codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Via delle Terme di Caracalla 00100 ROME: Tel. 57971 Telex: 610181 FAO I. Cables Foodagri Facsimile: 6799563

ALINORM 89/13

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Eighteenth Session
Geneva, 3-14 July 1989

REPORT OF THE TWENTY-THIRD SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

NOTE: This document incorporates Codex Circular Letter 1988/26-FH

W/Z 3438

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CX 4/20.2

CL 1988/26 FH
June, 1988

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

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

Subject: Distribution of the Report of the Twenty-third Session of the Codex Committee on Food Hygiene (ALINORM 89/13)

PART A: MATTERS OF INTEREST TO THE 18TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

1. Draft Code of Hygienic Practice at Step 8 of the Procedure

The following Code of Practice has been submitted to the 18th Session of the Commission for adoption, at Step 8 of the Procedure.

- Draft Revised Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (paragraph 53 and Appendix IV).

2. Draft Amendments at Step 8 of the Procedure

The following draft amendment to the Code of Hygienic Practice for Dried Milk (CAC/RCP 31-1983) has been submitted to the Commission for adoption at Step 8 of the procedure.

- Definition of Pasteurization (paragraph 70 and Appendix VIII).

3. Governments wishing to propose amendments to the Draft Revised Code of Practice, or to comment on the above Draft Amendment, should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see 6th ed. of the Procedural Manual of the Codex Alimentarius Commission) to the Chief, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy, not later than 28 February 1989.

4. Proposed Draft Codes and Guidelines at Step 5 of the Procedure

The following have been submitted to the 18th Session of the Commission at Step 5 of the Procedure:

- Proposed Draft Code of Hygienic Practice for Pre-Cooked and Cooked Foods in Mass Catering (paragraph 84 and Appendix IX).

- Proposed Draft Guidelines for Salvaging of Canned Foods exposed to Adverse Conditions (paragraph 56 and Appendix V).

5. Without prejudice to any decision to be taken by the Commission at Step 5, comments are invited from Governments and interested international organizations on the above texts. Comments should be sent to the Chairman of the Codex Committee on Food Hygiene, Dr. Douglas Archer, Chairman, Codex Alimentarius Committee on Food Hygiene, c/o Division of Microbiology (HFF-230), U.S. Food and Drug Administration, Washington, D.C. 20204, USA, with a copy to this office, not later than 28 February 1989.

PART B: MATTERS OF INTEREST TO GOVERNMENTS AND INTERESTED INTERNATIONAL ORGANIZATIONS

1. Proposed Draft Codes and Guidelines at Step 3 of the Procedure, and other Texts

Comments are requested on the following:

- Proposed Draft Code of Hygienic Practice for Asceptically Canned Foods, at Step 3 paragraph 63, Appendix VII).

Comments should be sent to the Chairman of the ad hoc Working Group, Dr. G. Jackson, Chief, Food Microbiology Methods, Development Branch (HFF-234), Division of Microbiology, US Food and Drug Administration, Washington, D.C. 20204, USA, with a copy to this office, not later than 30 November 1988.

- Proposed Draft Guideline Procedures to Establish Microbiological Causes of Spoilage in Canned Foods (paragraph 58 and Appendix VI).

Comments should be sent to the Chairman of the ad hoc Working Group on Canned Foods, Dr. B.E. Brown, Chief, Evaluation Division, Bureau of Microbial Hazards, Health Protection Branch, Health and Welfare Canada, Ottawa, Ontario K1A 0L2, Canada, with a copy to this office, not later than 30 November 1988.

- Proposed Draft General Provisions Relating to Food Hygiene (paragraph 29 and Appendix III).

Comments should be sent to the Chairman of the Codex Committee on Food Hygiene, Dr. Douglas Archer, Chairman, Codex Alimentarius Committee on Food Hygiene, c/o Division of Microbiology (HFF-230), US Food and Drug Administration, Washington, D.C. 20204, USA, with a copy to this office, not later than 30 November 1988.

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WORLD HEALTH ORGANIZATION

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ALINORM 89/13

CODEX ALIMENTARIUS COMMISSION

Eighteenth Session

REPORT OF THE TWENTY-THIRD SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

Washington, D.C., 21-25 March 1988

INTRODUCTION

1. The Twenty-Third Session of the Codex Committee on Food Hygiene was held in the Main Conference Room, Department of State, Washington, D.C., from 21 to 25 March 1988 through the courtesy of the Government of the United States of America. Representatives and observers from 30 countries and 6 international organizations were present. The Session was presided over by Dr. Douglas Archer, Director, Division of Microbiology, Food and Drug Administration of the USA and for certain items by C.W. Cooper, Assistant Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration of the USA. A list of participants is attached as Appendix I.

TRIBUTE TO DR. D.L. HOUSTON AND DR. R.W. WEIK

2. The Committee recalled, with sincere appreciation, the contributions made to its work, and to the work of the Codex Alimentarius Commission, by Dr. D.L. Houston, National Codex Coordinator for the USA, and former Administrator, Food Safety Inspection Service USDA, and Dr. R.W. Weik, long-serving delegate to this Committee from the USA and Chairman of the FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products. The Committee expressed its deep sympathy to their families.

OPENING OF THE SESSION

3. Dr. Archer opened the Session and introduced Dr. Robert M. Twedt, Chief, Virulence Assessment Branch, Division of Microbiology, Center for Food Safety and Applied Nutrition, FDA, who addressed the participants on Multiple Aspects of Foodborne Listeriosis. He provided a comprehensive overview of current research and epidemiological studies on the effects of Listeria monocytogenes.

4. The Committee expressed its appreciation for receiving this information. Several delegations drew attention to the need for sampling plans and methodology for the examination of susceptible foods, such as soft cheeses, before end-product specifications for L. monocytogenes could be considered.

5. Noting the work being undertaken by various organizations, the Delegation of Australia proposed that the Codex Committee on Food Hygiene should play a strong role in coordinating efforts related to the control of Listeria in foods in view of its importance to public health and international trade. Several delegations referred to the report of the WHO Expert Group on

Listeriosis which was being published and suggested that the Committee should await the publication of this report and the outcome of other expert meetings on Listeriosis. Other delegations were in favour of the Australian proposal and emphasized the coordinating function of this Committee in all matters relating to food hygiene. The Committee agreed to give further consideration to this matter when discussing its future work (see paras 96-97).

ADOPTION OF THE AGENDA

6. The Committee agreed to adopt the Provisional Agenda (CX/FH 88/1), but to change the order of discussion of the items and to consider all items related to milk and milk products together, and to discuss Item 11 Aseptic Packaging after Item 5.

7. Several delegations expressed concern at the late distribution of many of the working papers, especially because of the highly technical nature of some items which would have required examination by national experts. The Delegation of Argentina stated that the unusually late arrival of several documents prevented the Delegation from participating actively in the discussion of the items on the Agenda. The Chairman expressed the hope that draft documents for future meetings would be submitted in good time. Major documents which were currently elaborated by Working Groups could be considered by the plenary, and as such would form a part of the report of the Committee which would help to facilitate discussion and comments.

INFORMATION ON ACTIVITIES OF INTEREST TO THE COMMITTEE WITHIN FAO, WHO AND ISO

JOINT FAO/WHO ACTIVITIES

8. The Committee was informed of a Joint FAO/WHO Expert Consultation on Food Protection for Urban Consumers, which was held in Rome in December 1986. The Consultation reviewed problems facing authorities in guaranteeing adequate and safe food supplies in rapidly expanding urban areas. It identified the lack of infrastructure at the local level as the major problem and recommended assisting local food control agencies at national, regional and municipal level to improve the situation. The report of the Consultation was available from the FAO Secretariat.

9. The Committee noted that the Second FAO/WHO/UNEP International Conference on Mycotoxins had been held in Bangkok in September/October 1987, ten years after the first conference. The Conference discussed the health implications of mycotoxins; their distribution in the environment; trade and economic implications of mycotoxin contamination; methods of detection, prevention and control measures undertaken at national level; and international harmonization of requirements. The Conference issued general and specific recommendations to improve national capabilities and international action. The report would become available from the FAO Secretariat in the near future.

10. It was also noted that the 31st Session of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) had carried out a full evaluation of aflatoxins in 1987, and, based on the toxicological evaluation, stated that efforts should be made to limit their presence in food to irreducible levels. The report is available in the WHO Technical Report Series (TRS 759, 1987).

FAO ACTIVITIES

11. The Secretariat informed the Committee that FAO was continuing to assist developing countries in improving their food control infrastructures, including food hygiene measures. Special attention was being paid to street food activities in the various regions which had led to interest in developing related Codes of Practice for Street-Vended Foods through the Coordinating Committees.

WHO ACTIVITIES

12. Dr. F. Quevedo of PAHO informed the Committee of WHO and PAHO activities related to food hygiene, especially those organized under the Regional Programme of Technical Cooperation on Food Safety established by the XXIInd Pan-American Health Conference which was held in October 1986. These included:

- Second Subregional Workshop on Planning, Administration and Evaluation of Food Protection Programmes, Argentina, November 1986;
- Third Workshop on Food Standards and Health, in cooperation with the Codex Coordinating Committee for Latin America and the Caribbean, Cuba 1987;
- Jamaican National Seminar on Food Protection (with US/FDA collaboration);
- 3rd Course - Workshop on Planning, Management and Evaluation of Food Protection Programmes. Port of Spain, Trinidad and Tobago, June 1987 (with US/FDA collaboration);
- 2nd Sub-regional Workshop on National Food Protection;
- Programme for the Central American Isthmus, Mexico and the Dominican Republic; Tegucigalpa, Honduras, October 1987;
- Regional Seminar on Risk Analysis and the Determination of Critical Control Points (HACCP) for the Dominican Republic according to the WHO/PAHO/Industry Agreement, Santo Domingo, Dominican Republic, February 1987;
- National Seminar on Malacotoxicosis, Cumana, Venezuela, September 1987;
- Intensive Course on Inspection of Food Processing Plants, San José, Costa Rica, November 1987;
- Intensive Courses on Inspection of Fish Products, Guatemala City, Guatemala, October 1987 and Lima, Peru, November 1987;
- Regional Course on Analyses of Anabolic Agents in Meats, Buenos Aires, Argentina, March 1987;
- Regional Course on Microbiological and Chemical Contaminants in Meats and Derived Products, Buenos Aires, Argentina, November 1987;
- National Course on Risk Analysis and the Determination of Critical Control Points, Bogotá, Colombia, July 1987;

- Assistance in organizing the First Latin American Congress on Food Microbiology and the First Argentinian Symposium on Food Preservation, Buenos Aires, Argentina, December 1987;

- Several National Training Courses for Elementary Teachers on Hygienic Handling of Foods in Several Cities in Peru in 1986 and 1987. Publication of calendars with a food safety theme for 1987 and 1988 and of instruction sheets;

- Assistance in organizing and executing several national courses on chemical and microbiological food analysis;

- Assistance in computerizing hygiene data for food and inspection activities in plants in Argentina, Colombia, Mexico and Venezuela;

- Publications in Spanish of Technical Information Sheets on Pesticides;

- Technical Cooperation in the preparation of basic documents for national food protection programmes in various countries, as well as elaboration of financing proposals to obtain extrabudgetary resources;

- In April 1988 a FAO/PAHO workshop will be held in Mexico on Food Legislation and Standardization in Latin America.

13. The delegations of Nigeria and Côte d'Ivoire expressed their appreciation of the information related to the food protection activities of WHO in the Latin American Region. They pointed to the need for similar activities in the Region of Africa, and the need to be informed of international meetings in the field of food protection and food handling well in advance of their being held.

14. The delegation of Argentina expressed its appreciation to Dr. Quevedo for his undertaking to distribute the report of the recently held WHO Expert Group Meeting on Food-borne Listeriosis.

ACTIVITIES OF ISO

15. The delegation of France, on behalf of the ISO member body, AFNOR, presented a report of the activities of ISO in the field of food microbiology. The Committee was informed that the following Draft International Standards and Draft Proposals were in the course of preparation:

ISO/DP 8419: General Guidance for the Detection of Vibrio parahaemolyticus;

ISO/DIS 7954: General Guidance for Enumeration of Yeasts and Moulds - Colony Count Technique at 30°C;

ISO/DIS 7932: General Guidance for Enumeration of Bacillus cereus - Colony Count technique at 30°C;

ISO/DP 8523: General Guidance for the Detection of Enterobacteriacia with Resuscitation.

The Committee also noted that the following ISO Standards were being revised:

ISO/6579: General Guidance on Methods of Detection of Salmonella;

ISO 4831: General Guidance for the Enumeration of Coliforms - Most Probable Number Technique after Incubation at 30°C;

ISO 4832: General Guidance for the Enumeration of Coliforms - Colony Count Technique at 30°C:

ISO 4833: General Guidelines for the Enumeration of Microorganisms - Colony Count Technique at 30°C.

Other work being undertaken by Sub-Committee 9 of ISO Technical Committee 34 included:

- preparation of further information on reliability studies and additional general guidelines for interlaboratory collaborative studies;
- finalization of methods for Yersinia enterocolitica and Campylobacter;
- detection of Listeria monocytogenes; and
- determination of pH in canned foods.

MATTERS OF INTEREST ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

CODEX ALIMENTARIUS COMMISSION

17. The Committee had before it paper CX/FH 88/2 - Part I which summarized matters related to the work of this Committee which has been considered by the Seventeenth Session of the Codex Alimentarius Commission which had met in June/July 1987. The Committee noted that action taken by the Commission, in particular that the Commission had:

- Adopted the Revised Draft Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods at Step 5 and advanced it to Step 6.
- Advanced the Definition of Pasteurization to Step 6 only, having taken into account comments by the delegation of the Federal Republic of Germany;
- Agreed that the Code of Practice on Spices to be elaborated by the Codex Committee on Processed Meat and Poultry Products would follow the Step Procedure, but without further need for endorsement by the Codex Committee on Food Hygiene;
- Recognized that the immediate adoption of the general text on Hazard Analysis of Critical Control Points (ALINORM 87/13A, Appendix VI) might have implications in the future, and agreed that the text be sent to relevant commodity committees and governments for comments. This text had been recommended for adoption and incorporation as an addendum to the General Principles for the Establishment and

Application of Microbiological Criteria for Foods, contained in the Procedural Manual;

- Adopted the amendment to Section 3.7 of the Code of Hygienic Practice for the Collection, Processing and Marketing of Natural Mineral Waters, proposed by the 22nd Session of this Committee.

18. The delegation of Canada was of the opinion that the wording of paragraph 3.7 of the Mineral Water Code used unsatisfactory terminology and should be reconsidered.

19. Several delegations enquired about the reasons for the Commission's decision not to refer the Code of Practice for Spices to this Committee for Endorsement. The Committee recalled that it had, for several sessions, discussed the possibility of developing a Code of Hygienic Practice for Spices and that it had concluded, at its 22nd Session, that it was not in a position to develop a General Code for the Harvesting/Handling and Processing of Spices due to the wide variety of treatments required for the use of spices used in various food products. It had nevertheless recommended that, in view of the urgency attached to the matter, CCPMPP might develop its own Code. The Committee had also offered to provide advice to CCPMPP if requested. It was noted, however, that the Commission's decision was possibly linked to an agreement reached at its 8th Session (1971) that the Code of Hygienic Practice for Processed Meat Products need not be endorsed by this Committee and that, therefore, other Codes elaborated by CCPMPP need not be endorsed by this Committee. Several delegations while recognizing the difficulties mentioned above, urged that a Code of Practice on Spices be given more general consideration as the use of spices as food ingredients was not limited to meat and poultry products. It was proposed that more epidemiological data on problems related to spices used as food ingredients was required, as well as data on the efficacy of available treatments to improve the microbiological quality.

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS (CCFFP)

20. The Committee noted that the forthcoming session of the CCFFP would consider draft Microbiological Specifications for Quick Frozen Crab Meat in the light of Government comments. The specifications would be referred to this Committee for endorsement.

ENDORSEMENT OF PROVISIONS RELATING TO FOOD HYGIENE IN CODEX STANDARDS

21. The Committee had before it working paper CX/FH 88/2 - Part II containing hygiene provisions in Codex Standards and Draft Standards. The Committee noted that several of these provisions had already been endorsed in 1982 and 1983 and had been adopted by the Commission unchanged. The Committee agreed that no further consideration need be given to these standards.

22. The provisions identified as being endorsed previously were:

- Standard for Canned Mangoes

- Standard for Mango Chutney

- Standard for Quick Frozen Blocks of Fish Fillet, Minced Fish Flesh and Mixtures of Fillets and Mixed Fish Flesh

- Draft Standard for Quick Frozen Fish Sticks (Fish Fingers) and Fish Portions Breaded or in Batter

- Revised Standard for Table Olives

- European Regional Standard for Vinegar

- Standard for Specified Vegetable Fat Product

- Standard for Specified Animal or Mixed Animal and Vegetable Fat Product

23. The Committee discussed the Secretariat proposals contained in Part III of CX/FH 88/2 for harmonized texts for hygiene provisions in Codex standards, but in view of its decision to refer these proposals to Governments for comments (see para 29 below), decided to examine the standards submitted for endorsement in the light of the present criteria.

24. The attention of the Committee was drawn to small differences in the common wording of the hygiene provision and agreed to editorial amendments; e.g., the following wording was used as a standard text:

> "shall not contain any substance originating from microorganisms in amounts which may represent a hazard to health"

and to the deletion of the word "esentos" from the common provision (a) in the Spanish version.

25. The Committee decided that more significant concerns with some of the standard provisions should be taken up in connection with the consideration of harmonized texts mentioned in para 23, at the next session of the Committee.

26. The Committee decided to endorse the hygiene provisions in the following standards, amended as indicated:

- Draft General Standard for Fruit Nectars, preserved exclusively by physical means (ALINORM 87/14, App. 2), and

- Draft General Standard for Fruit Juices, preserved exclusively by physical means (ALINORM 87/14, App. III) amended as follows:

6.1 It is recommended that the products covered by the provisions of this Standard be prepared in accordance with the General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 1) recommended by the Codex Alimentarius Commission and the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23/1979).

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

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

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

- Draft Standard for Dried Salted Fish (Klippfish) of the Gadidae Family (ALINORM 87/18, App. VI), without amendment.

- Draft Standard for Sorghum Grains (ALINORM 87/29, Appendix III), without amendment.

- Draft Standard for Sorghum Flour (ALINORM 87/29, Appendix IV), without amendment.

- Draft European Regional Standard for Mayonnaise (ALINORM 87/19, Appendix III), amended as follows:

6. HYGIENE

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

6.2 When tested by appropriate methods of sampling and examination, the product shall be:

(a) free from microorganisms in amounts which may represent a hazard to health.

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

6.3 It is recommended that the products covered by the provision of this Standard be prepared and handled in accordance with the Recommended Code of Practice - General Principles of Food Hygiene (CAC/RCP 1/1969, Rev. 1) and the Recommended Code of Hygienic Practice for Egg Products (CAC/RCP 15 - 1976).

FUTURE RESPONSIBILITIES OF THE COMMITTEE WITH RESPECT TO ENDORSEMENT

27. The Committee had before it working paper CX/FH 88/2, Part III, containing a note prepared by the Secretariat, proposing the establishment of generally applicable uniform texts of hygiene provisions. Three different texts were proposed which took into account the nature of the foods covered by the standard concerned and the Codes of Practice which would apply to them.

28. Several delegations expressed their appreciation for this proposal which would serve to harmonize hygiene provisions and facilitate the work of Commodity Committees. However, the Committee drew attention to the following points which had not been addressed in the Secretariat's proposal:

- reference to the relevant codes was not always appropriately covered; e.g., in the proposed wording for shelf-stable products, heat processed in hermetically sealed containers, no reference had been included to the fish or processed meat codes;

- the need for appropriate methods of sampling and examination was mentioned, but no further advice was given on the methods to be used;

- it should be possible to elaborate additional or different specific provisions, if appropriate to the product.

29. The Committee agreed that the proposals included in the Annex to the working paper should be appended to this report (Appendix III) and sent to governments for comment. The Committee also agreed that the proposals would be discussed at its next session and recognized that the hygiene provisions in Codex Standards would have to be revised retrospectively once the harmonized provisions had been adopted by the Commission.

REPORT OF THE WORKING GROUP ON CANNED FOOD MATTERS

30. The Chairman of the Working Group, Dr. B.E. Brown (Canada) introduced the report of a meeting of the Working Group on Canned Food Matters which had been held in Paris in May 1987. The Working Group had reviewed the following documents and made comments as listed below:

(a) Guidelines for the Salvage of Canned Foods Exposed to Adverse Conditions

Document CX/FH 86/3 was reviewed in detail and amended. (See CX/FH 88/4).

In a brief discussion on the French language version, it was agreed to translate "adverse conditions" as "sinistre". The Working Group agreed that, since these guidelines would not be an appendix to the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods as originally intended, there should be references wherever necessary to those sections of the Code which applied. Canada undertook to complete this work. France and Switzerland would be responsible for the French version and Spain for the Spanish.

(b) Guideline Procedures to Establish Microbiological Causes of Spoilage in Canned Foods

Document CX/FH 86/5A was reviewed in detail. The amended version (including changing "Canned Foods" in the title to "Low-Acid and Acidified Low-Acid Canned Foods", and the addition of sections on micro-leak test, seam tear-down and references) had been distributed as CX/FH 88/5.

To assist in the discussion on the investigation procedures, Dr. George Thomas (France) prepared a chart for screening situations.

