-processing, diversion to non-human use or additional testing may be required.

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 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.
7.5.2 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 moisture and temperature controlled.

7.5.3 Packaging personnel should be instructed in Good Manufacturing Practices including high standards of personal hygiene. They should wear clean uniforms, gloves, etc. to minimize end-product contamination.

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

7.5.5 Lot identification

Each container should be permanently marked in code or in clear 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 particular time interval, and usually from a particular "line" or other processing unit.

7.5.6 Processing and production 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 the shelf-life of the food, but unless a specific need exists they need not be kept for more than 2 years. Records should also be kept of the initial distribution by lot.

7.6 Storage and Transportation of the End-Product (Fresh and Soft Cheeses)

7.6.1 The end-product should be stored and transported under such conditions as will preclude contamination with and/or proliferation of microorganisms and product against deterioration of the product or damage to the container.

7.6.2 During storage, periodic inspection of the end-product should take place to ensure that only food which is free from contamination and in compliance with end-product specifications is despatched. The product should be despatched in the sequence of lot numbers.

7.7 Sampling and Laboratory Control Procedures

7.7.1 The establishment should have access to adequate laboratory facilities to carry out routine testing needed to effect continuous control of all operations.

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

7.7.3 The following should be monitored:

(i) Incoming milk and milk products
(ii) Other ingredients
(iii) Packaging materials
(iv) Calibration of instruments, for example, gauges, thermometers, etc.
(v) Processing and manufacturing stages, including pasteurization
(vi) Cleaning and disinfection in the plant
(vii) End-products (fresh and soft cheeses)
(viii) Water quality
(ix) Air quality
(x) Steam quality
(xi) Microbiological monitoring of the environment within and immediately outside the plant
(xii) Pest control programmes.

7.7.4 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.
7.7.5 The performance of tests for pathogenic microorganisms in the establishment should be avoided. Such testing should be done within the confines of the establishment only when adequate precautions have been taken to ensure that no contamination of the ingredients or end-product arising from the laboratory is possible.

7.7.6 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.

7.7.7 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 2 years. It would also be appropriate to retain the records of examinations 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.

7.7.8 The person in charge of hygiene control should have authority commensurate with the responsibilities associated with planning, coordinating, executing and maintaining the establishment hygiene control programme and he/she should have a thorough understanding of the significance of contamination and the hazards involved.

8. END-PRODUCT (FRESH AND SOFT CHEESES) SPECIFICATIONS

Standard methods should be used for sampling and testing to determine compliance with the following specifications:

8.1 To the extent attainable with good manufacturing practice, cheeses should be free from contamination which is esthetically objectionable.

8.2 When examined by appropriate methods of sampling and testing the cheeses should, (i) be free from physical, chemical and microbial contaminants in amounts which may represent a hazard to health, and (ii) not exceed any tolerance levels or criteria established by the official agency having jurisdiction.

8.3 Microbiological Criteria

Fresh and soft cheeses should comply with the microbiological criteria in Section 9 of this Code.

9. MICROBIOLOGICAL CRITERIA FOR FRESH AND SOFT CHEESES

The microbiological criteria for fresh and soft cheeses contain:

(a) A microbiological end-product specification

It is intended to increase assurance that the provisions of hygienic significance in the Code have been met. It may include microorganisms which are not of direct public health significance.

(b) A microbiological guideline

It is applied at the establishment at a specific point during or after processing to monitor hygiene. It is intended to guide the manufacturer and is not intended for official control purposes.

(1) Sampling plans

(a) Selection of samples from a lot 1/ should be based on a statistically valid sampling plan. Refer to method Section 9.2(3) of this Code.

1/ See Section 7.5.5 - Lot identification, of this Code.
For microbiological tests, sampling should utilize aseptic procedures. Refer to method Section 9.2(3) of this Code.

Each sample taken should comprise 50 to 100 grammes of end-product.

Each (sample) container shall be permanently marked in code or in clear 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 particular time interval, and usually from a particular "line" or other processing unit.