In the preparation of the flow diagrams on cultural examinations (Figures No. 1 and No. 2 of the Guideline Procedures), the Working Group was assisted by M. Jacques Brossard, Chef des laboratoires, Groupe Carnaud (France). Switzerland agreed to update the preparation of the French version and Spain agreed to undertake the preparation of the Spanish version.

(c) Revised Draft Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (ALINORM 87/13A, Appendix VII)

The comments of Australia (which had not been reviewed at the 22nd Session of the CCFH) were considered, as well as other points raised by various members of the Working Group. It was noted that the table of contents had been removed inadvertently at some point in the review process. It was agreed that Canada would prepare a new table of contents.

There was considerable discussion on the meaning of "equilibrium pH" relative to acidified low-acid foods and how this should be measured. ISO had four different methods for determining pH depending on the nature of the product. It was decided to reserve further consideration of this matter for a future meeting.

It was agreed that Canada would send the amended Code to the French and Spanish delegations for use as the reference text in the preparation of their respective translations. The original French version before amendments required extensive editing, a most arduous task. France had undertaken this.

(d) A Guide to the Non-Destructive Visual Examination of Double-Seamed Metal Containers for Canned Foods

Defect Classification and Manual

The four objectives developed by the Working Group in Washington (October 15-17, 1986), and which were accepted by the 22nd Session of the CCFH, were reviewed. The group agreed to address the first objective: "Prepare a pictorial manual identifying those external defects which show visual evidence that a metal container is without a hermetic seal or that microbial growth has occurred in the container's contents".

The UK delegation noted that limitation of listed defects to only this definition would, in its opinion, be too restrictive and prohibit the inclusion of other conditions which would be reason for concern. The UK also noted that the same reservation would apply to its position for consideration of the subsequent objectives of the Working Group.

The question was raised as to the form (or presentation) of the manual and it was felt that "loose-leaf" would be most appropriate.

It was suggested that the Working Group identify additional pictures required for the manual. The following suggestions were made: (1) mislock side seam with leakage, (2) leakage with defect not evident, (3) severe soldering defect on side seam with leakage and (4) overview of a lot showing problems. Mr. Spinak (USA) offered to try to find pictures of any defects identified by the Working Group and send them to Dr. Brown (Canada).

(e) Inspection for Visual Can Defects

The Working Group discussed Objective II, "Provide guidance for the visual inspection of lots of canned food for the above (Objective I) defects". A general discussion on this subject produced a list of the various aspects which should be addressed in such a guide. Canada agreed to prepare a draft document for consideration by the Committee.

Members of the Working Group were encouraged to submit further suggestions for the guide to Dr. Brown (Canada) as soon as possible.

31. The Chairman of the Working Group also introduced a summary of the development of the above-mentioned documents and their interrelationship, one with another.

32. The Committee expressed its sincere thanks to the members of the Working Group and its Chairman for the significant work which it was carrying out on behalf of the Committee.

CONSIDERATION OF THE REVISED DRAFT CODE OF HYGIENIC PRACTICE FOR LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS AT STEP 7

33. The Committee had before it a revised version of the above Code which had been advanced to Step 6 as ALINORM 87/13A, Appendix VII, by the Commission, and government comments from the following countries: Argentina, Canada, France, Germany Federal Republic of, Norway, Spain, Thailand and the USA. (CX/FH 88/3-CRD. No. 2).

34. The Committee decided to consider the draft code section-by-section, and agreed to the following changes:

Section 2.20 Pasteurization (Definition)

35. The Committee noted that the proposed definition referred to heat treatment at temperatures not exceeding 100°C to achieve commercial sterility. In Section 2.9, the Definition of Commercial Sterility of Thermally-Processed Foods required a treatment which rendered the food free from microorganisms capable of growing in the food at normal non-refrigerated conditions which therefore included the proposed definition of "pasteurization". It was commonly understood in some countries that pasteurized foods required refrigerated storage, and therefore the term "pasteurization" in relation to shelf-stable foods was misleading and should be deleted. It was agreed that reference to "thermal processing" was sufficient and the term "pasteurization" throughout the Code was deleted accordingly.

Section 7.1.4 and 7.4.1

36. The Committee decided that these sections required clarification by the Working Group, and the text was subsequently amended by the Working Group, meeting in the present session.

Section 7.4.4

37. It was agreed to amend the second sentence by the use of the words "If this is not practicable, then the containers may be shielded..."

Section 7.4.8.1.2

38. The Committee agreed with the delegation of Spain that throughout the Code the term "costura" should be used to translate the English "seam".

Section 7.4.11.2

39. The Committee agreed with the written comment from Thailand to extend the sentence as follows:

> "...and also it may be more difficult to remove food debris from the container's external surface as they will adhere rather firmly after heating."

Section 7.5.2.10

40. Attention was drawn to the specific provisions for aseptically processed and packaged food in this Code which might have to be deleted once the Proposed Draft Code of Hygienic Practice for Aseptic Food Processing and Packaging Systems had been finalized (Note: In subsequent discussions, the Committee agreed to change the title of this Code to read "Code of Hygienic Practice for Aseptically Canned Foods". See para. 61).

41. The Committee agreed not to amend this Code at the present time, but to include an appropriate footnote where such appeared.

Heat Distribution in Retorting Systems (new)

42. The delegation of the United States proposed to include a new section as these aspects were not covered by existing provisions and were of technological importance. This matter was referred to the Working Group, which prepared a new statement for inclusion in Section 7.5.1.

Section 7.6.8 Cooling

43. Several delegations pointed to the need to improve the wording of this provision and this was subsequently amended by the Working Group.

Sections 7.6.6 and 7.6.7

44. The delegation of Norway suggested that these sections be amended to include other equipment which had been developed over recent years such as waterspray retorts. The Committee noted that Section 7.6.7 covered systems not specifically mentioned and agreed that there was no need for amendment.

Section 7.6.8.2

45. The Committee agreed that the 20 minute minimum contact time should relate to chlorination only.

Section 7.7.1

46. The Committee agreed to make specific reference to infection by pathogenic microorganisms in the first line of this Section.

Section 7.7.3

47. It was agreed to add the following words at the end of the first sentence:

"...and possible seam damage due to cable burn."

Appendix I

48. The Committee decided that reference to the terms "pasteurization" and "pasteurizer" would also be deleted from this Appendix.

Appendix II

49. The Committee noted that a footnote to the methodology for pH measurement indicated that if and when a suitable ISO text became available it

would be considered as a replacement for this Appendix. The Committee recalled that a draft proposal for pH measurement had been submitted to ISO and requested the French delegation to make this text available to the Chairman of the Canned Foods Working Group. The Committee agreed that in accordance with the Codex procedures, the Appendix, including the footnote, should be retained until the ISO text had been finalized and considered by the Committee. The Committee further agreed to update the current AOAC references included in Appendix II.

Appendix III

50. The Chairman of the Working Group, Dr. B.E. Brown, informed the Committee that Appendix III - References for the Tear-Down Evaluation of a Double Seam had been developed at the request of the previous session of the Committee.

51. Several delegations suggested improvements to the format of the Code to facilitate its application. The Committee agreed that:

- explanatory material should be presented in a way which would distinguish it clearly from the operative text of the Code;
- the French and Spanish versions would be based on the texts prepared by members of the Working Group to ensure technical accuracy;
- where possible, sections of the previous versions of the Code which had been amended would be clearly marked as such.

52. The Committee did not agree to include specific Critical Control Point (CCP) notes, since it was considered that the operative sections of this Code constituted the essential Critical Control Points.

Status of the Code

53. The revised Draft Code, as amended by the Working Group taking into account the above points, is contained in Appendix IV to the present report. The Committee decided to advance the Draft Code to Step 8 of the Procedure for adoption by the Commission.

CONSIDERATION OF GUIDELINES FOR THE SALVAGE OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS

54. The Committee had before it the above Guidelines as contained in CX/FH 88/4, and recalled that they had been extensively discussed in the light of government comments at several previous sessions and agreed that it was timely to place the Guidelines in the Step Procedures. The Committee noted that while standards and codes of practice were always developed in the Step Procedure, the Commission could decide to apply the Step Procedure to Guidelines.

55. The delegations of Belgium, Federal Republic of Germany and the Netherlands expressed concern at the responsibility which agencies having jurisdiction would be required to take in the event that they were notified in accordance with Section 3.2 of the Guidelines. The Secretariat informed the Committee that Codex Guidelines were supporting documents which could be applied by interested parties and that they were not subject to notification of acceptance.

Status of the Guidelines

56. The Committee decided to request the Commission to place the Guidelines, as contained in Appendix V to this report, in the Step Procedure. The Guidelines had been revised by the Working Group on Canned Foods during the course of the present session. The Committee recommended that the Guidelines be considered by the Commission at Step 5, since they had already been subject to extensive comment and review.

CONSIDERATION OF GUIDELINE PROCEDURES TO ESTABLISH CAUSES OF MICROBIOLOGICAL SPOILAGE IN CANNED FOODS

57. The Committee had before it the above Guideline Procedures as contained in CX/FH 88/5 (Conference Room Document). It was noted that these procedures had been reviewed by an FAO/WHO Working Group prior to the Committee's 20th Session and comments had been reviewed on two occasions by the Canned Foods Working Group.

58. The Committee agreed that it was timely for the Guideline Procedures to be distributed to Governments for comments, preferably in the Step Procedure at Step 3, and agreed to ask the Executive Committee to approve this action. The Proposed Draft Guideline Procedures, as amended by the Working Group on Canned Foods during this session, are contained in Appendix VI of this report.

CONSIDERATION OF "VISUAL EXAMINATION OF LOTS OF CANNED FOODS" AND "DEFECT CLASSIFICATION AND MANUAL"

59. The Committee noted the work carried out by the Canned Foods Working Group on these documents as recorded in paras 30-32 above, and agreed with the Chairman of the Working Group that both documents should be considered further by the Working Group. The Committee agreed to discuss these texts at its next session.

60. The Committee agreed to re-appoint the ad hoc Working Group on Canned Foods, under the Chairmanship of Canada, to complete the elaboration of the above texts. The Working Group consists of: Australia, Canada, France, Federal Republic of Germany, Norway, Switzerland, United Kingdom, United States. The Chairman of the Working Group, Dr. B.E. Brown (Canada), informed the Committee that the Working Group would meet in Paris (France) during the week of 14-18 November 1988.

PROGRESS REPORT ON A PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR ASEPTIC FOOD PROCESSING AND PACKAGING SYSTEMS

61. The Committee had before it document CX/FH 88/13 (C.R.D.) entitled "Draft Code of Hygienic Practice for Aseptically Canned Foods" prepared by the USA. The delegation of the United States introduced the document which had been prepared in response to a request of the 21st Session of the Committee. The delegation pointed out that many provisions were identical to the Draft Code for Low-Acid and Acidified Low-Acid Canned Foods, and that it might be considered appropriate to establish a Working Group to examine specifically those provisions relating to aseptic packaging only.

62. The Committee noted that the draft code also covered aseptic processing and packaging systems for milk and milk products.

63. The Committee agreed to establish an ad hoc Working Group under the Chairmanship of the USA, to assist the Committee in the further elaboration of the draft code. The delegations of Australia, Canada, France, Finland, Federal Republic of Germany, Hungary and the United Kingdom indicated their interest in participating in this Working Group. The Group would meet in Paris, in the week of 14-18 November 1988. It was also agreed that the proposed draft code as contained in Appendix VII of this report should be distributed for comments at Step 3 of the Procedure.

64. The Committee confirmed that until such time as the elaboration of the Code was finalized, there would be no need to revise or delete the sections dealing with aseptic packaging in the Low-Acid Canned Foods Code.

CONSIDERATION AT STEP 7 OF DEFINITION OF "PASTEURIZATION" - SECTION 2.9 OF THE RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR DRIED MILK

65. The Committee had before it the above definition as contained in Annex 2 to Appendix IV to ALINORM 87/13A, and comments thereon from the following countries: Argentina, Canada, Federal Republic of Germany, Ireland, Mexico, New Zealand, Thailand, United States (CL 1987/45 and CX/FH 88/8-CRD 3).

66. The Observer from the International Dairy Federation (IDF) in introducing this item, recalled that the 22nd Session of the Committee had advanced the definition to Step 5 of the Procedure with the recommendation to omit Steps 6 and 7 and to adopt the amendment to the Code at Steps 5 and 8. As indicated in working paper CX/FH 88/2, the delegation of the Federal Republic of Germany to the 17th Session of the Codex Alimentarius Commission had reserved its position in regard to the definition, and the Commission had advanced the amendment to Step 6 only.

67. The delegation of the Federal Republic of Germany explained that, in its view, it was necessary for certain reasons to distinguish between pasteurization and ultra-heat treatment or high temperature pasteurization by use of the milk alkaline phosphastase and peroxidase tests: anegative phosphatase test with a positive peroxidase test would indicate that the product had been properly pasteurized. The view of the Federal Republic of Germany was shared by the delegations of Belgium, Cuba, France and Italy.

68. The Committee decided that there was no need to make a distinction between pasteurization and other higher temperature heat treatments since the Code applied to the hygienic treatment of dried milk products only. However, upon the proposal of the delegation of New Zealand, the Committee decided to amend Section 7.7.3 (Sampling and Laboratory Control Procedures) so as to include under (iii) reference to the phosphatase test with appropriate methodology recommended by IDF/ISO/AOAC. The Committee also noted that no agreed methods were available for peroxidase tests.

69. Attention was drawn to the possibility of providing additional examples of time/temperature combinations in the definition, however the Committee felt that this would be adequately covered by the note attached to Section 2.9 of the Code, provided that reference would be made to information where complete time/temperature tables could be found. The observer from IDF agreed to

supply the appropriate references and to verify the examples included in the note.*

STATUS OF THE AMENDMENT

70. The Committee decided to advance the above amendments to the Code, as contained in Appendix VIII, to Step 8 of the Procedure.

PROGRESS REPORT ON A DRAFT CODE OF HYGIENIC PRACTICE FOR SOFT CHEESES

71. The Observer from IDF informed the Committee of further action taken by IDF since the 22nd Session of this Committee, on the first draft of a Code of Hygienic Practice for Fresh and Soft Cheeses. This draft had been examined by IDF member countries and reviewed by the IDF annual meetings in Helsinki in September 1987. A second draft had been prepared as a result of this review and had been made available to this Committee as Working Paper CX/FH 88/11 (CRD) for information.

72. The Observer from IDF indicated that the latter draft would be further reviewed by an IDF Group of Experts in Rennes (France) and by the Steering Committee of the FAO/WHO (Codex) Milk Committee in May 1988 and the IDF Annual Session in September 1988. He expressed the hope that the document could be made available for discussion at the next Session of this Committee.

73. The Committee requested IDF to ensure that the draft document would be in conformity with the General Principles of Food Hygiene, and to indicate those sections which were specific to soft and fresh cheeses or deviated from the General Principles.

CONSIDERATION OF A CODE OF HYGIENIC PRACTICE FOR RAW MILK PRESERVATION BY USE OF THE LACTOPEROXIDASE SYSTEM

74. The Observer from IDF introduced a report, document CX/FH 88/12 (Conference Room Document No. 9), on a Code of Practice for the Preservation of Raw Milk by the Lactoperoxidase system. He informed the Committee that the 21st Session of the Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products had considered the technical advice IDF had given on the use of the Lactoperoxidase System for the preservation of raw milk. That Committee had requested IDF to prepare the draft of a Code of Practice. The draft document had been amended at the 70th Annual Session of IDF (The Hague, 1986) and subsequently circulated to IDF members for comments. Comments had been received from 19 countries and had been incorporated in a revised text of the draft code of practice for submission to the IDF Sessions in Helsinki (1987) and to the Milk Committee (IDF Working Paper D-Doc 157/1987).

75. The representative of IDF noted that the additional comments received from Thailand and Denmark had been taken into consideration during the preparation of the present wording of the Code.

* IDF has subsequently notified the Secretariat of the following references for milk: Enright, J.B., W.W. Sadler and R.C. Thomas: Thermal inactivation of Coxiella burnetii in milk pasteurization. Pub. Hlth. Monograph No. 47. Pub. Hlth Service Pub. No. 517. U.S. Supt. Doc., Washington, D.C., 1957.

76. Several delegations inquired about the implications of elaborating a Code of Practice which might be used to discourage efforts to improve the use of refrigeration of raw milk. The delegation of Cuba expressed the view that, supported by such a Code adopted at the international level, the lactoperoxidase system might be used on a continuous basis for an indefinite period of time and questioned whether that was the intent of the Committee. The delegation of Australia questioned whether the holding of raw milk at ambient temperatures had effects on the chemical composition and nutritional qualities of the milk. Concern was also expressed about adequate control of the use of the chemical additives under practical conditions.

77. The Observer of IDF indicated that IDF had considered nutritional and safety aspects of the lactoperoxidase system especially in regard to the use of other chemicals which may be used to preserve milk. He stated that the final goal for good hygienic practices remained the use of refrigeration. He informed the Committee that the process was being introduced in certain areas of India and China, and that the draft document contained adequate provisions for the control of the chemicals used. The delegation of the United Kingdom stated the lactoperoxidase system operated naturally in raw milk and that the proposed application was an enhancement of the naturally-occurring bacteriostatic action.

78. It was proposed that the draft Code should be given only the status of a Guideline, in view of the opinion of several delegations that the procedure should be used only under specified conditions, and that this should also be indicated in the title and in the introductory sections. The Committee agreed that the following alternative title:

> "Draft Guidelines for the Preservation of Raw Milk by use of the Lactoperoxidase System where Refrigeration is Virtually Impossible"

should be included in the document, and that both titles should be placed in square brackets for further government comments.

79. Concerning the status of the Code/Guidelines within the Codex Procedures, it was agreed to advance the draft document to Step 3 for government comments and to request the Commission to decide whether further elaboration of the Code/Guidelines should be referred to this Committee in view of the extended period of time between sessions of the Milk Committee. In the meantime the Secretariat was requested to seek authorization from the Executive Committee for obtaining comments at Step 3. The document distributed for comments would carry references to both the Committee on Food Hygiene and the Milk Committee.

80. The Committee expressed its appreciation to IDF for the extensive work carried out in relation to these agenda items.

CONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-COOKED AND COOKED FOODS IN MASS CATERING, AT STEP 4

81. The Committee had before it the above Code as contained in ALINORM 87/13A, Appendix VII and comments thereon from Sweden and Thailand in CX/FH 88/9 - Add. 1 (Conference Room Document 4). The Committee noted that the first six sections of the Code had been revised at its previous session.

82. The Committee established an ad hoc Working Group under the Chairmanship of Dr. H.J. Beckers (the Netherlands) to review the Code in the light of comments. The following countries participated in the Working Group: Belgium, Canada, Côte d'Ivoire, Cuba, Denmark, Finland, France, Gabon, Italy, Jordan, New Zealand, Norway, Spain, Switzerland, United Kingdom, and the United States.

83. The Chairman of the Working Group reported that the Group had been advised of the following information relating to the document under consideration:

> This Code, as contained in Appendix VII ALINORM 87/13A, was discussed in part at the 22nd Session of this Committee. Instead of completing discussion at the 22nd Session it was decided to establish a working group and members of the group were invited to send further comments to the Netherlands. In addition to the comments of Cuba, New Zealand, United Kingdom and the Netherlands, which were already available at the 22nd Session, only France, Thailand and Sweden had sent comments.
>
> The United States had revised the proposed draft (Document CX/FH 88/9-CRD) to include all the above comments and previous discussions. The Working Group decided only to deal with those revisions which had not yet been agreed by this Committee and considered only section 7.1 through to the end of the document. Only those sections where changes were suggested were taken into consideration. Several of the comments which had been submitted and included in the proposal were discussed at length by the Group. Agreement was reached on all points of discussion and a revised document was completed. Finally, the Group decided to propose to the Committee to advance the document to Step 5 of the Codex Procedure.

STATUS OF THE CODE

84. The Committee expressed its appreciation to the Working Group. It recognized that more work would be required on certain sections of the Code and agreed to advance the Proposed Draft Code to Step 5 of the Procedure. Having regard to the timing of the session, the Secretariat was requested to obtain comments at Step 6 in advance of the Eighteenth Session of the Commission under the relevant Procedure. The revised Proposed Draft Code is contained in Appendix IX of this report.

MATTERS RELATED TO MICROBIOLOGICAL SPECIFICATIONS FOR NATURAL MINERAL WATERS

85. The Committee had before it document CX/FH 88/10 (Conference Room Document No. 5) containing comments received in reply to CL 1987/63 from the Netherlands and Thailand, on methods of analysis for microbiological specifications for natural mineral waters.

86. The Committee recalled that, for natural mineral waters, the 16th Session of the Codex Alimentarius Commission had adopted (a) an amendment at Step 8 containing microbiological requirements for inclusion in the European Regional Standard for Natural Mineral Waters and (b) a World-wide Code of Hygienic Practice for the Collecting, Marketing and Processing of Natural Mineral Waters containing microbiological end product specifications. These microbiological requirements, which had been elaborated by the Codex Regional

Coordinating Committee for Europe were identical, and had been endorsed by the 20th Session of this Committee. The Committee noted also that, at the time of adoption of these provisions, the relevant methods of analysis had not yet been finalized by ISO.

87. The Fifteenth Session of the Coordinating Committee for Europe (June 1986) had received a report from GESEM, containing advanced versions of these methods and had requested comments on them for consideration at its forthcoming 16th Session.