(2) Microbial limits

Microbial tests on end-products (fresh and soft cheeses) reveal the kind(s) and number(s) of organisms present. Tests may be conducted for specific pathogens, spoilage organisms, and organisms that indicate that pathogens may be present. Microbial limits are set for end-products to assure shelf-life and reduce hazards to health.

The tables which follow utilize the following symbols:

- **n** = number of samples to be tested
- **c** = maximum number of samples in which the number of organisms exceeded "m"
- **m** = maximum number of test organisms allowable in "c" samples
- **M** = maximum number of test organisms in any sample

### 9.1 Microbiological End-Product Specifications for Fresh and Soft Cheese Made from Heat Treated Milk

#### 1. Fresh cheese

<table>
<thead>
<tr>
<th>Organism</th>
<th>n</th>
<th>m</th>
<th>M</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>n = 5, m = 100, M = 1000, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coliforms</td>
<td>n = 5, m = 100, M = 1000, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. coli</td>
<td>n = 5, m = 10, M = 100, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmonella</td>
<td>n = 5, m = 0, c = 0 (25 g)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yeasts</td>
<td>n = 5, m = 1000, M = 10000, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moulds</td>
<td>n = 5, m = 100, M = 1000, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 2. Soft cheese

<table>
<thead>
<tr>
<th>Organism</th>
<th>n</th>
<th>m</th>
<th>M</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>n = 5, m = 100, M = 1000, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. coli</td>
<td>n = 5, m = 100, M = 1000, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmonella</td>
<td>n = 5, m = 0, c = 0 (25 g)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 9.2 Microbiological End-Product Specifications for Soft Cheese Made from Raw Milk

<table>
<thead>
<tr>
<th>Organism</th>
<th>n</th>
<th>m</th>
<th>M</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>n = 5, m = 100, M = 1000, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coliforms</td>
<td>n = 5, m = 1000, M = 10000, c = 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(E. coli</td>
<td>n = 5, m = 100, M = 1000, c = 2)*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmonella</td>
<td>n = 5, m = 0, c = 0 (25 g)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* To be reviewed with experience following application of the Code of Practice.

### 9.3 Microbiological Guidelines for Fresh and Soft Cheese Made from Heat Treated Milk and Soft Cheese Made from Raw Milk

<table>
<thead>
<tr>
<th>Organism</th>
<th>n</th>
<th>m</th>
<th>c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listeria monocytogenes</td>
<td>n = 5, m = 0, c = 0 (25 g samples tested separately)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The manufacturer should define his own statistical sampling plan for microbiological purposes and establish limits that will ensure that limits in microbiological end-product specifications will be consistently achieved.
Special consideration should be given to monitoring the establishment's ingredients, food contact surfaces, air, water, cleaning and sanitizing efficiency and end-product samples for coliform species, and yeasts and moulds as indicator micro-organism for the presence of pathogens and spoilage organisms.

Consideration should also be given to process steps in which Staphylococcus aureus can proliferate. S. aureus may be monitored by either monitoring for the organisms or thermonuclease.

Consideration should be given to pathogenic microorganisms that may be inherent in fresh and soft cheeses, particularly sampling and testing at whatever frequency is necessary to assure the end-product does not pose a threat to public health. Such organisms may include Salmonella, pathogenic Listeria, etc.

Reference Methods:


(b) IDF Standard 135: 1986 - Milk and Milk Products - Sampling - Inspection by Variables.

(c) IDF Standard 50B: 1985 - Milk and Milk Products - Methods of Sampling.

   (i) for groups of microorganisms;
   (ii) for specific indicator organisms;
   (iii) for specific pathogens;
   (iv) for residual and microbial phosphatase.

***

APPENDIX

HACCP: AN OUTLINE OF THE SYSTEM AND ITS APPLICATION

The Hazard Analysis Critical Control Points system is a preventative system of control which is based on applying an organized approach to food processes, and which may also be applied to products. The main focus of control is that of microbiological safety, so that a risk of food poisoning is kept to a minimum, but it should also be applied to the microbiological quality of a food and its processing, so that spoilage is also minimized.

Terms used in the application of HACCP:

Hazard: is the potential to cause harm to the consumer (the safety aspect) or the product (the spoilage aspect), and is present at any stage of the process where unacceptable microbiological contamination may occur, or where growth of unwanted microbes may occur.

Risk: is the probability that a hazard will, in fact, happen. Risk may be quantified, but this is not generally feasible for most food processing. However, risk may be ranked as low, medium or high, based on judgement or experience.

Concern: relates to the seriousness which would result from any failure to achieve control of the process, and is derived from the knowledge of the effect of a hazard not being controlled.

Critical Control Points: are those points in the process which, if controlled, minimize or prevent a hazard.
It should be emphasized that even when a hazard has been identified and the risk ranked or quantified, the time when that hazard will happen cannot be predicted. A low risk can happen at any time, and if associated with a high concern, that is a life threatening effect on consumers, must be addressed with the same care as any risk which is found in the process.

The two aspects of the HACCP system, namely Hazard Analysis of the process or product and identification of the Critical Control Points may be achieved by the following steps or stages:

1. Identifying the hazards, and assessing the severity of such hazards and their risks.
2. Determining the Critical Control Points (CCP's) at which the identified hazards may be controlled. A CCP can be either a location, practice, procedure or process where control can be exercised.
3. Specification of criteria that show that an operation is under control at any given CCP. 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.
4. Establishing and implementing the procedures used to monitor each CCP to check that it is under control.
5. Taking appropriate action when the monitoring results show that a CCP is not under control.
6. Verifying, by use of supplementary information, that the HACCP is working.

It must be emphasized that HACCP must be applied to the environment in which plant is sited and in which product is manufactured. Each factory, or part of a factory, will present its own particular hazards, and therefore the critical control points, and the specific controls to be applied at these points, cannot be given here. However, there must be a systematic identification of hazards and control points, and effective controls must be carried out, using the 6 steps given above as a guide.

The same attention must be given to plant, and to the cleaning given to the plant, whether it is CIP or manual or a combination of both. It is well known that improperly cleaned, or maintained, plant causes the majority of spoilage problems to processed foods, and must be systematically analysed to minimize such problems.

**HACCP Applied to Mould Ripened Soft Cheese as an Example of Process Analysis (See Flow Diagram)**

The **main hazards** are:

(i) Raw milk contaminated with pathogens.
(ii) Process area environment and services contaminated with pathogens.

The **main risks** are:

(a) That milk not correctly pasteurized will still contain pathogens.
(b) That pathogens contaminating the process area and equipment will recontaminate product during handling.

The **main concern** is that pathogens will cause illness in customers who consume the cheese.

**Secondary hazards** are:

(i) That raw milk may be of poor hygienic quality and that this might affect the efficiency of fermentation;
(ii) that fermentation may be impaired by milk contaminants or bacteriophage and this will prevent correct acid development;

(iii) that brining will be to an incorrect level and this will affect subsequent ripening of the cheese;

(iv) that ripening conditions will not allow correct maturation of the cheese. This will include prickling of the cheese where appropriate;

(v) that packing, storage and distribution conditions will be such that cheese quality deteriorates. This might include excessive growth of pathogens, if present.

N.B.: Any of the secondary hazards could have a contributory effect on the survival and/or development of pathogens in the cheese should the hazards not be properly controlled.

Application:

With the aid of a process flow diagram, which is specific to the factory and process under investigation, all hazards should be identified and risks assessed.

From this assessment Critical Control Points (CCP.1 or CCP.2) may be identified and appropriate process controls introduced to assure that the process is operated to minimize risks.

Critical Control Point monitors will include, for example:

(a) Quality control tests and records to assure that pasteurization is correctly carried out.

(b) Schedules of cleaning for process area and equipment with suitable monitoring to assure absence of pathogens (or spoilage organisms) as well as suitable monitors for other CCP's identified.

**PROCESS FLOW DIAGRAM**

*(Mould Ripened Soft Cheese as an Example)*

```
( Raw Milk Reception CCP 2
( Pasteurization CCP 1
( Renneting
( Fermentation CCP 2
( Brining CCP 2
( Prickling CCP 2
( Ripening CCP 2
( Packing and Distribution
```

CCP 1 = Effective control point.