88. The Committee agreed to refer the comments contained in CX/FH 88/10 to the European Committee for its consideration. It noted that once the methods of analysis had been accepted by the European Committee, they would be sent to this Committee for endorsement and incorporation in the two Codex documents relating to natural mineral waters following adoption by the Commission.

CONSIDERATION OF A GENERAL STATEMENT ON THE APPLICATION OF HACCP TO CODEX CODES OF HYGIENIC PRACTICE

89. The Committee had, for its consideration, Appendix VI of ALINORM 87/13A containing the above statement, and comments thereon from Denmark, France, Hungary and Thailand in working paper CX/FH 88/14 which had been received in reply to Circular Letter 1987/63.

90. The Committee recalled that it had discussed, over several sessions, the application of Hazard Analysis of Critical Control Points (HACCP) to Codex Codes of Practice. It confirmed its position that the technique represented a major element in assuring the safe processing of foods, and that its application within individual food processing establishments was essential. However, because the technique could only be applied following the assessment of individual establishments it was not considered possible to make general statements on critical control points in many Codex Codes.

91. A statement to this effect had been submitted to the Seventeenth Session of the Codex Alimentarius Commission with a view to its incorporation in the Procedural Manual. The Commission, however, accepted the views of the delegation of Denmark that the general statement in Appendix VI of ALINORM 87/13A, did not take into account the nature of individual codes, and that the HACCP concept would be applicable to several of them. The Commission, therefore, directed that comments should be sought from governments on the general statement.

92. The Committee noted that several competent authorities such as ICMSF and the National Academy of Sciences (USA),* had extensive documentation on the HACCP, which explained the HACCP concept in detail and how it should be

*1. Simonsen, B.; Bryan, F.L.; Christian, J.H.B.; Roberts, T.A.; Tompkin, R.B. and Silliker, J.H. (1987)
Prevention and control of food-borne salmonellosis through application of Hazard Analysis Critical Control Point (HACCP) Int. J. Fd. Microbiol. 4(3) 227.

2. National Research Council (US), (1985). An evaluation of the Role of Microbiological Criteria in Foods and Food Ingredients. National Academy Press, Washington, DC.

applied. In this light, the Committee decided that it was premature to issue a general statement on the use of HACCP in Codex Codes of Practice in its present form. It agreed to wait until further experience had been obtained in the elaboration of the Fish and other Codes of Practice.

93. The establishment of General Principles on HACCP was proposed as an alternative for providing advice. The Committee decided that a working paper should be prepared for consideration at its next session, at which time it might be necessary to appoint a working group to examine this document and comments received. The delegations of the United Kingdom and the United States undertook to prepare the paper jointly.

OTHER BUSINESS

INTERNATIONAL OFFICE OF COCOA, CHOCOLATE AND SUGAR CONFECTIONERY (IOCCC)

94. The Observer from IOCCC informed the Committee of activities being undertaken by the Working Group on Microbiology of the IOCCC's Technical Committee. These included the elaboration of microbiological methods of examination of cocoa powder and chocolate. Standard methods had been published for:

- General requirements for microbiological examination
- Aerobic count at 30°C
- Aerobic mesophilic spores count
- Lactose fermenting Enterobacteriaceae ("Coliforms") and E. coli
- Glucose fermenting Enterobacteriaceae (Total Enterobacteriaceae)
- Molds and yeasts
- S. aureus
- Salmonella

95. In 1983 IOCCC had decided to revise its methods in order to harmonize them with existing ISO methods. The revised methods for the General requirements and for the determination of Salmonella in cocoa and chocolate will be published shortly as an International Standard method. An interlaboratory study on the determination of Salmonella was carried out in 1985 (not published). Furthermore, in 1986, a sub-group has been established in order to deal with the preparation of a Code of Hygienic Practice for the Prevention of Salmonella contamination in cocoa, chocolate and confectionery products.

FUTURE WORK

96. Referring to the earlier discussion relating to the occurrence of Listeria monocytogenes in foods, the delegation of the Federal Republic of Germany proposed that existing recommendations made by various expert groups, including those of WHO, should be summarized in a working paper for this Committee. The delegation was of the opinion that, in this way, these

recommendations could be made available to governments through the Codex system. At the same time, the Committee would be able to determine what action it wished to take, if any, in making recommendations to the Commission. This proposal was supported by several delegations.

97. The Committee noted that its terms of reference were sufficiently broad to allow it to undertake work on specific hygiene problems. The Committee accepted the kind offer of the delegations of the Federal Republic of Germany and the Netherlands to act as rapporteurs and to prepare the paper mentioned above. The Committee agreed that any delegation wishing to submit information arising from expert meetings or other groups, to the rapporteurs, should be encouraged to do so.

98. The Committee noted that the agenda for its next meeting would include:

- Draft Code of Hygienic Practice for Pre-Cooked and Cooked Foods in Mass Catering (Step 7)
- Guidelines for the Salvaging of Canned Foods exposed to Adverse Conditions (Step 7)
- Guideline Procedures to establish Microbiological Causes of Spoilage in Canned Foods (Step 4)
- Visual Examination of Lots of Canned Foods
- Can Defect Classification and Manual
- Proposed Draft Code of Hygienic Practice for Aseptically Canned Foods (Step 4)
- Proposed Draft Code of Hygienic Practice for Soft and Fresh Cheeses (Step 4)
- Proposed Draft [Code/Guidelines] for the Preservation of Raw Milk by Use of the Lactoperoxidase System [where refrigeration is virtually impossible] (see also para 78)
- General Principles on the Application of HACCP (Working Paper)
- Summary paper on Listeria
- Endorsements of Hygiene Provisions in Codex Standards (including General Provisions)

DATE AND PLACE OF THE NEXT SESSION

99. The Committee was informed that its Twenty-Fourth meeting would be held in October 1989 in Washington, D.C.

CODEX COMMITTEE ON FOOD HYGIENE
Summary Status of Work

Standard/Code	Step	For action by:	Document Reference
General Principles of Food Hygiene	9	Governments	CAC/RCP 1-1969; Rev. 1(1979): Vol. A
Second Revision	9	Secretariat	ALINORM 85/13A, App. VI
Code of Hygienic Practice for Canned Fruit & Vegetable Products	9	Governments	CAC/RCP 2-1969: Vol. D
Code of Hygienic Practice for Dried Fruits	9	Governments	CAC/RCP 3-1969: Vol. D
Code of Hygienic Practice for Desiccated Coconut	9	Governments	CAC/RCP 4-1971: Vol. D
Microbiological Specifications	8	Governments	ALINORM 85/13A, App.
Code of Hygienic Practice for Dehydrated Fruits and Vegetables including Edible Fungi	9	Governments	CAC/RCP 5-1971: Vol. D
Code of Hygienic Practice for Tree Nuts	9	Governments	CAC/RCP 6-1972: Vol. D
Code of Hygienic Practice for Poultry Processing	9	Governments	CAC/RCP 14-1976: Vol. C
Code of Hygienic Practice for for Egg Products	9	Governments	CAC/RCP 15-1976: Vol. F
- Microbiological Specifications	9	Governments	- Annex II
Code of Hygienic Practice for Molluscan Shellfish	9	Governments	CAC/RCP 18-1978: Vol. B
Code of Hygienic Practice for Foods for Infants and Children	9	Governments	CAC/RCP 21-1979: Vol. IX

Code of Hygienic Practice for Groundnuts (Peanuts)	9	Governments	CAC/RCP 22-1979: Vol. D
Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods	9	Governments	CAC/RCP 23-1979: Vol. G
- First revision	8	18th CAC	ALINORM 89/13 App. IV
Code of Hygienic Practice for the Processing of Frogs Legs	9	Governments	CAC/RCP 30-1983: Vol. C
Code of Hygienic Practice for Dried Milk	9	Governments	CAC/RCP 31-1983: Vol. H
- Definition of Pasteurization	8	18th CAC	ALINORM 89/13 App. VIII
Guidelines for Salvaging of Canned Foods exposed to Adverse Conditions	5	18th CAC	ALINORM 89/13, App. V
Proposed Draft Code of Hygienic Practice for Pre-Cooked and Cooked Foods in Mass Catering	5	18th CAC	ALINORM 89/13 App. IX
Proposed Draft Code of Hygienic Practice for Soft and Fresh Cheeses	4	IDF/24th CCFH	CX/FH 89/-
Guideline Procedures to Establish Microbiological Causes of Spoilage in Canned Foods	3	Governments 24th CCFH	ALINORM 89/13, App. VI CL 1988/26
Proposed Draft/Guidelines of Hygienic Practice for Raw Milk Preservaton by use of the Lacto-peroxidase System [where refrigeration is virtually impossible]	3	Governments 24th CCFH	CL 1988/22
Code of Hygienic Practice for Asceptically Canned Foods	3	Governments 24th CCFH	ALINORM 89/13 App. VII CL 1988/26

Draft General Provisions Relating to Food Hygiene	-	24th CCFH Governments	ALINORM 89/13 App. III CL 1988/26
Canned Foods: Defect Classification	-	24th CCFH	CX/FH 89/-
Visual Examination of Canned Foods	-	24th CCFH	CX/FH 89/-
General Principles on the Hazard Analysis of Critical Control Points (HACCP)	-	UK/USA 24th CCFH	CX/FH 89/-
Summary paper on Listeriosis	-	Netherlands/ Fed.Rep.Germany 24th CCFH	CX/FH 89/-

Code of Hygienic Practice for Groundnuts (Peanuts)	9	Governments	CAC/RCP 22-1979: Vol. D
Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods	9	Governments	CAC/RCP 23-1979: Vol. G
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Canned Foods: Defect Classification	-	24th CCFH	CX/FH 89/-
Visual Examination of Canned Foods	-	24th CCFH	CX/FH 89/-
General Principles on the Hazard Analysis of Critical Control Points (HACCP)	-	UK/USA 24th CCFH	CX/FH 89/-
Summary paper on Listeriosis	-	Netherlands/ Fed.Rep.Germany 24th CCFH	CX/FH 89/-

ALINORM 89/13
APPENDIX I

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LISTE DES PARTICIPANTS
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APPENDIX II

LIST OF ISO EXISTING DOCUMENTS IN THE FIELD OF FOOD MICROBIOLOGY

MICROBIOLOGY - Sub-Committee ISO/TC 34/SC 9

ISO/DIS 4831	General guidance for the enumeration of coliforms - Most probably number technique at 30°C
ISO/DIS 4832	General guidance for the enumeration of coliforms - Colony count technique at 30°C
ISO/DIS 4833	General guidance for enumeration of microorganisms - Colony count at 30°C
ISO/DIS 6579	General guidance on methods for the detection of Salmonella
ISO 6887-1983	General guidance for the preparation of dilutions for microbiological examination
ISO 6887-1983	General guidance for the preparation of dilutions for microbiological examination
ISO 6888-1983	General guidance for enumeration of Staphylococcus aureus - Colony count technique
ISO 7218-1985	General guidance for microbiological examinations
ISO 7251-1984	General guidance for enumeration of presumptive Escherichia coli - Most probable number technique
ISO 7402-1985	General guidance for the enumeration of Enterobacteriaceae without resuscitation - MPN technique and colony count technique
ISO 7667-1983	Standard layout for methods of microbiological examination
ISO 7937-1985	General guidance for enumeration of Clostridium perfringens - Colony count technique
ISO 7932-1987	General guidance for enumeration of Bacillus cereus - Colony count technique at 30°C
ISO 7954-1987	General guidance for enumeration of yeasts and moulds - Colony count technique at 25°C
ISO/DIS 8523	General guidance for the detection of Enterobacteriaceae with resuscitation
ISO/DIS 8914	General guidance for the detection of Vibrio-parahaemolyticus

MILK AND MILK PRODUCTS - Sub-Committee ISO/TC 34/SC 5

ISO 5541-1986	Enumeration of coliforms - Part 1: Colony count technique at 30°C
ISO 5541/2-1986	Enumeration of coliforms - Part 2: Most probable number technique at 30°C
ISO 6785-1985	Detection of Salmonella
DP 5944	Dried milk - Detection of coagulase positive staphylococci - Reference method
DIS 6610	Enumeration of microorganisms - Colony count technique at 30°C
DIS 6611	Enumeration of yeasts and moulds - Colony count technique at 25°C
DIS 6730	Milk - Enumeration of psychrotrophic microorganisms - Colony count technique at 6.5°C
DIS 7889	Yoghurt - Enumeration of characteristic microorganisms - Colony count technique at 37°C
DP 7923	Milk, dried milk and cheese - Determination of aflatonine m_1 content
DP 7924	Dried milk, dried whey, lactose - Enumeration of microorganisms Colony count technique at 30°C
DI 8198	Casein and caseinates - Enumeration of microorganisms - Colony count technique at 30°C
DP 8260	Milk and milk products - determination of PCBs
DIS 8261	Milk and milk products - Preparation of test samples and dilutions for microbiological examination
DIS 8552	Milk - Enumeration of psychrotrophic microorganisms - Colony count technique at 21°C (Rapid method)
DIS 8553	Milk - Enumeration of microorganisms - Plate loop technique at 30°C
DIS 8889	Dried milk - Enumeration of Staphylococcus aureus - Colony count technique
DP 8870	Milk and milk products - Detection of thermonuclease produced by coagulase-positive staphylococci
DP 9232	Yoghurt - Detection of characteristic microorganisms
DP 9621/2	Cheese - Enumeration of presumptive Escherichia coli - Part 2: Most probable number technique

MEAT AND MEAT PRODUCTS - Sub-Committee ISO/TS 34/SC 6

ISO 3811-1979	Detection and enumeration of presumptive coliform bacteria and presumptive Escherichia coli (Reference method)
ISO 5552-1979	Detection and enumeration of Enterobacteriaceae (Reference method)
DIS 2293	Enumeration of microorganisms - Colony count technique at 30°C (Reference method) (revision of ISO 2293-1976)
DIS 3100/3	Sampling - Part 1: General instructions and taking primary samples (revision of ISO 3100/1-1975)
DIS 3565	Detection of Salmonella (revision of ISO 3565-1975)
DIS 5551	Enumeration of Staphylococcus aureus - Colony count technique
DIS 6391	Enumeration of Escherichia coli - Colony count technique at 44°C using membrane
DIS 6649	Detection and enumeration of Clostridium perfringens (Reference method)

Draft General Provisions Relating to Hygiene
(Submitted to governments for comment)

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. 1 - 1979).

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. 1) and, where appropriate, with the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (Ref. CAC/RCP 23-1979) 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 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 1-1969-1979), 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.

DRAFT RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR LOW AND ACIDIFIED LOW ACID CANNED FOODS

(At Step 8 of the Procedure)

TABLE OF CONTENTS

DRAFT RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS

1. SECTION I - SCOPE

This Code of practice is concerned with the canning and heat processing of low-acid and acidified low-acid foods packed in hermetically sealed containers. It does not apply to foods in hermetically sealed containers which require refrigeration. Annex I applies specifically to acidified low-acid foods.

2. SECTION II - DEFINITIONS

For the purposes 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 processing and packaging" means the filling of a commercially sterile product into sterilized containers followed by hermetical sealing with a sterilized closure in an atmosphere free from microorganisms.

2.4 "Bleeders" (Bleeds) means small orifices through which steam and other gases escape from the retort throughout the entire heat process.

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

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

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

2.8 "Coming-up-time" means the time, including venting time, which elapses between the introduction of the heating medium into the closed retort and the time when the temperature in the retort reaches the required sterilization temperatures.

2.9 "Commercial sterility of 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 at normal non-refrigerated conditions at which the food is likely to be held during distribution and storage.

2.10 "Commercial sterility of equipment and containers used for aseptic processing and packaging of food" means the condition achieved and maintained by application of heat, or other appropriate treatment, which renders such equipment and containers free from microorganisms capable of growing in the food at temperatures at which the food is likely to be held during distribution and storage.

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" is the pH of the macerated heat processed food product.

2.13 "Flame sterilizer" means an apparatus in which hermetically sealed containers of foods are agitated at atmospheric pressure, by either continuous, discontinuous or reciprocating movement, over gas flames to achieve commercial sterility of foods.

2.14 "Heating curve" means a graphical representation of the rate of temperature change in the food throughout the heat process; this is usually plotted on semi-log graph paper so that the temperature on an inverted log scale is plotted against time on a linear scale.

2.14.1 "Broken heating curve" means a heating curve which shows a distinct change in the rate of heat transfer such that the curve may be represented by two or more distinct straight lines.

2.14.2 "Simple heating curve" means a heating curve which approximates a straight line.

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

2.16 "Holding time", see sterilization time.

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 "Initial temperature" means the temperature of the contents of the coldest container to be processed at the time the sterilizing cycle begins, as specified in the scheduled process.

2.19 "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 "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.

2.21 "Product container" means a container designed to be filled with food and hermetically sealed.

2.21.1 "Hermetically sealed containers" are containers which are sealed to protect the contents against the entry of microorganisms during and after heat processing.

2.21.2 "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 firm finger pressure).

2.21.3 "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 firm finger pressure).

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

2.22 "Retort" means a pressure vessel designed for thermal processing of food packed in hermetically sealed containers.

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

2.24 "Seals" of a semi-rigid container and lid or flexible container, means those parts which are fused together in order to close the container.

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

2.26 "Sterilization time" means the time between the moment sterilization temperature is achieved and the moment cooling started.

2.27 "Thermal process" means the heat treatment to achieve commercial sterility and is quantified in terms of time and temperature.

2.28 "Venting" means thorough removal of the air from steam retorts by steam prior to a scheduled process.

2.29 "Water Activity (a_w)" is the ratio of the water vapour pressure of the product to the vapour pressure of pure water at the same temperature.

3. SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA

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.

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 that 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 non-corrodible material. 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. Canneries should have suitable conveyor systems to transport empty product containers to the filling stations. Their design, structure and installation should ensure that such containers do not become contaminated or unacceptable because of damage.

4.5.2.2 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.

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

4.5.2.4 Retorts must be designed, installed, operated and maintained in accordance with the safety standards for pressure vessels of the agency having jurisdiction. Over-pressure facilities required (e.g., for flexible containers) may mean that the safe working pressure rating of the retort may have to be considerably increased.

4.5.3 Equipment identification

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

4.6 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.

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

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 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, 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 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 of 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, equipment and utensils from contamination. After application, contaminated equipment 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 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 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 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-proofing 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 water in compliance with Sub-Section 7.3 of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1 of this Code. 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 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.

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 substances 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 in to 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 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 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 production process, including filling, closing, heat processing and cooling should be performed as rapidly as possible and under conditions which will prevent contamination, and deterioration, and minimize the growth of microorganisms in the food.

7.2 Prevention of Cross-Contamination

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 prior to being used for contact with end-products.

7.3 Use of Water

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

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

7.4 Packaging

7.4.1 Storage and characteristics of containers

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. 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 the sealed jars.

7.4.2 Inspection of empty product containers

7.4.2.1 Appropriate sampling and inspection schemes should be used by both container manufacturer and canner 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 fault operation of depalletizers and by badly designed or controlled conveyors to filling and seaming machines.**

7.4.2.2 Dirty containers should not be filled. Immediately prior to filling, rigid containers should be cleaned mechanically in an inverted position by suitable air or water jet appliances. Glass containers may also be cleaned by suction (vacuum). Containers intended for use on aseptic filling lines should not be cleaned with water unless they are thoroughly dried prior to sterilization. Inspection is particularly important in the case of glass containers which might possibly contain fragments of glass and glass defects which are difficult to see.

7.4.2.3 Faulty containers should not be filled. Faulty rigid containers and covers include those that have punctures or severe dents, defective side or bottom seams, deformed body flanges or cover curls, abnormal levels of scratches or flaws in the plating or enamel (lacquer) and covers with defective sealing compound or gaskets. Care should be taken to avoid damage to empty containers, closures and container materials which can result from faulty handling prior to closure. **If these are filled, material will be wasted and there is always a danger of damaged containers jamming a filling or sealing machine and necessitating a shutdown. Faulty containers may leak during or after thermal processing and storage.**

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

7.4.3 Proper use of product containers

Product containers must never be used within the cannery for any purpose other than packing food.
They should 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 accidentally find their way back onto the production line and result in the packing of food in the same container with very objectionable or possible dangerous material.

7.4.4 Protection of empty product containers during plant cleaning

Empty containers 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 the containers may be shielded or located so they will not become contaminated or obstruct clean-up operations.

7.4.5 Filling of product containers

7.4.5.1 During filling of containers, contamination of seal or seam areas with product should be avoided and seam or seal areas should be kept as clean and dry as necessary to obtain a satisfactory closure.
Overfilling can lead to contamination of seam or seals and adversely affect container integrity.

7.4.5.2 The filling of containers, either mechanically or by hand, should be controlled so as to meet the filling and headspace requirements as specified in the scheduled process. It is important to achieve a constancy of filling, not only for economic reasons, but also because both the heat penetration and the container integrity may be affected by excessive fill variation. In rotationally processed containers the headspace should be accurately controlled and sufficient to ensure consistent and adequate agitation of the contents. When flexible packaging is used, variations in product particle size, fill-weight and/or headspace may lead to variations in the filled pouch dimensions (thickness) which may adversely affect the heat penetration.

7.4.5.3 Air content of filled flexible and semi-rigid containers should be kept to within specified limits to prevent excessive stressing of the seals during thermal processing.

7.4.6 Exhausting of containers

The exhausting of containers for the removal of air should be controlled so as to meet the conditions for which the scheduled process was designed.