CCP 2 = Not absolute control point.

Ref.: ICMSF Microorganisms in Foods 4 - The Application of the Hazard Analysis Critical Control Point (HACCP) system to ensure microbiological safety and quality.
GUIDELINES FOR THE PRESERVATION OF RAW MILK
BY USE OF THE LACTOPEROXIDASE SYSTEM
(At Step 5 of the Procedure)

Table of Contents

Introduction

1. Scope
2. Principles of the Method
3. Intended Utilization of Method
4. Practical Application of the Method
5. Control of Usage

Appendix I - Technical Specification of Sodium Thiocyanate
Appendix II - Technical Specification of Sodium Percarbonate
Appendix III - Analysis of Thiocyanate in Milk
INTRODUCTION

Milk is an easily perishable raw material. Contaminating bacteria may multiply rapidly and render it unsuitable for processing and/or unfit for human consumption. Bacterial growth can be retarded by refrigeration, thereby slowing down the rate of deterioration. Under certain conditions refrigeration may not be feasible due to economical and/or technical reasons. Difficulties in applying refrigeration are specially a problem for certain areas in countries setting up or expanding their milk production. In these situations, it would be beneficial to have access to a method, other than refrigeration, for retarding bacterial growth in raw milk during collection and transportation to the dairy processing plant.

In 1967 the FAO/WHO Expert Panel on Milk Quality concluded that the use of hydrogen peroxide might be an acceptable alternative in the early stages of development of an organized dairy industry, provided that certain conditions were complied with. However, this method has not achieved any general acceptance as it has several drawbacks, most important of which is the difficulty of controlling its use: it may be misused to disguise milk of inferior basic hygienic quality produced under poor hygienic conditions. The toxicological aspects of the use of relatively high concentrations of hydrogen peroxide in milk have also been questioned.

A chemical method for preserving milk would still be of great advantage in certain situations. The search for such a method has therefore continued. Interest has recently been focused on the indigenous antibacterial systems in milk to determine if these could be applied practically to preserve raw milk. During the last decade, basic and applied research has demonstrated that one of these systems, the lactoperoxidase/thiocyanate/hydrogen peroxide system (LP-system) can be used successfully for this purpose.

1. SCOPE

This Code of Practice describes the use of the lactoperoxidase system for preventing bacterial spoilage of raw milk (bovine and buffalo) during collection and transportation to a dairy processing plant. It describes the principles of the method, in what situations it can be used, its practical application and control of the method. It should be stressed that this method should only be utilized when refrigeration of the raw milk is not feasible.

2. PRINCIPLES OF THE METHOD

The lactoperoxidase/thiocyanate/hydrogen peroxide system is an indigenous antibacterial system present in milk and human saliva. The enzyme lactoperoxidase is present in bovine and buffalo milk in relatively high concentrations. It can oxidize thiocyanate ions in the presence of hydrogen peroxide. By this reaction, thiocyanate is converted into hypothiocyanous acid (HOSCN). At the pH of milk HOSCN is dissociated and exists mainly in the form of hypothiocyanide ions (OSCN⁻). This agent reacts specifically with free sulphydryl groups, thereby inactivating several vital metabolic bacterial enzymes, consequently blocking their metabolism and ability to multiply. As milk proteins contain very few sulphydryl groups and those that are present are relatively inaccessible to OSCN⁻ (masked), the reaction of this compound is in milk quite specific and is directed against the bacteria present in the milk.

The effect against bacteria is both species and strain dependent. Against a mixed raw milk flora, dominated by mesophilic bacteria, the effect is bacteriostatic (predominantly inhibitory). Against some gram-negative bacteria, i.e. pseudomonads, Escherichia coli, the effect is bactericidal. Due to the mainly bacteriostatic effect of the system it is not possible to disguise poor quality milk, which originally contained a high bacterial population, by applying this method.
The antibacterial oxidation products of thiocyanate are not stable at neutral pH. Any surplus of these decomposes spontaneously to thiocyanate. The velocity of this reaction is temperature dependent, i.e. more rapid at higher temperatures. Pasteurization of the milk will ensure a complete removal of any residual concentrations of the active oxidation products.

Oxidation of thiocyanate does not occur to any great extent in milk when it has left the udder. It can, however, be initiated through addition of small concentrations of hydrogen peroxide (see Section IV). The high concentrations of hydrogen peroxide used to preserve milk (300-800 ppm), destroy the enzyme lactoperoxidase and thereby preclude the oxidation of thiocyanate. With this method the antibacterial effect is thus an effect of hydrogen peroxide itself.

The antibacterial effect of the LP-system is, within certain limits, proportional to the thiocyanate concentration in the milk (provided that an equimolar amount of hydrogen peroxide is provided). The level of thiocyanate in milk is related to the feeding of the animals and can thus vary. The practical use of the method consequently requires addition of some thiocyanate to ensure that a level necessary to achieve the desired effect, is present in the milk.

The levels of thiocyanate resulting from this treatment are within the physiological levels reported to occur in milk under certain circumstances and feeding regimes. They are also far below the thiocyanate levels known to exist in human saliva and certain common vegetables, e.g. cabbage and cauliflower. In addition, results from clinical experiments have clearly demonstrated that milk treated according to this method will not cause any interference of the iodine uptake of the thyroid gland, neither in persons with a normal iodine status nor in cases of iodine deficiency.

3. **INTENDED UTILIZATION OF METHOD**

3.1 This method should only be used in situations when technical, economical and/or practical reasons do not allow the use of cooling facilities for maintaining the quality of raw milk. Use of the LP-system in areas which currently lack an adequate infrastructure for collection of liquid milk, would ensure the production of milk as a safe and wholesome food, which otherwise would be virtually impossible.

3.2 The method should not be used by the individual farmers but at a suitable collecting point/centre. These centres must be equipped with proper facilities for cleaning and sanitizing the vessels used to hold and transport milk.

3.3 The personnel responsible for the collection of milk should be in charge for the treatment of the milk. They should be given appropriate training, including training in general milk hygiene, to enable them to fulfill this in a correct way.

3.4 The dairy processing the milk collected by use of the lactoperoxidase system should be made responsible for ensuring that the method is used as intended. This dairy should set up appropriate control methods (see Section V) to monitor usage of the method, raw milk quality and quality of the milk prior to processing.

3.5 The method should primarily be used to prevent undue bacterial multiplication in raw milk during collection and transportation to the dairy processing plant under conditions stated in 3.1. The inhibitory effect of the treatment is dependent on the temperature of the stored milk and has been found to act for the following periods of time in laboratory and field-experiments carried out in different countries with raw milk of an initial good hygienic standard:

<table>
<thead>
<tr>
<th>Temperature, °C</th>
<th>Time, hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>7-8</td>
</tr>
<tr>
<td>25</td>
<td>11-12</td>
</tr>
<tr>
<td>20</td>
<td>16-17</td>
</tr>
<tr>
<td>15</td>
<td>24-26</td>
</tr>
</tbody>
</table>
3.6 The use of the lactoperoxidase method does not exclude the necessity of pasteurization of the milk before human consumption. Neither does it exclude the normal precautions and handling routines applied to ensure a high hygienic standard of the raw milk.

4. **PRACTICAL APPLICATION OF THE METHOD**

4.1 The lactoperoxidase system can be activated in raw milk to give the above stated antibacterial effect by an addition of thiocyanate as sodium thiocyanate and hydrogen peroxide in the form of sodium percarbonate by the following procedure:

14 mg of NaSCN is added per litre of milk. The milk should then be mixed to ensure an even distribution of the SCN⁻. Plunging for about 1 minute with a clean plunger is normally satisfactory.

Secondly, 30 mg of sodium percarbonate is added per litre of milk. The milk is then stirred for another 2-3 minutes to ensure that the sodium percarbonate is completely dissolved and the hydrogen peroxide is evenly distributed in the milk.