7.4.7 Closing operations

7.4.7.1 Particular attention should be given to the operation, maintenance, routine checking and adjustment of closing equipment. Sealing and closing machines should be fitted and adjusted for each type of container and cover used. Seams and other closures should be tight and secure and meet the requirements of the container manufacturer, the canner and those of the agency having jurisdiction. The equipment manufacturer's or supplier's instructions should be followed meticulously.

7.4.7.2 For heat sealing, seal jaws should be plane-parallel to each other with one or both jaws being heated. The temperature of the jaws should be maintained at the specified temperature over the whole seal area. Pressure build-up on the jaws should be fast enough and final pressure high enough to allow product to be squeezed away from the seals before bonding commences. Flexible pouches are normally sealed in the vertical position. The requirements for the control and operation of sealing equipment are similar to those for semi-rigid containers. The sea area should be free from product contamination.

7.4.8 Inspection of closures

7.4.8.1 Inspection for external defects

During production runs, regular observations should be made for external container defects. At intervals of sufficient frequency to ensure proper

closure, the operator, closure supervisor, or other person competent to inspect container closures should visually examine either the top seam of a can randomly selected from each seaming head, or the closure of any other type of container being used, and should make a record of the observations. Additional visual closure inspections should be made immediately following a jam in a closure machine, after adjustment of closure machines, or after starting up of machines following a prolonged shutdown. Side seams should be visually examined for defects or product leakage.

All pertinent observations should be recorded. Where irregularities are found, corrective action should be taken and recorded.

7.4.8.1.1 Inspection of glass container closures

Glass containers consist of two pieces, viz., a glass container and lid (closure) usually metal, which can be twisted or pried off according to the closure design. 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 should be maintained.

7.4.8.1.2 Inspection and tear-down of double seams

In addition to regular observations for external container defects by visual inspections, tear-down inspections should be performed by a competent individual and the results recorded at intervals of sufficient frequency at each seaming station to ensure maintenance of seam integrity. In the case of reformed cans, both double seams should be observed and inspected. When abnormalities are found, the corrective actions taken should be recorded. Both the measurements and their trends are important in the assessment of seam quality for control purposes.
(Note: References to standard texts or manuals dealing with methods for the tearing down of double seams can be found in Appendix III.)

Either of the two following systems should be used to evaluate can seams:

Micrometer measurement:

The following measurements should be made to the nearest 0.1 mm (0.001 in) using a suitable micrometer. The dimension of each measurement is indicated in figure 1.

Prior to tearing down the double seam, measure and record the following:

a) countersink depth (A)
b) double seam width (length or height) (W)
c) double seam thickness (S)

The following measurements and evaluations should be made on the torn down seam:

a) body hook length (BH)
b) cover hook length (CH)

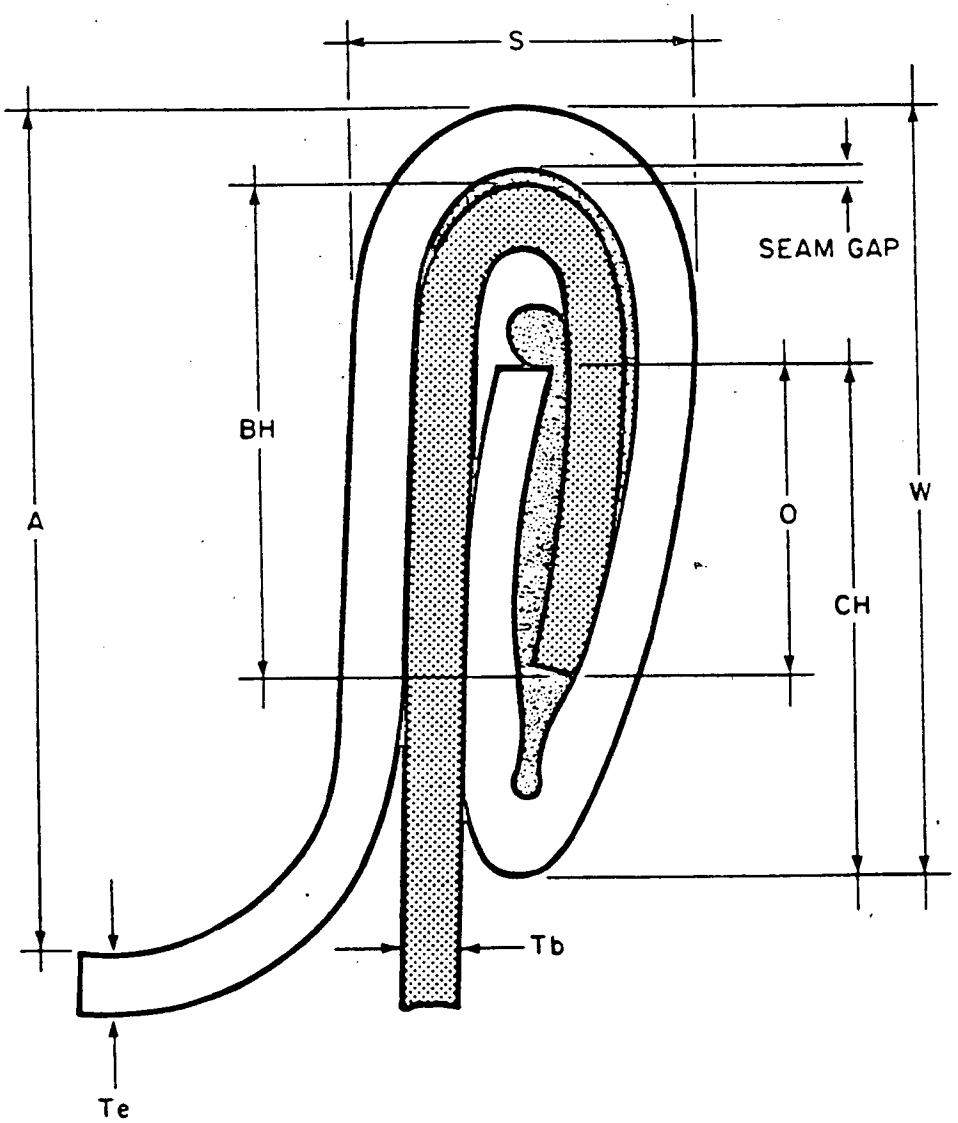
c) end plate thickness (Te)
d) body plate thickness (Tb)
e) overlap (OL)
f) tightness rating
g) juncture rating
h) pressure ridge (chuck impression)

The overlap can be calculated by either of the following two equations:

i) Overlap = 0 = (CH + BH + Te) - W

ii) Percent Overlap = % 0 = $\frac{(BH + CH + Te - W)}{(W - (2Te + Tb))} \times 100$

Figure 1



DOUBLE SEAM DIMENSIONAL TERMINOLOGY

For evaluation of the tightness, juncture (internal droop) and pressure ridge the references given above should be consulted. For round cans the above measurements should be made at a minimum of three points approximately 120° apart around the double seam, (excluding the point of juncture with the side seam).

The free space and body hook butting are also measurements useful in the evaluation of double seam quality. These may be calculated by the following formulae:

Free Space = S - (2Tb + 3Te)

$$\text{Percent Body Hook Butting} = \frac{(BH - 1.1\ Tb)}{(W - 1.1\ (2\ Te + Tb))} \times 100 \quad \underline{\text{or}}$$

$$= b/c \times 100 \text{ (fig. 2)}$$

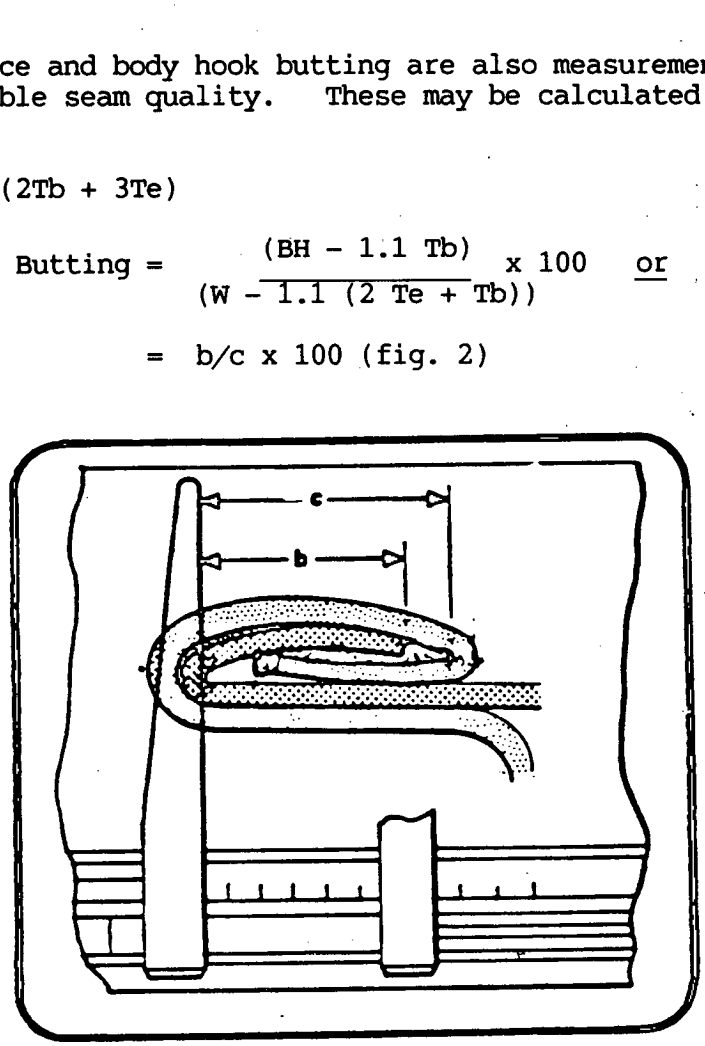


Figure 2

Optical measurements: overlap, body and coverhook lengths are directly visible in a cross-section of the double seam. Dimensions which cannot be optically measured should be measured by the micrometer. (See 7.4.8.1.2). **Wrinkling and other visual attributes can only be observed by stripping of the coverhook.** The segments of the double seam to be examined should, for example, be taken at two or more places on the same double seam of round cans.

The instructions of the container supplier and seaming machine manufacturer should be accurately followed in the assessment of the results by either system and any additional tests. The agency having jurisdiction may have additional requirements which must be met.

Non-round cans require special consideration. Container manufacturer's specifications should be consulted and followed to ensure that the appropriate measurements and observations are made at the critical locations.

7.4.8.1.3 Inspection of heat seals

Appropriate visual inspections and tests should be conducted daily 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.

The strength of a heat seal may be reduced at the elevated temperatures used in retorts, hence it is important that such seals uniformly have the required strength prior to retorting. Small leaks or seal imperfections which may lead to loss of integrity can be aggravated by the physical strains induced by retorting and can permit microbial contamination after heat processing. Inspection should include some physical testing of the uniformity of strength of heat seals. There are several ways of checking seal integrity, for example, burst-pressure testing, seal thickness measurements. Appropriate methods should be obtained from the manufacturers of these containers or materials.

7.4.8.1.4 Closure defects

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

7.4.9 Handling of containers after closure

7.4.9.1 At all times containers should be handled in a manner that protects container and closures from damage which may cause defects and subsequent microbial contamination. Design, operation and maintenance or container handling methods should be appropriate for the types of containers used. Poorly designed or incorrectly operated container conveying and loading systems are known to cause damage. For example, cans which are scramble packed may suffer damage, even when water cushioned, when the level of the cans in a crate or the crateless retort reduces the effectiveness of the cushion. Additionally, damage which may adversely affect integrity may be caused by poor alignment of the can feed mechanism, or by the presence of floaters.

Care should also be taken with semi and fully automatic crate loading systems as well as in-feed conveyor systems to continuous sterilizers. The accumulation of stationary containers on moving conveyors should be kept to a minimum, as this may also damage containers.

7.4.9.2 Semi-rigid and flexible containers may be prone to certain types of damage, (for example, snagging, tearing, cutting and flex cracking). Containers having sharp edges should be avoided as they may cause damage. Semi-rigid and flexible containers should be handled with special care. (See also Sub-Section 7.7.)

7.4.10 Coding

7.4.10.1 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.

7.4.10.2 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.

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

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

7.4.11 Washing

7.4.11.1 Where necessary, filled and sealed containers should be thoroughly washed before sterilization to remove grease, dirt and product from the outside of the container.

7.4.11.2 Washing containers after sterilization should be avoided as it increases the risk of post-processing contamination and also it may be more difficult to remove food debris from the container external surface as it will adhere rather firmly after heating.

7.5 Thermal Processing

7.5.1 General considerations

7.5.1.1 Prior to use, after installation of a thermal processing system or following any modification to or in the use of a system, temperature distribution studies should be carried out to determine the uniformity of temperature within the thermal processing system. Appropriate records should be maintained.

7.5.1.2 Scheduled processes for low-acid canned foods must be established only by competent persons having expert knowledge of thermal processing and having adequate facilities for making such determinations. It is absolutely necessary to establish the required heat process with accepted scientific methods.

The heat process required to make low-acid canned foods commercially sterile depends on the microbial load, storage temperature, the presence of various preservatives, water activity, composition of the products and container size and type. Low-acid foods with pH values above 4.6 may be able to support the growth of many kinds of microorganisms including the heat resistant sporeforming pathogens such as Clostridium botulinum. It should be emphasized that the thermal processing of low-acid canned foods is a very critical operation, involving public health risks and appreciable losses of finished product if under-sterilization occurs.

7.5.2 Establishing scheduled processes

7.5.2.1 The procedure to establish the required heat treatment for a product can be divided into two steps. First the required heat process to achieve commercial sterility should be established on the basis of factors such as:

Microbial flora including Clostridium botulinum and spoilage microorganisms;

Container size and type;
pH of the product;
Product composition or formulation;
Levels and types of preservatives;
Water activity; and
Likely storage temperature of the product.

Due to the nature of the packaging materials used, flexible, and to some extent semi-rigid, containers will change dimensions when exposed to applied physical stress. It is extremely important that the package dimensions, particularly the depth or thickness, shall be as specified in the scheduled process.

7.5.2.2 The second step is to determine the scheduled process taking into account the sterilizing facilities available and the desired product quality by carrying out heat penetration tests. The heat penetration into the product must be determined under the most adverse conditions that are likely to be met in production. For this purpose the temperature in the slowest heating point in the container contents should be monitored during a heat process. It is essential to carry out an adequate number of heat penetration tests to determine the variations which should be taken into account in the scheduled process. The scheduled process can be determined from the time temperature graph obtained.

7.5.2.3 Because of the nature of the packaging materials used in flexible and semi-rigid containers, the container alone cannot generally be used to fix the heat sensing element at the "cold point" in the container contents, which is vital to the proper interpretation of the results. Therefore, other means may be required to ensure that the temperature sensing device is maintained at the pre-determined point in the container contents without altering the heat penetration characteristics. During such testing the container dimensions, specially the thickness, must be controlled.

7.5.2.4 If the heat penetration tests have been made using laboratory simulators, the results should be verified in the production retort under conditions of commercial operation because there may be unexpected deviations in product heating and cooling characteristics.

7.5.2.5 If accurate heat penetration data cannot be obtained, alternative methods acceptable to the agency having jurisdiction should be used.

7.5.2.6 For products showing a simple heating curve only, where size of the container, sterilization temperature, initial temperature or process time are changed from an existing scheduled process the original heat penetration tests can be used to calculate the scheduled process for the new conditions. The

results should be verified by further heat penetration tests when the size of the container is substantially changed.

7.5.2.7 With products showing a broken heating curve, changes in the scheduled processes should be determined using further heat penetration tests or other methods acceptable to the agency having jurisdiction.

7.5.2.8 The result of these heat process determinations together with established critical factors should be incorporated into the scheduled process. For conventionally sterilized canned products such a scheduled process should include as a minimum the following data:

- Products and filling specification, including any restrictions on ingredient changes;
- Container size (dimensions) and type;
- Container orientation and spacing in retort where appropriate;
- Ingoing weight of product(s) including liquor where appropriate;-Headspace, where applicable;
- Minimum initial product temperature;
- Venting procedures, and come-up procedures for certain retort systems, where applicable, should be determined on fully loaded retorts;
- Type and characteristics of heat processing system;
- Sterilization temperature;
- Sterilization time;
- Overpressure, where applicable;
- Cooling method.

Any changes in the product specifications should be evaluated as to their effect on the adequacy of the process. If the scheduled process is found to be inadequate it must be re-established.
Product and filling specifications should contain at least the following where applicable: full recipe and preparation procedures, filling weights, headspace, drained weight, temperature of product at filling, consistency. Small deviations from the product and filling specifications which may seem negligible can cause serious deviations in the heat penetration properties of the product. For rotational sterilization, viscosity (rather than consistency) can be an important factor, and this should be specified.

7.5.2.9 Air content of filled flexible and semi-rigid containers should be kept to a minimum to prevent excessive stressing of the seals during thermal processing.

7.5.2.10 For aseptically processed packs a similar list should be made which also should include equipment and container sterilization requirements.

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

7.5.3 Heat processing room operations

7.5.3.1 Scheduled processes and venting procedures to be used for products and container sizes being packed should be posted in a conspicuous place near the processing equipment. Such information should be readily available to the retort or processing system operator and to the agency having jurisdiction.

It is essential that all heat processing equipment should be properly designed, correctly installed and carefully maintained. Only properly determined scheduled processes must be used.

7.5.3.2 Heat processing and associated processing operations should be performed and supervised only by properly trained personnel. It is extremely important that the heat processing is carried out by operators under the supervision of personnel who understand the principles of heat processing and who realize the need to follow instructions closely.

7.5.3.3 Heat processing should be commenced as soon as possible after closing to avoid microbial growth or changes in heat transfer characteristics of the products. If during breakdowns the production rate is low, the product should be processed in partly filled retorts. Where necessary, a separate scheduled process should be established for partly filled retorts.

7.5.3.4 In batch operations the sterilization status of the containers should be indicated. All retort baskets, trucks, cars or crates containing unretorted food product or at least one of the containers on the top of each basket, etc., should be plainly and conspicuously marked with a heat sensitive indicator, or by other effective means, which will visually indicate whether or not each such unit has been retorted. Heat sensitive indicators attached to baskets, trucks, cars or crates must be removed before they are refilled with containers.

7.5.3.5 The initial temperature of the contents of the coldest containers to be processed should be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process.

7.5.3.6 An accurate, clearly visible clock or other suitable timing device should be installed in the heat processing room and times should be read from this instrument and not from wristwatches, etc. Where two or more clocks or other timing devices are used in a heat processing room they should be synchronized.

7.5.3.7 Generally temperature/time recording devices are not satisfactory for measuring the sterilization or thermal process times.

7.5.4 Critical factors and the application of the scheduled process

In addition to the minimum product initial temperature, sterilization time and temperature together with overpressure, where applicable, as specified in the scheduled process, other critical factors specified should be measured, controlled and recorded at intervals of sufficient frequency to ensure that these factors remain within the limits specified in the scheduled process. Some examples of critical factors are:

(i) Maximum fill-in or drained weight.

(ii) Minimum headspace of product containers.

(iii) Product consistency or viscosity as determined by objective measurement on product taken before processing.

(iv) Product and/or container type which may result in layering or stratification of the product, or in changes in the container dimensions hence requiring specific orientation and spacing of the containers in the retort.

(v) Percent solids.

(vi) Minimum net weight.

(vii) Minimum closing vacuum (in vacuum packed products).

7.6 Equipment and Procedures for Heat Processing Systems

7.6.1 Instruments and controls common to different heat processing systems

7.6.1.1 Indicating thermometer

Each retort and/or product sterilizer should be equipped with at least one indicating thermometer. The mercury-in-glass thermometer is recognized as the most reliable temperature indicating instrument at the present time. An alternative instrument having equal or better accuracy and reliability may be used subject to the approval of the official agency having jurisdiction. The mercury-in-glass thermometer should have divisions that are easily readable to 0.5°C (1°F) and whose scale contains not more than 4.0°C per cm (17°F per inch) of graduated scale. Thermometers 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 of aspect to that which it is installed in the retort. Such tests should be performed just 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 thermometer that deviates more than 0.5°C (1°F) from the standard should be replaced. A daily inspection of mercury-in-glass thermometers should be made to detect and replace, if found, thermometers with divided mercury column or other defects.

7.6.1.2 Where other types of thermometer are used, routine tests should be made which ensure at least equivalent performance to that described for mercury-in-glass thermometers. Thermometers which do not meet these requirements should be replaced or repaired immediately.

7.6.1.3 Temperature/time recording devices

Each retort and/or product sterilizer should be equipped with at least one temperature/time recording device. This recorder may be combined with the steam controller and may be a recording-controlling instrument. It is important that the correct chart is used for each device. Each chart should have a working scale of not more than 12°C per cm (55°F per in.) within a range of 10°C (20°F) of the sterilizing temperature. The recording accuracy should be equal to or better than ± 0.5°C (1°F) at the sterilizing temperature. The recorder should agree as closely as possible (preferably within 0.5°C (1°F)) and should not be higher than the indicating thermometer at the sterilizing temperature. 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.

7.6.1.4 Pressure gauges

Each retort should be equipped with a pressure gauge. The gauge should be checked for accuracy at least once a year. The gauge should have a range from zero such that the safe working pressure of the retort is about two-thirds of the full scale and be graduated in divisions not greater than 0.14 kg/cm² (2 p.s.i.). The gauge dial should not be less than 102 mm (4.0 in.) in diameter. The instrument may be connected to the retort by means of a gauge cock and syphon.