4.2 It is essential that the sodium thiocyanate and sodium percarbonate are added in the order stated above. The enzymatic reaction is started in the milk when the hydrogen peroxide (sodium percarbonate) is added. It is completed within about 5 minutes from the addition of $\text{H}_2\text{O}_2$; thereafter, no hydrogen peroxide is present in the milk.

4.3 The activation of the lactoperoxidase system should be carried out within 2-3 hours from the time of milking.

4.4 Quantities of sodium thiocyanate and sodium percarbonate needed for the treatment of a certain volume of milk, for example 40 or 50 litre milk churns, should be distributed to the collecting centre/point in prepacked amounts lasting for a few weeks at a time. The technical specifications of the thiocyanate and sodium percarbonate which should be used are stated in Appendix I and II.

5. **CONTROL OF USAGE**

The use of the lactoperoxidase system for preserving raw milk must be controlled by the dairy processing plant receiving the milk. This should be a combination of currently used acceptance tests, e.g. titratable acidity, methylene blue, resazurin, total viable count, and analyses of the thiocyanate concentration in the milk. Since the thiocyanate is not consumed in the reaction, treated milk arriving at the dairy plant would contain approximately 10 mg above the natural amount of thiocyanate (the latter can be determined by analysing untreated milk from the same area) per litre of milk. The analytical method for SCN⁻ is described in Appendix 3. Testing should be undertaken at random. If the concentration of thiocyanate is too high (or too low), investigation must be carried out to determine why the concentration is outside specification. The dairy processing plant should also be responsible for the control of the chemicals to be used at the collection centre for the activation of the lactoperoxidase system.

Analysis of the bacteriological quality of the milk (methylene blue, resazurin, total plate count) should also be carried out to ensure that good hygienic standards are not neglected. Since the effects of the system are predominantly bacteriostatic, an initial high bacterial population in the milk can still be revealed by such tests.
Appendix I

TECHNICAL SPECIFICATION OF SODIUM THIOCYANATE

Definition

Chemical name: Sodium thiocyanate
Chemical formula: NaSCN
Molecular weight: 81.1
Assay content: 98-99%
Humidity: 1-2%

Purity (according to JECFA* specification)

- Heavy metals (as Pb) < 2 ppm
- Sulphates (SO₄) < 50 ppm
- Sulphide (S) < 10 ppm

* Joint FAO/WHO Expert Committee on Food Additives.

Appendix II

TECHNICAL SPECIFICATION OF SODIUM PERCARBONATE

Definition

Chemical name: Sodium percarbonate (*)
Chemical formula: 2Na₂CO₃·3H₂O₂
Molecular weight: 314.0
Assay content: 85%

Commercially available sodium percarbonate recommended to be used has the following specification:

- Sodium carbonate peroxyhydrate > 85%
- Heavy metals (as Pb) < 10 ppm
- Arsenic (as As) < 3 ppm

(*) For information where sodium percarbonate could be obtained commercially, please apply to IDF General Secretariat, 41 Square Vergote, B-1040 Brussels, Belgium.

Appendix III

ANALYSIS OF THIOCYANATE IN MILK

Principle

Thiocyanate can be determined in milk, after deproteinisation with trichloracetic acid (TCA), as the ferric complex by measuring the absorbance at 460 nm. The minimum level of detection by this method is 1 to 2 ppm of SCN⁻.

Reagent Solutions

1. 20% (w/v) trichloracetic acid: 20 g TCA is dissolved in 100 ml of distilled water and filtered.

2. Ferric nitrate reagent: 16.0 g Fe(NO₃)₃·9H₂O is dissolved in 50 ml 2 M HNO₃* and then diluted with distilled water to 100 ml. The solution should be stored dark and cold.