7.6.1.5 Steam controller

Each retort should be equipped with a steam controller to maintain the retort temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

7.6.1.6 Pressure relief valve

An adjustable pressure relief valve of a capacity sufficient to prevent undesired increase in retort pressure and approved by the agency having jurisdiction should be fitted.

7.6.1.7 Timing devices

These should be checked as often as necessary to ensure accuracy.

7.6.2 Pressure processing in steam

7.6.2.1 Batch (Still retorts)

7.6.2.1.1 Indicating thermometers and temperature/time recording devices (see Sub-Sections 7.6.1.1, 7.6.1.2 and 7.6.1.3)

Bulb sheaths of indicating thermometers and probes of temperature recording devices should be installed either within the retort shell or in external wells attached to the retort. External wells should be equipped with an adequate bleeder opening so located as to provide a constant flow of steam past the length of the thermometer bulb or probe. The bleeder for external wells should emit steam continuously during the entire heat processing period. Thermometers should be installed where they can be accurately and easily read.

7.6.2.1.2 Pressure gauges (see sub-section 7.6.1.4)

7.6.2.1.3 Steam controllers (see Sub-Section 7.6.1.5)

7.6.2.1.4 Pressure relief valve (see Sub-Section 7.6.1.6)

7.6.2.1.5 Steam inlet

The steam inlet to each retort should be large enough to provide sufficient steam for proper operation of the retort, and should enter at a suitable point to facilitate air removal during venting.

7.6.2.1.6 Crate supports

A bottom crate support should be employed in vertical still retorts so as not to substantially affect venting and steam distribution. Baffle plates should not be used in the bottom of retorts. Centering guides should be installed in vertical retorts to ensure adequate clearance between the retort crate and the retort wall.

7.6.2.1.7 Steam spreaders

Perforated steam spreaders, if used, should be checked regularly to ensure they are not blocked or otherwise inoperative. Horizontal still retorts should be equipped with perforated steam spreaders that extend for the full length of the retort. In vertical still retorts the perforated steam spreaders, if used, should be in the form of a cross or coil. The number of perforations in spreaders for both horizontal and vertical still retorts should be such that the total cross-sectional area of the perforations is equal to 1 1/2 to 2 times the cross-sectional area of the smallest part of the steam inlet line.

7.6.2.1.8 Bleeders and condensate removal

Bleeders should be of suitable size, (e.g., 3 mm (1/8 in.)), and location and should be fully open during the entire process, including the coming-up-time. In retorts having top steam inlet and bottom venting, a suitable device should be installed in the bottom of the retort to remove condensate and a bleeder fitted to indicate condensate removal. All bleeders should be arranged in such a way that the operator can observe that they are functioning properly. Bleeders are not part of the venting system.

7.6.2.1.9 Stacking equipment

Crates, trays, gondolas, dividers, etc., for holding product containers should be so constructed that steam can adequately be circulated

around the containers during the venting, coming-up and sterilization times.

7.6.2.1.10 Vents

Vents should be located in that portion of the retort opposite the steam inlet and should be designed, installed and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents should be fully opened to permit rapid removal of air from retorts during the venting period. Vents should not be connected directly to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single still retort, it should be controlled by a single suitable valve. The manifold should be of a size such that the cross-sectional area of the manifold is larger than the total cross-subsection area of all connecting vents. The discharge should not be directly connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts should lead to the atmosphere. The manifold header should not be controlled by a valve and should be of a size such that the cross-subsectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Other vent piping arrangements and operating procedures which differ from the above specifications may be used, provided that there is evidence that they accomplish adequate venting.

7.6.2.1.11 Air inlets

Retorts using air for pressure cooling should be equipped with an adequate tight closing valve and piping arrangement on the air line to prevent air leakage into the retort during processing.

7.6.2.1.12 Critical factors (see Sub-Section 7.5.4)

7.6.2.2 Batch agitating retorts

7.6.2.2.1 Indicating thermometers and temperature/time recording devices (see Sub-Sections 7.6.1.1, 7.6.1.2 and 7.6.1.3)

7.6.2.2.2 Pressure gauges (see Sub-Section 7.6.1.4)

7.6.2.2.3 Steam controller (see Sub-Section 7.6.1.5)

7.6.2.2.4 Pressure relief valve (see Sub-Section 7.6.1.6)

7.6.2.2.5 Steam inlet (see Sub-Section 7.6.2.1.5)

7.6.2.2.6 Steam spreaders (see Sub-Section 7.6.2.1.7)

7.6.2.2.7 Bleeders and condensate removal (see Sub-Section 7.6.2.1.8)

At the time the steam is turned on, the drain should be opened for a time sufficient to remove steam condensate from the retort and provision should be made for continuing drainage of condensate during the retort operation. The bleeders in the bottom of the shell serve as an indicator of continuous condensate removal. The retort operator should observe and periodically record how this bleeder is functioning.

7.6.2.2.8 Stacking equipment (see Sub-Section 7.6.2.1.9)

7.6.2.2.9 Vents (see Sub-Section 7.6.2.1.10)

7.6.2.2.10 Air inlets (see Sub-Section 7.6.2.1.11)

7.6.2.2.11 Retort or reel speed timing

The rotational speed of the retort or reel is critical and should be specified in the scheduled process. The speed should be adjusted and recorded when the retort is started, and at intervals of sufficient frequency to insure that the retort speed is maintained as specified in the scheduled process. If a change of speed inadvertently occurs such should be recorded together with corrective action taken. Additionally, a recording tachometer may be used to provide a continuous record of the speed. The speed should be checked against a stop watch at least once per shift. A means of preventing unauthorized speed changes on retorts should be provided.

7.6.2.2.12 Critical factors (see Sub-Section 7.5.4)

7.6.2.3 Continuous agitating retorts

7.6.2.3.1 Indicating thermometers and temperature/time recording devices (see Sub-Sections 7.6.1.1, 7.6.1.2 and 7.6.1.3)

7.6.2.3.2 Pressure gauges (see Sub-Section 7.6.1.4)

7.6.2.3.3 Steam controllers (see Sub-Section 7.6.1.5)

7.6.2.3.4 Pressure relief valve (see Sub-Section 7.6.1.6)

7.6.2.3.5 Steam inlet (see Sub-Section 7.6.2.1.5)

7.6.2.3.6 Steam spreaders (see Sub-Section 7.6.2.1.7)

7.6.2.3.7 Bleeders and condensate removal (see Sub-Section 7.6.2.2.7)

7.6.2.3.8 Vents (see Sub-Section 7.6.2.1.10)

7.6.2.3.9 Retort and reel speed timing (see Sub-Section 7.6.2.2.11)

7.6.2.3.10 Critical factors (see Sub-Section 7.5.4)

7.6.2.4 Hydrostatic retorts

7.6.2.4.1 Indicating thermometers (see Sub-Section 7.6.1.1)

Thermometers should be located in the steam dome near the steam-water interface and preferably also at the tope of the dome. Where the scheduled process specifies maintenance of particular temperatures of water in the hydrostatic water legs, at least one indicating thermometer should be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read.

7.6.2.4.2 Temperature/time recording device (see Sub-Section 7.6.1.3)

The temperature recorder probe should be installed either within the steam dome or in a well attached to the dome. Additional temperature recorder probes should be installed in the hydrostatic water legs if the scheduled process specifies maintenance of particular temperatures in these hydrostatic water legs.

7.6.2.4.3 Pressure gauges (see Sub-Section 7.6.1.4)

7.6.2.4.4 Steam controllers (see Sub-Section 7.6.1.5)

7.6.2.4.5 Steam inlet (see Sub-Section 7.6.2.1.5)

7.6.2.4.6 Bleeders

Bleeders should be of suitable size, (e.g., 3 mm (1/8 in.)) and location and should be fully open during the entire process, including the come-up-time and should be suitable located in the steam chamber or chambers to remove air which may enter with the steam.

7.6.2.4.7 Venting

Before the start of processing operations, the retort steam chamber or chambers should be vented to ensure removal of air.

7.6.2.4.8 Conveyor speed

The speed of the container conveyor should be specified in the scheduled process and should be determined with an accurate stop watch, and recorded at the start of processing and at intervals of sufficient frequency to insure that the conveyor speed is maintained as specified. An automatic device should be used to stop the conveyor and provide warning when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes should be provided. Additionally a recording device may be used to provide a continuous record of the speed.

7.6.2.4.9 Critical factors (see Sub-Section 7.5.4)

7.6.3 Pressure processing in water

7.6.3.1 Batch (Still retorts)

7.6.3.1.1 Indicating thermometer (see Sub-Section 7.6.1.1)

Bulbs of indicating thermometers should be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts this should be in the side at the centre, and the thermometer bulbs should be inserted directly into the retort shell. In both vertical and horizontal retorts, the thermometer bulbs should extend directly in to the water for a minimum of at least 5 cm (2 in.).

7.6.3.1.2 Temperature/time recording device (see Sub-Section 7.6.1.3)

When the retort is equipped with a temperature recording device, the recording thermometer bulb should be at a location adjacent to the indicating thermometer or at a location which adequately represents the lowest temperature in the retort. In any case, care should be taken that the steam does not strike the controller bulb directly.

7.6.3.1.3 Pressure gauge (see Sub-Section 7.6.1.4)

7.6.3.1.4 Pressure relief valve (see Sub-Section 7.6.1.6)

7.6.3.1.5 Pressure control valve

In addition to the pressure relief valve an adjustable pressure control valve of a capacity sufficient to prevent undesired increases in retort pressure, even when the water valve is wide open, should be installed in the overflow line. This valve also controls the maximum water level in the retort. The valve should be suitable screened to prevent blockage by floating containers or debris.

7.6.3.1.6 Pressure recorder

A pressure recorder device is needed and may be combined with a pressure controller.

7.6.3.1.7 Steam controller (see Sub-Section 7.6.1.5)

7.6.3.1.8 Steam inlet

The steam inlet should be large enough to provide sufficient steam for proper operation of the retort.

7.6.3.1.9 Steam distribution (see Sub-Section 7.6.2.1.7)

Steam should be distributed from the bottom of the retort in a manner to provide uniform heat distribution throughout the retort.

7.6.3.1.10 Crate supports (see Sub-Section 7.6.2.1.6)

7.6.3.1.11 Stacking equipment

Crates, trays, gondolas, etc. and divider plates when used for holding product containers, should be so constructed that the heating water can adequately circulate around the containers during the coming-up and sterilization times. Special equipment will be required to ensure that the thickness of filled flexible containers will not exceed that specified in the scheduled process and that they will not become displaced and overlap one another during the thermal process.

7.6.3.1.12 Drain valve

A screened, non-clogging, water-tight valve should be used.

7.6.3.1.13 Water level

There should be a means of determining the water level in the retort during operation (e.g. by using a water gauge glass or petcock(s)). Water should adequately cover the top layer of containers during the entire coming-up, sterilizing and cooling periods. This water level should be at least 15 cm (6 in.) over the top layer of product containers in the retort.

7.6.3.1.14 Air supply and controls

In both horizontal and vertical still retorts for pressure processing in water, a means should be provided for introducing compressed air at the proper pressure and rate. The retort pressure should be controlled by an automatic pressure control unit. A non-return valve should be provided in the air supply line to prevent water from entering the system. Air or water circulation should be maintained continuously during the coming-up-time, processing and cooling periods. Air is usually introduced with steam to prevent "steam hammer". If air is used to promote circulation it should be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort.

7.6.3.1.15 Cooling water entry

In retorts processing glass jars the cooling water should be introduced in a manner which avoids direct impingement on the jars, in order to prevent breakage by thermal shock.

7.6.3.1.16 Retort headspace

The air pressure in the headspace of the retort should be controlled throughout the process.

7.6.3.1.17 Water circulation

All water circulations systems, whether by pumps or air, used for heat distribution should be installed in such a manner that an even temperature distribution throughout the retort is maintained. Checks for correct operation should be made during each processing cycle, for example, alarm systems to indicate malfunction of water circulation.

7.6.3.1.18 Critical factors in the application of the scheduled process (see Sub-Section 7.5.4)

7.6.3.2 Batch agitating retorts

7.6.3.2.1 Indicating thermometer (see Sub-Section 7.6.3.1.1)

7.6.3.2.2 Temperature/time recording device (see Sub-Section 7.6.1.2)

The recording thermometer probe should be located adjacent to the bulb of the indicating thermometer.

7.6.3.2.3 Pressure gauges (see Sub-Section 7.6.1.3)

7.6.3.2.4 Pressure relief valve (see Sub-Section 7.6.1.5)

7.6.3.2.5 Pressure control valve (see Sub-Section 7.6.3.1.5)

7.6.3.2.6 Pressure recorder (see Sub-Section 7.6.3.1.6)

7.6.3.2.7 Steam controller (see Sub-Section 7.6.1.4)

7.6.3.2.8 Steam inlet (see Sub-Section 7.6.2.1.5)

7.6.3.2.9 Steam spreader (see Sub-Section 7.6.2.1.7)

7.6.3.2.10 Drain valve (see Sub-Section 7.6.3.1.12)

7.6.3.2.11 Water level indicator (see Sub-Section 7.6.3.1.13)

7.6.3.2.12 Air supply and controls (see Sub-Section 7.6.3.1.14)

7.6.3.2.13 Cooling water entry (see Sub-Section 7.6.3.1.15)

7.6.3.2.14 Water circulation (see Sub-Section 7.6.3.1.17)

7.6.3.2.15 Retort speed timing (see Sub-Section 7.6.2.2.11)

7.6.3.2.16 Critical factors in the application of the scheduled process (see Sub-Section 7.5.4)

7.6.4 Pressure processing in steam-air mixtures

Both the temperature distribution and the rates of heat transfer are critically important in the operation of steam-air retorts. There should be a means of circulating the steam-air mixtures to prevent formation of low temperature pockets. The circulating system used should provide acceptable heat distribution as established by adequate tests. The operation of the processing system should be the same as that required by the scheduled process. A recording pressure controller should control the air inlet and the steam-air mixture outlet. Because of the variety of existing designs, reference should be made to the equipment manufacturer and to the agency having jurisdiction for details of installation, operation and control. **Some items of equipment may be common to those already in this code and those standards given may be relevant.**

7.6.5 Aseptic processing and packaging systems

7.6.5.1 Product sterilization equipment and operation

7.6.5.1.1 Temperature indicating device (see Sub-Section 7.6.1.3)

The device should be installed in the product holding section outlet in such a way that it does not interfere with product flow.

7.6.5.1.2 Temperature recording device (see Sub-Section 7.6.1.3)

The temperature sensor should be located in the sterilized product at the holding section outlet in such a way that it does not interfere with the product flow.

7.6.5.1.3 Temperature recorder-controller

An accurate temperature recorder-controller should be located in the product sterilizer at the final heater outlet in such a way as not to interfere with product flow. It should be capable of ensuring that the desired product sterilization temperature is maintained.

7.6.5.1.4 Product-to-product regenerators

Where a product-to-product regenerator 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 ensures that any leakage in the regenerator will be from the sterilized product into the unsterilized product.

7.6.5.1.5 Differential pressure recorder-controller

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 in.) 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.

7.6.5.1.6 Metering pump

A metering pump should be located upstream from the holding section and should be operated consistently to maintain the required rate of product flow. A means of preventing unauthorized speed changes should be provided. The product flow rate, which is the critical factor controlling the sterilization holding time, should be checked with sufficient frequency to ensure that it is as specified in the scheduled process.

7.6.5.1.7 Product-holding section

The product sterilizer holding section should be designed to give continuous holding of the product, including particulates, for at least the minimum holding time specified in the scheduled process. It should be sloped upward at least 2.0 cm/m (0.25 in. per foot). The holding section should be designed so that no portion between the product inlet and the product outlet can be heated.

7.6.5.1.8 Startup

Prior to the start of aseptic processing operations, the product sterilizer should be brought to a condition of commercial sterility.

7.6.5.1.9 Temperature drop in product holding section

When product temperature in the holding section drops below the temperature specified in the scheduled process, the product in the holding section and any downstream portions affected should be diverted to recirculation or waste and the system returned to a condition of commercial sterility before flow is resumed to the filter.

7.6.5.1.10 Loss of proper pressures in the regenerator

Where a regenerator 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 in.) 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.

7.6.5.2 Product container sterilization, filling and closing operations

7.6.5.2.1 Recording device

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 pre-sterilization 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.

7.6.5.2.2 Timing method(s)

A method(s) should be used either to give the retention time of containers, and closure 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.

7.6.5.2.3 Startup

Prior to the start of filling, both the container and closure sterilizing system and the product filling and closing system should be brought to a condition of commercial sterility.

7.6.5.2.4 Loss of sterility

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

7.6.6 Flame sterilizers, equipment and procedures

The container conveyor speed should be specified in the scheduled process. The container conveyor speed should be measured and recorded at the start of operations and at intervals of sufficient frequency to ensure that the conveyor speed is as specified in the scheduled process. Alternatively, a recording tachometer may be used to

provide a continuous record of the speed. Speed should be checked against a stop watch at least once per shift. A means of preventing unauthorized speed changes on the conveyor should be provided. The surface temperature of at least one container from each conveyor channel should be measured and recorded at the end of the pre-heat section and at the end of the holding period at intervals of sufficient frequency to ensure that the temperatures specified in the scheduled process are maintained.

7.6.7 Other systems

Systems for the thermal processing of low-acid foods in hermetically sealed containers should conform to the applicable requirements of this Code and should ensure that the methods and control used for the manufacture, processing and/or packing of such foods are operated and administered i a manner adequate to achieve commercial sterility.

7.6.8 Cooling

To avoid thermophilic spoilage and/or organoleptic deterioration of the product, the containers should be cooled as rapidly as possible to an internal temperature of 40°C (104°F). In practice, water cooling is usually used for this purpose. Further cooling is done in air to evaporate the adhering water film. This aids in preventing both microbiological contamination and corrosion. Air cooling alone may also be used for products in which thermophilic spoilage is not a problem, provided that the product and the containers are suitable for air cooling. Unless otherwise indicated, extra pressure should be applied during cooling to compensate for the internal pressure inside the container at the beginning of cooling to prevent the deformation or leakage of containers. This can be minimized by equating the over pressure with the internal pressure.

When the integrity of the container is not adversely affected, water or air under atmospheric pressure may be used for cooling. Extra pressure is commonly achieved by introducing water or compressed air into the retort under pressure.

To reduce thermal shock to glass containers the temperature of the cooling medium in the retort should be reduced slowly during the initial cooling phase.

In all instances the container and closure manufacturers' instructions should be followed.

7.6.8.1 Cooling water quality

Cooling water should consistently be of low microbial content, for example, with an aerobic mesophile count of less tan 100 c.f.u./ml. Records should be kept of cooling water treatment and of its microbiological quality.

Although containers may normally be considered hermetically sealed, a small number of containers may allow intake of water during the cooling period mainly due to mechanical stress and pressure differential.

7.6.8.2 To ensure effective disinfection, chlorine or an alternative disinfectant must be thoroughly mixed with the water to a level which will

minimize the risk of contamination of the can contents during cooling: for chlorination a 20 minute minimum contact time at suitable pH and temperature is normally considered adequate.

The adequacy of a suitable chlorination treatment may be established by:

a) the presence of a measurable residual free chlorine in the water at the end of the contact time; and

b) detectable amounts of residual free chlorine in the water after it has been used for cooling containers. (Residual free chlorine content of 0.5 to 2 p.p.m. is usually considered adequate. Chlorine levels in excess of this may accelerate corrosion of certain metallic containers.)

c) a low microbial content of the water at the point of use. The temperature and pH of the water should be measured and recorded for reference.

Once a suitable system has been established, the adequacy of treatment is indicated by measuring and recording the free residual chlorine according to b) above. In addition water temperature and pH should be measured and recorded since marked changes from the reference values previously established may adversely affect the disinfecting action of the added chlorine.

The amount of chlorine required for adequate disinfection will depend upon the chlorine demand of the water, its pH and temperature. Where water with a high level of organic impurity, (e.g. surface water) is used as a source of supply, it will usually be necessary to provide suitable treatment for separation of impurities, prior to disinfection by chlorine thereby reducing excessive chlorine demand. Recirculated cooling water may gradually increase in organic load and it may be necessary to reduce this by separation or other means. If the pH of cooling water is greater than 7.0 or its temperature is above 30oC it may be necessary to increase the minimum contact time or concentration of chlorine to achieve adequate disinfection. Similar actions may be necessary with water disinfected by means other than addition of chlorine.

It is essential that cooling water storage tanks be constructed of impervious materials and protected by close-fitting covers thus preventing contamination of the water by seepage, entry of surface waters or other sources of contamination. These tanks should also be fitted with baffles or other means of ensuring thorough mixing of water and chlorine or other disinfectant. They should be of sufficient capacity to ensure that the minimum residence time is achieved under maximum throughput conditions. Particular attention should be paid to positioning of inlet and outlet pipes to ensure all water follows a pre-determined flow pattern within the tank. Cooling tanks and systems should be drained, cleaned and refilled periodically to prevent excessive organic and microbial buildup. Records should be kept of such procedures.

Measurements of microbial content and chlorine or alternative disinfectant levels should be made with sufficient frequency to enable adequate control of cooling water quality. Records should be kept of cooling water treatment and of its microbiological quality.