* 2M HNO₃ is obtained by diluting 138.5 ml 65% HNO₃ to 1000 ml with distilled water.
3. **Determination:** 4.0 ml of milk is mixed with 2.0 ml of 20% TCA solution. The mixture is blended well and then allowed to stand for at least 30 minutes. It is thereafter filtered through a suitable filter paper (Whatman No. 40). 1.5 ml of the clear filtrate is then mixed with 1.5 ml of the ferric nitrate reagent and the absorbance measured at 460 nm. As a blank, a mixture of 1.5 ml of ferric nitrate solution and 1.5 ml of water is used. The measurement must be carried out within 10 minutes from the addition of the ferric nitrate solution as the colored complex is not stable for any length of time. The concentration of thiocyanate is then determined by comparison with standard solutions of known thiocyanate concentration, e.g. 10, 15, 20 and 30 mg/ml of thiocyanate.
PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS
(At Step 3 of the Procedure)

Table of Contents

1. Scope
2. Definitions
3. Hygienic Requirements of Raw Spices and Condiments
4. Establishment Design and Facilities
5. Establishment of Hygiene Requirements
6. Personnel Hygiene and Health Requirements
7. Hygienic Processing Requirements
PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND CONDIMENTS

(At Step 3 of the Procedure)

1. SCOPE

This Code of hygienic practice applies to spices and condiments, whole, broken or ground, spice blends or processed spice products. 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, extraction of essential oils and oleoresins, frozen and freeze dried or dehydrated, etc.) packaging and storage of processed products.

2. DEFINITIONS

2.1 Spices and Condiments

The term spices and condiments relates to the natural 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. There are about 86 spices and condiments. These may be arils, barks, berries, bulbs, buds, capsules, floral parts (stigma), fruits and kernels, leaves, roots, seeds and other parts of the aromatic plants.

2.2 Spice Products

2.2.1 Curry powder and spice blends (whole or ground)

Curry powder is the product obtained by mixing and grinding, cleaned, dried and sound selected spices and condiments. The proportion of spices and condiments used in curry powder is not less than 85%. It may also contain not more than 5% (m/m) food grade sodium chloride. It may also contain farinaceous (starchy) matter. The curry powder shall be free from any artificial colouring matter and any other preservative other than common salt.

2.2.2 Spice essential oils - are the volatile aromatic extracts prepared by steam distillation of ground spices.

2.2.3 Spice oleoresins - comprise both the volatile and non-volatile resins present in spices and prepared by solvent extraction of coarsely ground spices using suitable food grade solvents like hexane, ethylene-dichloride, etc.

2.2.4 Other spice products

Other spice products are spice concentrates, spray-dried and encapsulated spices, green pepper in brine (canned, bottled or bulk packed in jerrycan) frozen and freeze dried green pepper, etc.

3. HYGIENIC REQUIREMENTS OF RAW SPICES AND CONDIMENTS

3.1 General

Adequate precautions should be taken during growing, harvesting, handling and drying of spices and condiments etc., so as to avoid any organic or inorganic contamination.

3.2 Curing (Drying)

Spices should be dried on clean concrete floors to a safe moisture level so as to prevent the growth of microorganisms specially mycotoxin producing mould, etc. Excessive heating/drying of material should be avoided in order to retain its aromatic principles. Suitable precautions shall 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 and Grading

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

3.4 Packaging

The cleaned, dried spices and condiments should be packed in suitable hygienic and water-vapour proof containers. Second-hand containers like jute bags, plastic bags, etc., should be cleaned and disinfected properly before re-use. The jute bags should normally be lined with suitable plastic film in order to avoid the ingress of moisture.

3.5 Transportation

The conveyances for transporting the harvested, cleaned, dried and packed spices from the place of production to storage godown for processing should be cleaned and disinfected 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 cooler region or from day to night.

4. ESTABLISHMENT DESIGN AND FACILITIES

4.1 Location

Establishments should 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 for efficient cleaning.

4.3 Building 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 harbouring of pests and the entry of environmental contaminants such as smoke, dust, etc. Suitable ultrasonic rodent control devices should be installed in the building. For elimination of flying insect menace, wherever possible, suitable electrically operated flying insect control devices consisting of electrified grid and a collection tray for collecting dead insects should be provided. These devices may be installed at strategic points in the premises, specially near the entry points.

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.
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, washable and non-toxic material 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.

4.3.7.3 Ceiling - 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 suitable screens to make them fly/insect proof. 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. In addition suitable external screen shutters should also be provided which open outwards.