7.6.8.3 Where contaminated water with a high level of organic impurity, such as river water, is used as a source of supply it will be necessary to provide a suitable treatment system to cope with suspended impurities followed by chlorination or other suitable disinfection treatment.

7.7 Post Process Container Handling

A small proportion of correctly made and closed cans may be subject to temporary leaks (microleakage) during the later stages of cooling and for as long as the cans and their seams remain externally wet. The risk of microleakage may be increased if poor seam quality and inadequately designed container conveyor, handling, labelling and packaging equipment result in increased can abuse. When such leakage occurs, water on the can provides a source and a transport medium for microbial contamination from conveyor and equipment surfaces to areas on or near the can seams. To control leaker infection it is necessary to ensure that:

1) cans are dried as soon as possible after processing;

2) conveying systems and equipment are designed to minimize abuse of the containers; and

3) conveyor and equipment surfaces are effectively cleaned and disinfected.

Glass jars may be similarly affected.

The post-process area should be effectively separated from raw food to avoid cross contamination. Precautions should also be taken to ensure personnel from the raw food areas do not have uncontrolled access to the post-process area.

Temporary leaks are not a problem with correctly formed heat seals on semi-rigid and flexible containers. However, leakage may occur through defective seals and perforations in the container bodies. Therefore the requirements for drying containers, minimizing abuse and ensuring effective cleaning and disinfection of conveyor systems are equally applicable to these types of containers.

7.7.1 Retort crate unloading

To minimize leaker infection especially by pathogenic microorganisms, processed containers should not be manually handled while still wet.

Before unloading retort crates, water should be drained from container surfaces. In many instances this can be accomplished by tilting the retort crates as far as possible and allowing sufficient time for the water to drain. The containers should remain in the crates until dry before manual unloading. Manual unloading of wet containers presents a risk of contamination from pathogenic microorganisms which may be transferred from the hands onto the container.

7.7.2 Container drying precautions

Where used, dryers should be shown not to cause damage to or contaminate containers and should be readily accessible for routine cleaning and disinfection. Not all driers meet these requirements. The drying unit should be employed in the line as soon as practicable after cooling.

Driers do not remove all cooling water residues from container external surfaces but they reduce significantly the time containers are wet. This reduces the length of post-drier conveying equipment that becomes wet during production periods and which requires extra cleaning and disinfection measures.

The drying of batch processed containers may be accelerated by dipping the filled retort crates in a tank of a suitable surfactant solution. After immersion (15 sec) the crates should be tipped and allowed to drain.

It is essential that any dipping solution be kept at not less than 80°C to avoid microbial growth and be changed at the end of each shift. Technically appropriate anti-corrosion agents may also be incorporated in dipping solutions.

7.7.3 Container abuse

Mechanical shock or abuse is mainly caused by either containers knocking into each other, (for example, on gravity runways), or by pressing against each other, for example, when the backup of containers on cable runways results in the development of excessive pressure and possible seam damage due to cable burn. Abuse may also be caused by containers hitting protruding sections on conveying systems. Such mechanical shocks may cause temporary or permanent leaks and result in infection if the containers are wet.

Careful attention to the design, layout, operation and maintenance of conveying systems is necessary if abuse is to be reduced to a minimum. One of the commonest design faults is unnecessary changes in the height of different sections of the conveying system. For lines speeds above 300 cpm, (containers per minute), multi-lane conveying systems coupled with container accumulation tables are recommended. Sensors should be installed to allow the conveyor to be stopped if excessive buildup of containers occur. Poor seam quality in combination with inadequately designed, adjusted or maintained unscrambling, labelling and packaging equipment increases the risk of microleakage. Special care should be taken to prevent abuse to glass containers and their closures, as well as to semi-rigid and flexible containers.

Abuse of semi-rigid and flexible containers may lead to perforation of the container or to flexcracking in the case of pouches. Therefore these types of containers should not be allowed to fall or slide from one section to another of the conveying system.

7.7.4 Post process cleaning and disinfection

Any container conveyor or equipment surface that is wet during production periods will permit rapid growth of infecting microorganisms unless it is effectively cleaned at least once every 24 hours and, in addition,l regularly disinfected during production periods. The chlorine in the cooling water deposited on these surfaces from cooled cans is not an adequate disinfectant. Any cleaning and disinfection program that is instituted should be carefully evaluated before being adopted as a routine procedure. For example, properly treated surfaces should have a mesophilic aerobic bacterial level of less than 500 c.f.u. per 25/cm² (4/in²). The assessment of the continuing effectiveness of post process cleaning and disinfection programs can only be made by bacteriological monitoring.

Conveying systems and equipment should be critically examined with the view to replacing unsuitable materials. Porous materials should not be used and surfaces which become porous, heavily corroded or damaged should be repaired or replaced.

All personnel should be made fully aware of the importance of personal hygiene and good habits in relation to the avoidance of post process container recontamination through handling of containers.

Post-cooling areas of continuous cookers, including hydrostatic cookers, may constitute continuing sources of high bacterial concentrations unless stringent measures are taken to clean and disinfect them regularly to avoid microbial buildup.

7.7.5 Containers should be overwrapped if such is required to protect container integrity. If they are overwrapped containers should be dry.

7.8 Evaluation of Deviation in Heat Processing

7.8.1 Whenever the in-process monitoring records, processor check or other means disclose that a low-acid food or container system 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 the 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.

7.8.2 In the case of continuous agitating retorts emergency scheduled processes may be established to permit compensation for temperature deviations, not to exceed 5°C (10°F). Such scheduled processes must be established in accordance with Sub-Sections 7.5.1 and 7.5.2 of this Code.

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

Permanent and legible dated records of time, temperature, code mark and other pertinent details should be kept concerning each load. Such records are essential as a check on processing operations and will be invaluable if some question arises as to whether a particular lot had received adequate heat processing. These records should be made by the retort or processing system operator or other designated person, on a form which should include: product name and style, the code lot number, the retort or processing system and recorder chart identification, the container size and types, the approximate number of containers per code lot interval, the minimum initial temperature, the scheduled and actual processing time and temperature, the indicator and recorder thermometer reading, and other appropriate processing data. Closing vacuum (in vacuum-packed products), fill-in weights, filled flexible pouch thickness, and/or other critical factors specified in the scheduled process should also be recorded. Records of water quality and plant hygiene should be kept. When deviations occur in the application of the scheduled process refer to Sub-Section 7.8 of this Code. In addition, the following records should be maintained.

8.1.1 Processing in steam

8.1.1.1 Batch still retorts

Time steam on, venting time and temperature, time sterilization temperature reached, time steam off.

8.1.1.2 Batch agitating retorts

As for still retorts (Sub-Section 8.1.1.1) with additions of functioning of condensate bleeder as well as retort and/or reel speed. Where specified in the scheduled process it is important to also record containers headspace and critical factors such as in-going product consistency and/or viscosity, maximum drained weight, minimum net weight and percent solid (Sub-Section 7.5.4).

8.1.1.3 Continuous agitating retorts (see Sub-Section 8.1.1.2)

8.1.1.4 Hydrostatic retorts

The temperature in the steam chamber at just above the steam-water interface, at the top of the dome, if applicable, speed of the container conveyor, and, where the scheduled process specifies, measurements of particular temperatures and water levels in the hydrostatic water legs.

In addition, for agitating hydrostatic retorts, rotative chain speed, and other critical factors such as the headspace and in-going product consistency.

8.1.2 Processing in water

8.1.2.1 Batch still retorts

Time steam on, coming-up time, time sterilization starts, sterilization temperature, water level, water circulation and pressure maintained, time steam off.

8.1.2.2 Batch agitating retorts

As for still retorts (Sub-Section 8.1.2.1) with the addition of retort and reel speed. where specified in the scheduled process it is important to record container headspace and critical factors such as in-going product consistency, maximum drained weight, minimum net weight and percent solids (Sub-Section 7.5.4).

8.1.3 Processing in steam/air mixtures

8.1.3.1 Batch still retorts

Time steam on, coming-up-time, time sterilization starts, maintenance of circulation of steam/air mixture, pressure, sterilization temperature, time steam off.

8.1.4 Aseptic processing and packaging

Detailed automatic and manual record requirements depend on the type of aseptic processing and packaging system, but they must provide complete and accurate documentation of the pre-sterilization and running conditions actually used.

8.1.4.1 Product container sterilization conditions

Sterilization media flow rate and/or temperature, where applicable, retention time in the sterilizing equipment of containers and closures. Where a batch system is used for container and/or closure sterilization, sterilization cycle times and temperatures.

8.1.4.2 Product line conditions

Pre-sterilization of the product line, "stand-by" and/or "change-to-product", as well as running conditions. Running condition records should include product temperature at the final heater outlet,

product temperature at holding section outlet, differential pressures if a product-to-product regenerator is used, and the product flow rate.

8.1.4.3 Filling and closing conditions (see Sub-Section 8.1.4.1)

8.1.5 Flame sterilizers

Container conveyor speed, can surface temperature at the end of the process holding period, nature of container.

8.2 Record Review and Maintenance

8.2.1 Process Records

Recorder charts should be identified by date, code lot and other data as necessary, so they can be correlated with the written record of lot processed. Each entry of the record should be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and the retort of processing system operator or such designated person should sign or initial each record form. Prior to shipment or release for distribution, but not later than one working day after the actual process, a representative of plant management who is competent should review and ensure that all processing and production records are complete and that all products received the scheduled process. The records, including the recorder thermometer chart, 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 initialed by the container closure inspector and should be reviewed by a representative of plant management, who is competent, 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 tests showing that effective treatment was maintained or that the microbiological quality was suitable.

8.2.4 Distribution of product

Records should be maintained identifying initial distribution of the 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 Sub-Section 7.6.1.1, 8.1 and 8.2, should be retained for not less than three years. They should be held in a manner which will permit ready reference.

9. SECTION IX - STORAGE AND TRANSPORT 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 incubatory conditions for the growth of thermophilic organisms.

9.2 If containers are kept at high humidities particularly for a long time especially in the presence of mineral salts or substances which are even very weakly alkaline or acidic they are likely to corrode.

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 corrosin.

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. 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 corrosin.

9.6 Any of the above conditions may necessitate reference to the guidelines for the Salvage of Canned Foods Exposed to Adverse Conditions, (currently under preparation).

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.

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 methodology 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 product will be sold.

APPENDIX I

ACIDIFIED LOW-ACID CANNED FOODS

1. SECTION I - SCOPE

This Appendix applies to the manufacture and processing of low-acid canned foods which have been acidified, fermented and/or pickled prior to canning to have an equilibrium pH of 4.6 or less after heat processing. These foods include but are not limited to, artichokes, beans, cabbage, cauliflower, cucumber, fish, olives (other than ripe olives), peppers, puddings and tropical fruits, singly or in combination.

Excluded are acid beverages and foods, jams, jellies, preserves, salad dressings, vinegar, fermented dairy products, acid foods that contain small amounts of low-acid foods but having a resultant pH that does not significantly differ from that of the predominant acid food, and those foods where scientific evidence clearly shows that the product does not support the growth of Clostridium botulinum; for example, those tomato or tomato products where the pH does not exceed 4.7.

2. SECTION II - DEFINITIONS

(See definitions, SECTION II of the principal document)

3. SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA

As stated in SECTION III of the principal document.

4. SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

As stated in Sub-Section 4.1 in the principal document.

4.2 Roadways and Yards

As stated in Sub-Section 4.2 in the principal document.

4.3 Buildings and Facilities

As stated in Sub-Section 4.3 in the principal document.

4.4 Sanitary Facilities

As stated in Sub-Section 4.4 in the principal document.

4.5 Equipment and Utensils

As stated in Sub-Section 4.5 in the principal document, except that 4.5.2.4 is modified as follows:

4.5.2.4 Retorts and product sterilizers are pressure vessels and as such must be designed, installed, operated and maintained in accordance with the safety standards for pressure vessels of the agency having jurisdiction. Where open canal cookers, spray cookers and heat exchangers are used to achieve commercial sterility of acidified low-acid foods they must be designed, installed, operated and maintained in accordance with applicable safety standards of the agency having jurisdiction.

5. SECTION V - ESTABLISHMENT: HYGIENIC REQUIREMENTS

All this section as stated in SECTION V of the principal document.

6. SECTION VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

All this section as stated in SECTION VI of the principal document.

7. SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements and Preparation

7.1.1 As stated in Sub-Section 7.1.1 of the principal document.

7.1.2 As stated in Sub-Section 7.1.2 of the principal document.

7.1.3 As stated in Sub-Section 7.1.3 of the principal document.

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.

7.1.5 All steps in the process, including canning, should be performed under conditions which will prevent contamination, deterioration, and/or the growth of microorganisms of public health significance in the food product.

7.2 Prevention of Cross-Contamination

As stated in Sub-Section 7.2 of the principal document.

7.3 Use of Water

As stated in Sub-Section 7.3 of the principal document.

7.4 Packaging

As stated in Sub-Section 7.4 of the principal document.

7.4.1 Storage of Containers

As stated in Sub-Section 7.4.1 of the principal document.

7.4.2 Inspection of Empty Product Containers

As stated in Sub-Section 7.4.2 of the principal document.

7.4.3 Proper Use of Product Containers

As stated in Sub-Section 7.4.3 of the principal document.

7.4.4 Protection of Empty Product Containers During Plant Cleaning

As stated in Sub-Section 7.4.4 of the principal document.

7.4.5 Filling of Product Containers

As stated in Sub-Section 7.4.5 of the principal document.

7.4.6 Exhausting of Containers

As stated in Sub-section 7.4.6 of the principal document.

7.4.7 Closing Operations

As stated in Sub-Section 7.4.7 of the principal document.

7.4.8 Inspection of Closures

7.4.8.1 Inspection for gross defects.

As stated in Sub-Section 7.4.8.1 of the principal document.

7.4.8.1.1 Inspection of glass container closures.

As stated in Sub-Section 7.4.8.1.1 of the principal document.

7.4.8.1.2 Inspection of can seams.

As stated in Sub-Section 7.4.8.1.2 of the principal document.

7.4.8.1.3 Inspection of seams for deep-drawn aluminum containers.

As stated in Sub-Section 7.4.8.1.3 of the principal document.

7.4.8.1.4 Inspection of seals of semi-rigid and flexible containers.

As stated in Sub-Section 7.4.8.1.4 of the principal document.

7.4.9 Handling of Containers After Closure

As stated in Sub-Section 7.4.9 of the principal document.

7.4.10 Coding

As stated in Sub-Section 7.4.10 of the principal document.

7.4.11 Washing

As stated in Sub-Section 7.4.11 of the principal document.

7.5 Acidification and Heat Processing

7.5.1 General Considerations

Scheduled processes for acidified low-acid canned foods must be established only by competent persons having expert knowledge of acidification and thermal processing and having adequate facilities for making such determinations. It is absolutely necessary to establish the required acidification and heat process with accepted scientific methods.

The microbiological safety of acidified low-acid foods depends primarily upon the care and accuracy by which the process has been carried out.

The acidification and heat process required to make acidified low-acid canned foods commercially sterile depends upon the microbial load, type and procedure of acidification, storage temperature, the presence of various preservatives and composition of the products. Acidified low-acid foods with pH values above 4.6 may be able to support the growth of many kinds of microorganisms including the heat resistant spore-forming pathogens such as Clostridium botulinum. It should be emphasized that acidification and heat processing of acidified low-acid canned foods are very critical operations involving public health risks and appreciable losses of finished product if inadequately processed.

Instances have been known where improperly processed or sealed acidified canned foods have supported mold and other microbial growth which raised the product pH to above 4.6 and allowed the growth of Clostridium botulinum.

7.5.2 Establishing Scheduled Processes

7.5.2.1 A scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and heat processing of acidified, fermented and pickled foods.

7.5.2.2 The required acidification and heat process to achieve commercial sterility should be established on the basis of factors such as:

- pH of the product;
- time to reach equilibrium pH;
- product composition or formulation, including dimensional tolerances of solid ingredients;
- levels and types of preservatives;
- water and activity;
- microbial flora including Clostridium botulinum and spoilage microorganisms;
- container size and type; and
- organoleptic quality.

7.5.2.3 The heat treatment necessary to achieve commercial sterility of an acidified low-acid canned food is much less than that necessary for low-acid canned foods.

7.5.2.4 Since the acidity of the final product will generally prevent bacterial spore outgrowth, the heat treatment may only be required to kill molds, yeasts, vegetative cells of bacteria and to inactivate enzymes.

7.5.2.5 The results of these acidification and heat process determination together with established critical factors should be incorporated into the scheduled process. Such a scheduled process should include as the minimum the following data:

- product code or recipe identification; -container size (dimensions) and type;
- pertinent details of the acidification process;
- in-going weight of product(s) including liquor where appropriate;
- minimum initial temperature;
- type and characteristics of heat processing system;
- sterilization temperature;
- sterilization time; and
- cooling method.

7.5.2.6 For aseptically processed foods a similar list should be made which also should include equipment and container sterilization requirements.

7.5.2.7 The product code (identity) should correspond clearly to a complete and accurate product specification containing at least the following where applicable:

- full receipt and preparation procedures;
- pH;
- in-going weight of product(s), including liquor where appropriate;
- headspace;
- drained weight;
- maximum dimensions of product components;
- temperature of product at filling; and
- consistency.

7.5.2.8 Small deviations from the product specification which may seem negligible may seriously affect the adequacy of the process for that product. any changes in product specifications should be evaluated as to their effect on the adequacy of the process. If the scheduled process is found to be inadequate it must be re-established.

7.5.2.9 Complete records concerning all aspects of the establishment of the scheduled process, including any associated incubation tests, should be permanently retained by the processing plant or by the laboratory establishing the scheduled process.

7.5.3 Acidification and Heat Processing Operations

7.5.3.1 Processing operations for control of pH and other critical factors specified in the scheduled process should be performed and supervised only by properly trained personnel.

7.5.3.2 Acidified, fermented and pickled foods shall be so manufactured, processed and packaged that an equilibrium pH value of 4.6 or lower is

achieved within the time designated in the scheduled process and maintained.

7.5.3.3 To accomplish this the processor should monitor, using pertinent tests, the acidification process at critical control points with sufficient frequency to assure the safety and quality of the product.

7.5.3.4 Commercial sterility must be accomplished using such equipment and instruments as are needed to ensure that the scheduled process is achieved and to provide proper records.

7.5.3.5 Both temperature distribution and rates of heat transfer are important; because of the variety of existing designs in equipment, reference should be made to the equipment manufacturers and to the agency having jurisdiction for details of installation, operation and control.

7.5.3.6 Only properly determined scheduled processes must be used. Scheduled processes to be used for products and container sizes and types being packed should be posted in a conspicuous place near the processing equipment. Such information should be readily available to the retort or processing system operator and to the agency having jurisdiction.

7.5.3.7. It is essential that all processing equipment should be properly designed, correctly installed and carefully maintained.

7.5.3.8 In batch operations the sterilization status of the containers should be indicated. All retort baskets, trucks, cars or crates containing food product not thermally processed, or at least one of the containers on the tope of each basket, etc., should be plainly and conspicuously marked with a heat sensitive indicator, or by other effective means which will visually indicate whether or not each unit has been thermally processed. Heat sensitive indicators attached to baskets, trucks, cars or crates must be removed before they are refilled with containers.

7.5.3.9 The initial temperature of the contents of the coldest containers to be processed should be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process.

7.5.3.10 An accurate, clearly visible clock or other suitable timing device should be installed in the processing room and times should be read from this instrument and not from wristwatches, etc. When two or more clocks are used in a processing room they should be synchronized.

7.5.4 Critical Factors and the Application of the Scheduled Process

In addition to the maximum pH, minimum initial product temperature, sterilization time and temperature specified in the scheduled process, other critical factors specified should be measured, controlled and recorded at intervals of sufficient frequency to ensure that these factors remain within the limits specified in the scheduled process. Some examples of critical factors are:

i) maximum fill-in or drained weight;

ii) headspace of filled product containers;

iii) product consistency as determined by objective measurement on product taken before processing;

iv) product style and/or container type which results in layering or stratification of the product in the containers or alteration of the container dimensions (thickness) requiring specific orientation of the containers in the retort;

v) percent solids;

vi) net weight;

vii) minimum closing vacuum (in vacuum packed product);

viii) pH equilibrium time;

ix) salt, sugar and/or preservative concentrations; and

x) dimensional tolerance of solid ingredients.

7.6 Equipment and Procedures for Acidification and Heat Processing Systems

7.6.1 Acidification Systems

The manufacturer shall employ appropriate control procedures to ensure that the finished goods do not present a health hazard. Sufficient control, including frequent testing and recording of results, shall be exercised so that the equilibrium pH values for acidified, fermented and pickled foods are not higher than 4.6. Measurements of acidity of foods in-process may be made by potentiometric methods, titratable acidity, or in certain instances colourimetric methods. In-process measurements by titration or colourimetry should be related to the finished equilibrium pH. If the finished equilibrium pH is 4.0 or below, the acidity of the final product may be determined by any suitable method. If the finished equilibrium pH of the food is above 4.0 the measurement of the finished equilibrium pH shall be by a potentiometric method.

7.6.1.1 Direct Acidification

Procedures for acidification to attain acceptable pH levels in the final food include, but are not limited to the following:

i) blanching of the food ingredients in acidified aqueous solutions;

ii) immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, care should be taken to assure that the acid concentration is properly maintained;

iii) direct batch acidification. This can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification;

iv) direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than solid or pelleted acids. Care should be taken to ensure that the proper amount of acids is added to each container and distributed uniformly;

v) addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations; and

vi) the time for equilibrium and buffering effects should always be taken into account.