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. Chutes should be constructed with inspection and cleaning hatches.

4.3.7.7 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.

4.3.8 Residential quarters and toilets - should be completely separated from and should not open directly to handling and processing areas.

4.3.9 Where appropriate, establishments should be so designed that access to various sections can be regulated.

4.3.10 The use of material 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

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. 7 – 1985), 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.

4.4.1.1 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.

4.4.2 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 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 the processing area wherever the process demands. 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 pasted directing personnel to wash their hands after using the toilet. Where appropriate, facilities for hand disinfection should also be provided.

4.4.3.1 Separate conveniences should be provided for each sex.

4.4.4 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.

4.4.5 Lighting

Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colours. Light bulbs and fixtures suspended in the processing area should be of a safety type and protected to prevent contamination of the material in case of breakage.

4.4.6 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. Ventilators should be provided with a screen or other protective enclosure of non-corrodable material. Screens should be easily removable for cleaning.

4.4.7 Facilities for storage of waste and inedible material

4.4.7.1 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 the product, potable water, equipment and buildings or roadways on the premises.

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

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

4.4.7.4 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.

4.5 Equipment and Utensils

4.5.1 Material

All equipment and utensils used in handling areas should be made of material which does not transmit toxic substances, odour 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.

4.5.2 Sanitary design, construction and installation

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.

4.5.3 All refrigerated spaces – should be equipped with temperature measurement and recording devices.

5. ESTABLISHMENT OF HYGIENE REQUIREMENTS

5.1 Maintenance

The buildings, equipment, utensils and all other physical facilities of the establishment, including drains should be maintained in good 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.

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 thorough rinsing with water.

5.2.4 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 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 Pest Control

5.3.1 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.

5.3.2 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.

5.3.3 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.
5.4 Storage of Hazardous Substances

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 contamination.

6. 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. Instructions should include relevant parts of this code.

6.2 Medical Examination

Persons who come in contact with spices 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 it necessary because of epidemiological considerations, the nature of the spices prepared in a particular establishment or the medical history of the prospective handler. Medical examination of a worker 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 material handling area in any capacity in which there is any likelihood of such a person directly or indirectly contaminating material 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

Every person, while on duty in a spice handling area should wash his 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/BCP 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. 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, which should be washable. Aprons and similar items should not be washed on the floor. Where hands are coming in direct contact with spices, any jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any loose and fragile ornament when engaged in spice handling. Personal effects and clothing should not be deposited in the material handling areas.
6.7 **Personal Habits**

Any habit 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**

Gloves, if used, 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 6.7.

6.10 **Supervision**

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

7. **HYGIENIC PROCESSING REQUIREMENTS**

7.1 **Raw Material Requirements**

7.1.1 **Acceptance criteria**

Spices should not be accepted by the plant if known to contain 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. Spices with animal or human faecal material suspected of being contaminated 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 **Storage**

Raw materials stored in the plant premises should be maintained under conditions that will protect 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 storages or at the design stage in new storages 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 Inspection and Sorting

Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials.

7.3 Prevention of Cross-Contamination

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

7.4 Water

7.4.1 As a general principle, only potable water as defined in the latest edition of "International Standards on Drinking Water" (WHO) should be used.

7.4.2 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 spice processing.

7.4.3 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.

7.5 Processing

7.5.1 Processing should be supervised by technically competent personnel.

7.5.2 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.

7.5.3 Rough handling of containers should be avoided to prevent the possibility of contamination of the processed product.

7.6 Packaging

7.6.1 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.

7.6.2 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.

7.6.3 Packing should be done under hygienic conditions to avoid contamination.

7.7 Storage of the End-Product

7.7.1 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.

7.7.2 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.

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

7.7.4 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, these may be removed for fumigation. In this case, the storage areas should separately be cleaned and disinfected.

7.8 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.

7.9 Sampling and Laboratory Control Procedures

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

7.9.2 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.

7.9.3 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 aflatoxin, in amounts which exceed the tolerances or criteria established by the official agency having jurisdiction.

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