7.6.1.2 Acidification by Fermentation and Salt Curing

Temperature, salt concentration and acidity are important factors in controlling the fermentation and salt-curing in foods. The process and control of the fermentation should be monitored by appropriate tests. The concentration of salt in the brine should be determined by a chemical or physical test, at sufficient intervals to assure the control of the fermentation. The process of the fermentation should be monitored by pH measurements or acid/base titrations or both according to the methods set forth in Sub-Section 7.6.2 or by equivalent methods, at sufficient intervals to assure the control of the fermentation. The concentration of salt or acid in the brine in bulk tanks containing salt stock may become significantly diluted. Therefore it should be routinely checked and adjusted as necessary.

7.6.2 Instruments and Control Procedures for Acidification Processes (see Appendix II)

7.6.3 Instruments and Controls Common to Different Heat Processing Systems

7.6.3.1 Indicating Thermometer

Each sterilizer or cooker should be equipped with at least one indicating thermometer. the mercury-in-glass thermometer is recognized as the most reliable temperature indicating instrument at the present time. An alternative instrument having equal or better accuracy and reliability may be used subject to the approval of the official agency having jurisdiction. The mercury-in-glass thermometer should have divisions that are easily readable to 1C° (2F°) and whose scale contains not more than 4C°/cm (17F° per in.) of graduated scale.

Thermometers should be tested for accuracy, in steam or water as appropriate, in the operational aspect against a known accurate standard thermometer. This should be done upon installation, and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. A thermometer that deviates more than 0.5C° (1F°) from the standard should be replaced. A daily inspection of mercury-in-glass thermometers should be made to detect, and if found, replace thermometers with divided mercury columns or other defects.

7.6.3.2 Where other types of thermometer are used, routine tests should be made which ensure at least equivalent performance to that described for

mercury-in-glass thermometers. Thermometers which do not meet these requirements should be replaced.

7.6.3.3 Temperature/Time Recording Devices

Each sterilizer or cooker should be equipped with at least one temperature/time recording device. This recorder may be combined with the steam controller and may be a controlling recording instrument. It is important that the correct chart is used for each device. The recording accuracy should be equal to or better than ± 1C° (± 2F°) at the process temperature. The recorder should agree within 1C° (2F°) of the indicating thermometer at the process temperature. 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 time. The chart timing device should also be accurate.

7.6.3.4 Pressure Gauges

As stated in sub-Section 7.6.1.3 of the principal document with the addition of the following sentence:

If a retort is only used at atmospheric pressure, a pressure gauge may not be necessary.

7.6.3.5 Steam Controller

When appropriate each sterilizer or cooker should be equipped with a steam controller to maintain temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

7.6.3.6 Pressure Relief Valves

As stated in Sub-Section 7.6.1.5 of the principal document with the addition of the following sentence:

If a retort is only at atmospheric pressure, a pressure relief valve may not be necessary.

7.6.4 Commonly Used Heat Processing Systems

7.6.4.1 Processing at Atmospheric Pressure or by Hot-fill and Hold

Commercial sterility should be accomplished using suitable equipment and the necessary instrumentations as in Sub-Section 7.6.3 of this Appendix to ensure that the scheduled process is achieved and to provide proper records. Both temperature distribution and rates of heat transfer are important. Because of the variety of equipment available, reference should be made to the manufacturer and the agency having jurisdiction for details of installation, operation and control. Where a hot-fill and hold technique is used it is important that all inner surfaces of the container reach the scheduled container sterilization temperature.

7.6.4.2 Processing Under Pressure in Retorts

As stated in Sub-Sections 7.6.2, 7.6.3 and 7.6.4 in their entirety in the principal document.

7.6.5 Aseptic Processing and Packaging Systems

As stated in Sub-Section 7.6.5 in its entirety in the principal document.

7.6.6 Flames Sterilizers, Equipment and Procedures

As stated in Sub-Section 7.6.6 in its entirety in the principal document.

7.6.7 Other Systems

Systems for thermal processing of acidified low-acid foods in hermetically sealed containers should conform to the applicable requirements of this Code and should ensure that the methods and controls used for the manufacture, processing and/or packaging of such foods are operated and administered in a manner adequate to achieve commercial sterility.

7.6.8 Cooling

As stated in Sub-Section 7.6.8 of the principal document.

7.6.8.1 Cooling Water Quality

As stated in Sub-Section 7.6.8.1 of the principal document.

7.7 Post-Processing Contamination

As stated in Sub-Section 7.7 of the principal document.

7.8 Evaluation of Deviations in the Scheduled Process

Whenever any process operation deviates from the scheduled pressures for any acidified, fermented or pickled food, or whenever the equilibrium pH value of the finished product is higher than 4.6 as determined by appropriate analysis (see Appendix II of this Code as disclosed from records, or otherwise, the commercial processor) should either:

a) fully reprocess that code lot of the food by a process established by a competent processing authority as adequate to assure a safe product; or

b) set aside that portion of the food involved for further evaluation as to any potential public health significance. Such evaluation should be made by competent processing experts in accordance with procedures recognized as being adequate to detect any potential hazard to public health and should be acceptable to the agency having jurisdiction unless such evaluation demonstrates that the food code lot has undergone a process that has rendered it safe, the food set aside shall either be fully reprocessed to render it safe or destroyed. A record should be made of the procedures used in the evaluation, the results obtained, and the actions taken on the product involved. Either upon completion of full reworking and

the attainment of a safe food or after the determination that no potential for public health hazard exists, that portion of the food involved may be shipped in normal distribution. Otherwise, the portion of the food involved shall be suitably disposed of under adequate and proper supervision to assure the protection of the public health.

8. SECTION VIII - QUALITY ASSURANCE

As stated in Section 8 of the principal document.

8.1 Processing and Production Records

Records should be maintained of examination of raw materials, packaging materials and finished products, and of suppliers' guarantees or certifications that verify compliance with the requirements of this Code.

8.2 Record Review and Maintenance

Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, should be maintained and should contain sufficient additional information such as product code, date, container size and product, to permit a public health hazard evaluation of the processes applied to each code lot, batch or other portion of production.

8.3 Deviations from Scheduled Processes

All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified. Such departures should be recorded and made the subject of a separate file, or a log identifying the appropriate data and delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.

8.4 Distribution of Product

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

8.5 Retention of Records

Copies of all records provided for in Sub-Sections 8.2, 8.3 and 8.4 above should be retained at the processing plant or other reasonably accessible location for a period of three years.

9. SECTION IX - STORAGE AND TRANSPORT OF THE FINISHED PRODUCT

As stated in SECTION IX of the principal document.

10. SECTION X - LABORATORY CONTROL PROCEDURES

As stated in SECTION X of the principal document.

11. SECTION XI - END-PRODUCT SPECIFICATIONS

As stated in SECTION XI in its entirety in the principal document, except that Sub-Section 11.3 will be altered to read, "Acidified low-acid foods should have received a processing treatment sufficient to provide commercial sterility".

APPENDIX II

1. ANALYTICAL METHODOLOGY FOR pH MEASUREMENT[1]

Methods that may be used to determine pH or acidity for acidified, fermented and pickled food include, but are not limited to the following:

1.1 Potentiometric Method for the Determination of pH

1.1.1 Principles

The term "pH" is used to designate the intensity or degree of acidity. The value of pH, the logarithm of the reciprocal of the hydrogen ion concentration in solution, is determined by measuring the difference in potential between two electrodes immersed in a sample solution. A suitable system consists of a potentiometer, a glass electrode, and a reference electrode. A precise pH determination can be made by making an electromotive force (emf) measurement of a standard buffer solution whose pH is known, and then by comparing that measurement to an emf measurement of a sample of the solution to be tested.

1.1.2 Instruments

The primary instrument for use of pH determination is the pH meter or potentiometer. For most work, an instrument with a direct-reading pH scale is necessary. Battery and line-operated instruments are available commercially. If the line voltage may be unstable, line-operated instruments should be fitted with voltage regulators to eliminate drifting of meter-scale readings. Batteries should be checked frequently to assure proper operation of batter operated instruments. An instrument using an expanded unit scale or a digital readout system is preferred since it allows more precise measurements.

1.1.3 Electrodes

The typical pH meter is equipped with a glass membrane electrode. The most commonly used reference electrode is the calomel electrode, which incorporates a salt bridge filled with saturated potassium chloride solution.

i) Care and use of electrodes. Calomel electrodes should be kept filled with saturated potassium chloride solution, or other solution specified by the manufacturer because they may become damaged if they are allowed to dry out. For best results, electrodes should be soaked in buffer solution, distilled or deionized water or other liquid specified by the manufacturer for several hours before using and kept ready by storing with tips immersed in distilled water or in buffer solution used for standardization. Electrodes should be rinsed with water before

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[1] (If and when a suitable I.S.O. text becomes available it will be considered as a replacement for this Appendix)

immersing in the standard buffers and rinsed with water or the solution to be measured next between sample determinations. A lag in meter response may indicate aging effects or fouling of the electrodes, and cleaning and rejuvenation of the electrodes may be necessary. This may be accomplished by placing the electrodes in 0.1 molar sodium hydroxide solution for 1 minute and then transferring them to 0.1 molar hydrochloric acid solution for 1 minute. The cycle should be repeated twice, ending with the electrodes in the acid solution. The electrodes should then be thoroughly rinsed with water and blotted with soft tissue before proceeding with the standardization.

ii) Temperature. To obtain accurate results, the same temperature should be used for the electrodes, the standard buffer solutions, the samples, for the standardization of the meter, and pH determinations. Tests should be made at a temperature between 20°C to 30°C (68°F to 86°F). When tests have to be made outside this temperature range appropriate correction factors should be established and applied. While thermal compensators are available, they should not be relied upon to give accurate results.

iii) Accuracy. The accuracy of most pH meters is stated to be approximately 0.1 pH unit, and reproducibility is usually ± 0.05 pH unit or less. Some meters permit the expansion of any pH unit range to cover the entire scale and have an accuracy of approximately ± 0.01 pH unit and reproducibility of ± 0.005 pH units.

1.1.4 General Procedure for Determining pH

When operating an instrument, the manufacturer's instructions should be used and the following techniques for pH determination observed:

i) switch the instrument on and allow the electronic components to warm up and stabilize before proceeding;

ii) standardize the instrument and electrodes with commercially-prepared standard 4.0 pH buffer or with freshly prepared 0.05 molar potassium acid phthalate buffer solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th ed., 1984, section 50.007(c). Note the temperature of the buffer solution and set the temperature compensator control at the observed temperature;

iii) rinse the electrodes with water and blot but do not wipe with soft tissue;

iv) immerse the tips in the buffer solution and take the pH reading, allowing about 1 minute for the meter to stabilize. Adjust the standardization control so that the meter reading corresponds to the pH of the known buffer (for example, 4.0) for the temperature observed. Rinse the electrodes with water and blot with soft tissue. Repeat procedure with fresh portions of buffer solution unitl the instrument remains in balance on two successive trials. To check the operation of the pH meter, check the pH reading

using another standard buffer such as one having a pH of 7.0 or check it with freshly prepared 0.025 molar phosphate solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th ed., 1984, section 50.007(e). Expanded scale pH meters may be checked with pH 3.0 or pH 5.0 standard buffers. Buffers and instruments can be further checked by comparison with values obtained with a second properly standardized instrument;

v) indicating electrodes may be checked for proper operation by first using an acid buffer then a base buffer. First standardize the electrodes using a pH 4.0 buffer at or near 25°C. Standardization control should be adjusted so that the meter reads exactly 4.0. Electrodes should be rinsed with water, then blotted and immersed in a pH 9.18 borax buffer prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th ed., 1984, section 50.007(f). The pH reading should be within ± 0.3 units of the 9.18 value; and

vi) the pH meter can be tested for proper operation by shorting the glass and reference electrode inputs, thereby reducing the voltage to zero. In some meters this is done by switching the instrument to standby, and in other instruments by use of a shorting strap. With the instrument shorted out, standardization control should be turned from one extreme to another. This operation should produce a deflection greater than ± 1.5 pH unit from centre scale.

1.1.5 Determining pH on Samples

i) adjust the temperature of the sample to room temperature (25°C), and set the temperature compensator control to the observed temperature. With some expanded scale instruments, the sample temperature must be the same as the temperature of the buffer solution used for the standardization;

ii) rinse and blot the electrodes. Immerse the electrodes in the sample and take the pH reading, allowing 1 minute for the meter to stabilize. Rinse and blot the electrodes and repeat on a fresh portion of sample. Oil and grease from the samples may coat the electrodes, therefore, it is advisable to clean and standardize the instrument frequently. When oily samples cause fouling problems, it may become necessary to rinse the electrode with ethyl ether; and

iii) determine two pH values on the well-mixed sampled. These readings should be in agreement with one another to indicated that the sample is homogeneous. Report values to the nearest 0.05 pH unit.

1.1.6 Preparation of Samples

Some food products may consist of a mixture of liquid and solid components that differ in acidity. Other food products may be semi-solid in character. The following are examples of preparation procedures for pH testing for each of these categories.

i) Liquid and solid component mixtures. Drain the contents of the container for 2 minutes on a U.S. standard No. 8 sieve (preferably stainless steel) or equivalent inclined at a 17 to 20° angle. Record weights of the liquid and solid portions and retain each portion separately.

a) if the liquid contains sufficient oil to cause electrode fouling, separate the layer with a separatory funnel and retain the aqueous layer. The oil layer may be discarded. Adjust the temperature of the aqueous layer to 25°C and determine its pH;

b) remove the drained solids from the sieve. Blend to a uniform paste, adjust the temperature of the paste to 25°C and determine its pH; and

c) mix aliquots of solid and liquid fractions in the same ratio as found in the original container and blend to a uniform consistency. Adjust the temperature of the blend to 25°C and determine the equilibrated pH. Alternately, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25°C and determine the equilibrated pH.

ii) Marinated oil products. Separate the oil from the solid product. Blend the solid in a blender to a paste consistency; it may become necessary to add a small amount of distilled water to some samples to facilitate the blending. A small amount of added water will not alter the pH of most food products, but caution must be exercised concerning poorly buffered foods. No more than 20 milliliters of distilled water should be added to each 100 grams of product. Determine the pH by immersing electrodes in the prepared paste after adjusting the temperature to 25°C.

iii) Semi-solid products. Food products of semi-solid consistency such as puddings, potato salad, etc., may be blended to a paste consistency, and the pH may be determined on the prepared paste. Where more fluidity is required, 10 to 20 milliliters of distilled water may be added to 100 grams of product. Adjust the temperature of the prepared paste to 25°C and determine its pH.

iv) Special product mixtures. For special product mixtures such as antipasto, pour off the oil, blend the remaining product to a paste and determine the pH of the blended paste. Where more fluidity is required, add 10 to 20 milliliters of distilled water to each 100 grams of product and blend. Adjust the temperature of the prepared paste to 25°C and determine its pH.

v) Large solid components. The internal pH should be checked with spear electrodes as near as possible to the geometric centre.

1.1.7 Process pH Determination

Standardize the meter against standard buffer solution having a pH as close as possible to that of the product. This should be done at the

beginning and end of each series of product determination or not less than twice daily.

i) for process liquids, adjust the temperature of the liquid to 25°C and determine the pH by immersing the electrodes in the liquid;

ii) drain solid materials on a sieve and blend to a workable paste. Adjust the temperature of the prepared paste to 25°C and determine its pH; and

iii) where enough solid materials are available to make a paste, blend representative aliquots of liquid and solid materials to a workable paste. Adjust the temperature of the prepared paste to 25°C and determine the equilibrated pH. Alternately, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25°C and determine the equilibrated pH.

1.2 Colorimetric Method for the Determination of pH

This method may be used in lieu of potentiometric method if the pH is 4.0 or lower.

1.2.1 Principle

The colormetric method for pH involves the use of indicator dyes in solution that gradually change colour over limited pH ranges. An indicator that has the greatest colour change at approximately the pH of the sample being tested is selected. The pH is determined by the colour of the indicator when exposed to the sample under tests.

1.2.2 Indicator Solutions

Most indicator solutions are prepared as a 0.04 percent solution of the indicator dye in alcohol. In testing, a few drops of indicator solution are added to 10 millilitre portions of the sample solution. Colours should be compared using a bright background. Approximate determinations can be made on white porcelain spot plates, the test colours being compared thereon with a set of colour standards. More accurate colourmetric tests can be made using a comparator block fitted with sets of tubes of standard indicator solutions of known pH. Indicators should be verified regularly, at least once per day before use, against the standard buffer solution.

1.2.3 Indicator Paper

A paper tape treated with indicator dye is dipped into the sample solution. Depending upon the pH of the solution, the tape will change colour and an approximate pH can be determined by comparison with a standard colour chart.

1.3 Titratable Acidity

Acceptable methods for determining titratable acidity are described in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th ed., 1984, sections 22.060-22.061. The procedure for preparing of standardizing the sodium hydroxide solution is described in ibid, sections 50.032-50.035.

APPENDIX III

REFERENCES FOR THE TEAR-DOWN EVALUATION OF A DOUBLE SEAM

1. Canned Food: Principles of Thermal Process Control, Acidification, and Container Closure Evaluation, Revised 4th edition, 1982, Chapter 9 (Container Closure Evaluation) (English). Item #FB 7500, the Food Processors Institute, 1401 New York Ave., N.W., Washington D.C. 20005, U.S.A.

A Spanish version may be obtained from Jose R. Cruz, University of Puerto Rico, Mayagues Campus, College of Agricultural Sciences, Venezuela Contact Station, Rico Piedras, Puerto Rico.

2. Can Seam Formation and Evaluation, Item #FA 0003 (English) - audio/visual presentation 16 mm film, 20 minutes. The Food Processors Institute, 1401 New York Ave., N.W., Washington, D.C. 20005, U.S.A.

3. Evaluation of Double Seams, Parts 1 and 2 (English), audio/visual presentation, 138 slides and audio cassette with illustrated script/employees handbook. The Food Processors Institute, 1401 New York Ave., N.W., Washington, D.C. 20005, U.S.A.

4. Draft Recommended Hold for Investigation Guidelines for Double Seam Measurements, Round Metal Containers for Low-Acid Foods, 1984 (English). NFPA/CMI Container Integrity Task Force, National Food Processors Association, 1401 New York Ave., N.W., Washington, D.C. 20005, U.S.A.

5. Evaluating a Double Seam, 1971 (English, French and Spanish). Dewey and Almy Chemical Division of W.R. Grace & Co., Cambridge, Massachusetts, U.S.A.

6. Double Seam Manual, (English) 1978, Metal Box Ltd., England.

7. Top Double Seam Manual (English), Continental Can Company, Inc., 633 Third Avenue, New York, N.Y., 10017, U.S.A.

8. Examination of Metal Container Integrity, Chapter XXII, U.S.F.D.A. Bacteriological Analytical Manual (BAM) 6th edition 1984 (English), Association of Official Analytical Chemists.

9. Method for the Tear-Down Examination of Double Seams of Meatal cans, MFHPB-25(f) (English & French), Bureau of Microbial Hazards, Health Protection Branch, Health and Welfare Canada, Ottawa, Ontario, K1A 0L2, Canada.

10. Double Seams for Steel-Based Cans for Foods (English), 1984, Australian Standard 2730-1984, Standards Association of Australia, Standards House, 80 Arthur St., North Sydney, N.S.W., Australia.

11. Défauts et Altérations des Conserves - Nature et Origine (French), 1982, lère édition, Edité par AFNOR Tour Europe, Cedex 7, 92080, Paris, la Défense.

12. Le Sertissage - boîtes rondes (French) 1977, Carnaud s.a., 65 av. Edouard Vaillant, B.P. 405, 92103 Boulogne s/Seine, Cedex.

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APPENDIX V

PROPOSED DRAFT GUIDELINES FOR THE SALVAGE OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS

PROPOSED DRAFT GUIDELINES FOR THE SALVAGE OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS

Table of Contents

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) 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 (C.R.) 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 by the application of heat to render the contents commercially sterile.

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 situation 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.). 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 doubleseam 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".

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", 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", 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

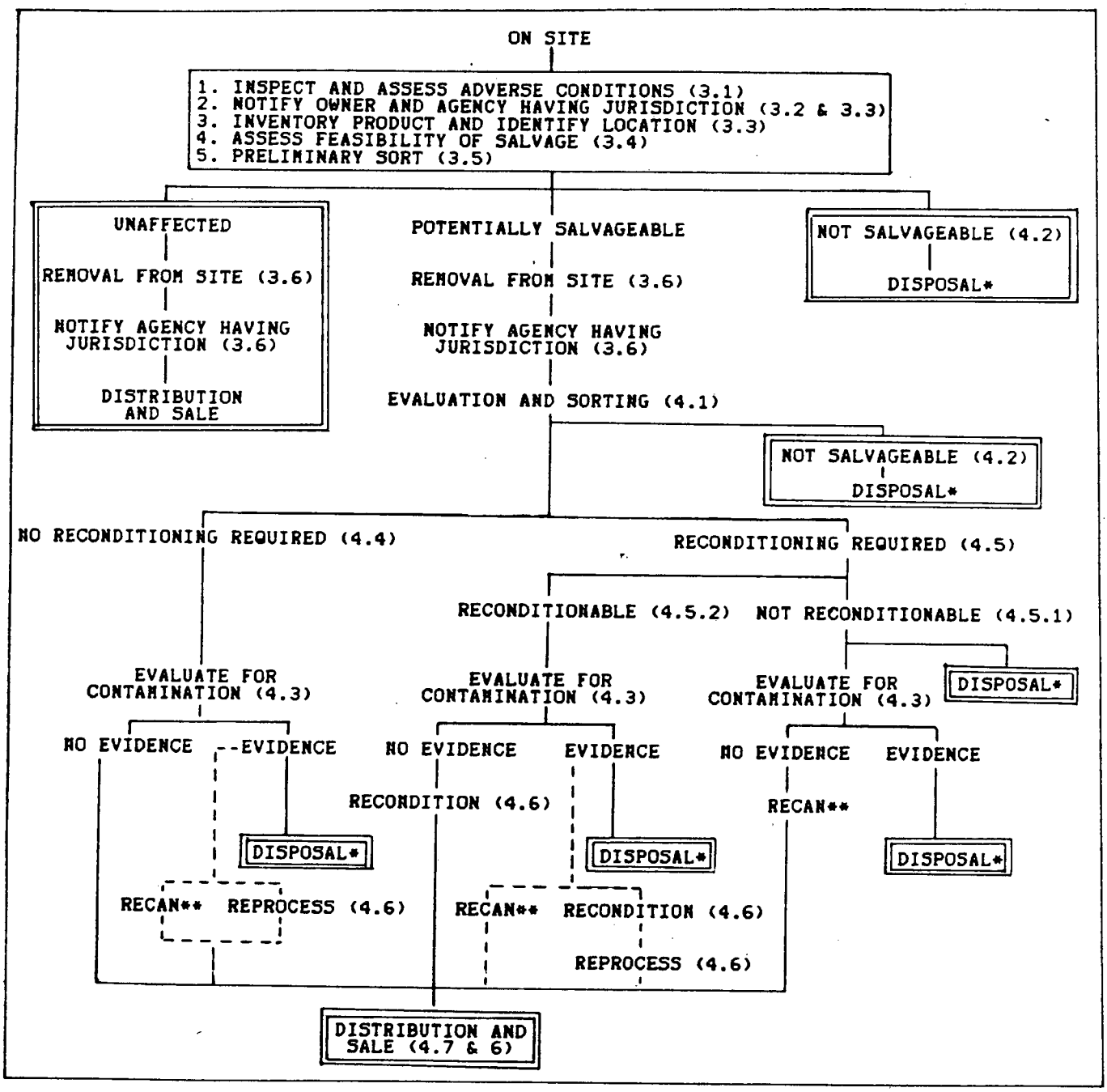
As given in the "International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods, CAC/RCP 23-1979".

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".

Appendix 1

FLOW CHART SHOWING THE SEQUENCE OF EVENTS IN THE SALVAGE OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS (DETAILS PROVIDED IN TEXT OF MAIN DOCUMENT)



(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.

PROPOSED DRAFT GUIDELINE PROCEDURES TO ESTABLISH MICRBIOLOGICAL CAUSES OF SPOILAGE IN LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS
(At Step 3 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, 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 means insufficient thermal processing. A mixed flora of different vegetative organisms usually means leakage. Therefore to distinguish between thermally resistant and labile organisms, heat treatment of inocula prior to cultural examination is necessary. 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.

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.

Figure 1

FLOW DIAGRAM OF THE PROCEDURES FOR THE EXAMINATION OF A THERMALLY PROCESSSED 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.
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*

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

* Based on R.H. Thorpe and P.M. Baker, "Visual can defects", 1984, Campden Food Preservation Research Association, Chipping Campden, England

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., half Petri dish).

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.

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.

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 4oC 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., half Petri dish).

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 (specially 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 a 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 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.

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 a 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) and compared to that of normal cans. A significant change in the pH of the contents from that of 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.

Normal changes in texture of solid products can be perveived 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 invest- igated. 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 provide 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.

Procedures and discussions of various methods of container leakage testing may be found in the following references: U.S. F.D.A. (1984), N.C.A. (1972), C.F.P.R.A. (1987), AFNOR-CERNA (1982), H.W.C. (1983) and Buckle (1985).

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.

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.

Table 2

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

Condition of Can	Odour	Apearance (3)	pH (1)	Smear	Key Points From Cultures (2)	Possible Interpretations
Swell	Sour	Frothy, Possibly ropy brine	Below normal	Cocci and/or rods and/or yeasts	Positive aerobe and/or Anaerobe; growth at 30° C and/or 37° C	Post-process leakage
Swell	Slightly off (Sometimes ammoniacal)	Normal to frothy	Slighlty to definitely abnormal may be higher	Rods (spores sometimes seen)	Positive; aerobe and/or anaerobe; growth at 30°C; often pellicle formation in aerobic broths	Post-process leakage or gross underprocessing
Swell	Sour	Frothy possibly ropy brine. Food firm and uncooked	Below normal	Mixed Population (often spores)	Positive; aerobe and/or anaerobe; growth at 30°C & 37°C and often at 55°C	No thermal process given
Swell	Normal to sour or	Pale colour or distinct colour change, frothy	Slightly to definitely below normal	Medium to long rods, often granular, spores seldom seen	Positive anaerobic growth at 55°C. No growth at 30°C, possibly growth at 37°C	Thermophilic anaerobe; inadequate cooling or storage at elevated temperatures
Swell	Normal to cheesy to putrid	Usually frothy with disintegration of solid particles	Slightly to definitely below normal	Rods (spores may be seen)	Growth and gas in anaerobic culture at 37°C and or 30°C but no growth in aerobic cultures	Under-processing, mesophilic anaerobic HIGH RISK consider survival of Clostridium botulinum
Swell	Normal	Normal	Normal	Normal	Negative	Low filling temperature; insufficient exhausting of can before seaming; overfill or hydrogen swell
Swell or flat	Little or no gas on opening; fruity odour	normal	Normal to below normal	Large numbers of evenly stained cocci and/or rods	Negative	Pre-process (incipient) spoilage
Swell	Sour to cheesy	Frothy	Often below Normal	Poorly stained cocci and/or rods	Negative	Leaker spoilage followed by auto-sterilization

Table 2 (continued)

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

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

(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 Association

Table 3

Interpretation of Laboratory Data Concerning Acidified Low-Acid Canned Food

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

* 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.

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 1 and 2 (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 may increase likelihood of leaker spoilage. If there is a high proportion of spoiled containers and only sporeformers are present, underprocessing is usually indicated.
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.
		c) Thermophilic spoilage may result from storage at high temperatures, e.g., 37°C (99°F) and above.
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 underprocessing.
6.4	Processing records	a) Records showing poor control of thermal processing may correlate with spoilage from underprocessing.
		b) Adequate processing records may eliminate underprocessing 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 re-evaluation 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 1 and 2 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 may be used for lots in which spoilage has been identified.

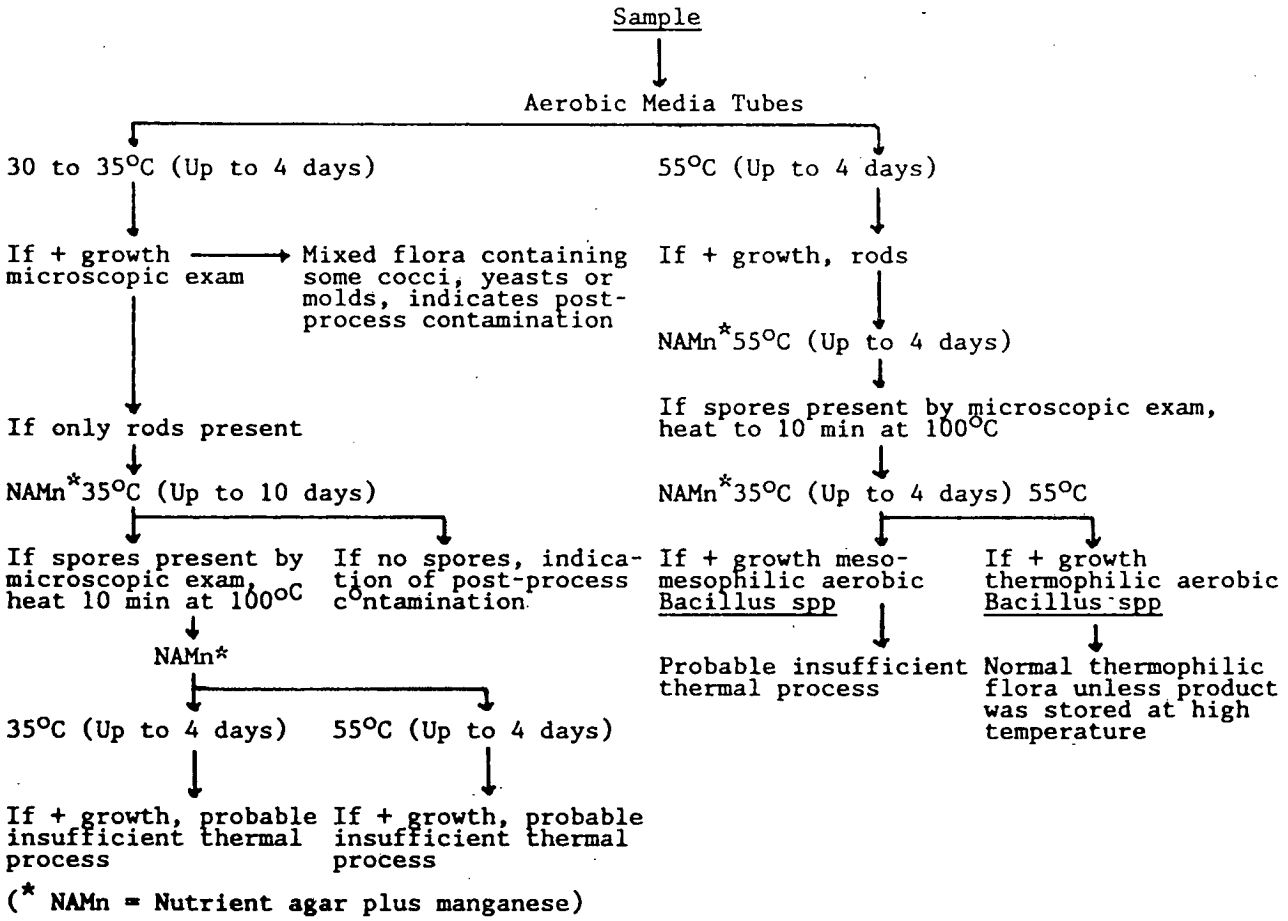
Figure 2

Flow Sheet For

The Aerobic Cultural Examination of Low-Acid Canned Foods for Spoilage

and

Diagnosis of Results



(* NAMn = Nutrient agar plus manganese)

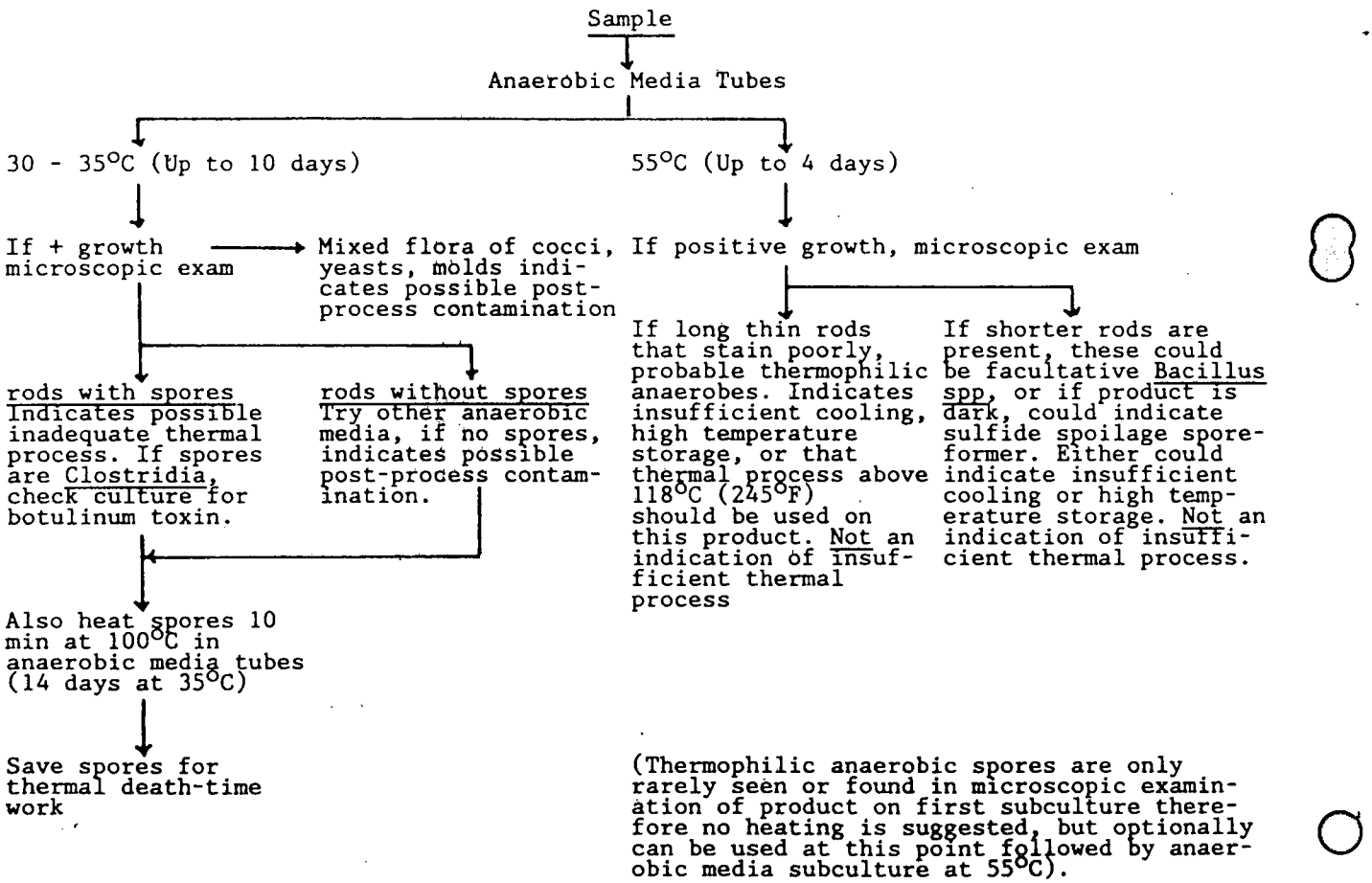
Figure 3

Flow Diagram For

The Anaerobic Cultural Examination of Low-Acid Canned Foods For Spoilage

and

Diagnosis of Results



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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

(A more complete list of essential information for the investigation of foodborne illness can be found in the Procedures to Investigate Foodborne Illness, 4'th Edition, 1986, International Milk, Food and Environmental Sanitarians Inc., P.O. 701, Ames, Iowa, 50010, U.S.A. The 3'rd edition, published in 1976 is available in French and Spanish.)

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
   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

APPENDIX 2

PROCEDURES FOR MICROBIOLOGICAL ANALYSIS OF THE ANALYTICAL SAMPLE

A. Mesophiles

1. Media and Incubation Conditions

	Low-Acid Foods (pH > 4.6)				Acidified Low-Acid Foods (ph =< 4.6)	
1. Incubation Conditions	Aerobic		Anaerobic		Aerobic	
2. Media (2)	Liquid	Solid	Liquid	Solid	Liquid	Solid
	DTB PE2	PCA DTA NAMn	PE2 CMM LB RCM	LVA PIA RCA BA	OSB TJB APTB APT	PDA TJA SDA
3. Quantity of medium	15 ml/ tube	15 ml/ tube	15 ml/ tube	15 ml/ tube	15 ml/ tube for APTB 200 ml/flask	15 ml/ tube
4. Replication	=> 2 tubes	=> 2 plates	=> 2 tubes	=> 2 plates	=> 2 tubes for APTB => 3/flask	=> 2 plates
5. Incubation Temperature (3)	30°C	30°C	30°C	30°C	30°C (1)	30°C(1)
6. Incubation Time (4)	to 14 days	to 5 days	to 14 days	to 5 days	to 14 days	to 5 - 10 days

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 medium
LVA - Liver veal agar
PIA - Pork infusion agar
PE2 - Peptone, yeast extract medium, Folinazzo (1954)
OSB - Orange serum broth
APTB - Acid products test broth
APT - All purpose tween
PDA - Potato dextrose agar
SDA - Sabourad dextrose agar
TJB - Tomato juice broth
DTA - Dextrose tryptone agar
NAMn - Nutrient agar plus manganese
DTB - Dextrose tryptone broth
RCA - Reinforced clostridial agar
BA - Blood Agar
TJA - Tomato juice agar

(3) 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.

(4) Examine tubes and plates periodically, e.g., at least every two days. Incubation is terminated when positive growth is observed.

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)

* 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.

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 H_2S - Corn liver medium*

C. thermosaccharolyticum - Liver broth*

Anaerobes producing H_2S - 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.

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Appendix VII

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR ASEPTICALLY PACKAGED LOW-ACID CANNED FOODS
(At Step 3 of the Procedure)

Table of Contents

1.0 SECTION I - SCOPE

This Code of Practice is concerned with the aseptic processing and packaging of low-acid foods. "Aseptic processing packaging" means the filling of a commercially sterile product into sterilized containers followed by hermetical sealing with a sterilized closure in an atmosphere free from microorganisms. It does not apply to foods in hermetically sealed containers that require refrigeration or to acid or acidified low-acid foods.

2.0 SECTION II - DEFFINITIONS

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 there is an absence of viable microorganisms, including viable spores. In the food industry, the terms aseptic, sterile and commercially sterile are often used interchangeably.

2.4 "Aseptic processing and packaging" means the filling of a commercially sterile product into sterilized containers followed by hermetic sealing with a sterilized closure in an atmosphere free from microorganisms. Aseptic processing and packaging differs from canning because in canning the food is placed in the can, sealed and heat processed in that order.

2.5 "Aseptic surge tank" means a sterilizable vessel located between the product cooler and product filler which is used for storage of commercially sterile product.

2.6 "Aseptic zone" means the area of the aseptic filling and sealing equipment within which commercially sterile containers, product, or container material could potentially be exposed to recontamination. This area is generally located between the point at which the containers are treated to achieve commercial sterility and the filled containers are sealed to exclude the entry of microorganisms.

2.7 "Batch sterilization" means application of a scheduled process to achieve commercial sterility in a batch rather than in a continuous manner.

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

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

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

2.11 "Commercial sterility of equipment and containers used for aseptic processing and packaging of food" means the condition achieved and maintained by application of heat, or other appropriate treatment, which renders such equipment and containers free from microorganisms capable of growing in the food at temperatures at which the food is likely to be held during distribution and storage.

2.11.1 "Commercial sterility of 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 at normal nonrefrigerated conditions at which the food is likely to be held during distribution and storage.

2.11.2 "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, sterilant and concentration, etc.

2.12 "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.

2.13 "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.

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

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

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

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

2.16.2 "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 firm finger pressure.

2.17 "Hold tube" means the tube through which the heated food is transported to assure that every particle of food is maintained at the sterilization temperature for at least the minimum sterilization time as specified in the scheduled process. It should be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be sloped upward at least 0.25 inch per foot.

2.18 "Hold time" means the minimum holding period specified in the scheduled process.

2.19 "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.

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

2.21 "Package sterilization" means bringing all food contact surfaces of the package including the lid material to a condition of commercial sterility.

2.22 "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.

2.23 "Preproduction sterilization" or "presterilization" means that part of the scheduled process which is designed to bring all product contact surfaces downstream from the holding tube, including the aseptic zone within packaging equipment, to a condition of commercial sterility prior to the initiation of production.

2.24 "Product heater" means the equipment used to heat product to a temperature necessary to begin delivery of the scheduled process.

2.25 "Product-to-product regenerator (heat exchanger)" means the equipment designed such that enclosed, sterile product is transported adjacent to, but completely separated by a common barrier from, unsterile product (or any other unsterile medium) for the purpose of heat exchange or any other reason.

2.26 "Product sterilizer" means that device used to deliver the heat process to the product which is designed to render the product commercially sterile. Examples include a pressure vessel to deliver a batch type process, or a heat exchanger and hold tube combination to deliver a continuous process to a product fed at a constant rate.

2.27 "Scheduled process" means the process used to achieve and maintain commercial sterility of equipment, containers, and food.

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

2.29 "Steam seal" means an enclosure that utilizes steam as a barrier to entry of microorganisms at susceptible points downstream from the holding tube (e.g. rotating or reciprocating shafts, valve stems, etc.) in the sterile zones.

2.30 "Sterilant" means any physical agent or chemical treatment used to achieve commercial sterility.

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

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

2.33 "Thermal process" means the heat treatment to achieve commercial sterility and is quantified in terms of time and temperature.

3. SECTION III - HYGIENE REQUIREMENTS IN THE PRODUCTION/HARVESTING AREA

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 measure should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

3.2 Harvesting and Production

3.2.1 Techniques

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

3.2.2 Equipment and containers

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

3.2.3 Removal of obviously unfit raw materials

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

3.2.4 Protection against contamination and damage

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

3.3 Storage at the Place of Production/Harvesting

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

3.4 Transportation

3.4.1 Conveyances

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

3.4.2 Handling procedures

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

4.0 SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

Establishments should be located in areas which are free from objectionable 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 furnished as to prevent the accumulation of dirt and minimize condensation, mould development and flaking, and should be easy to clean.

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

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

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

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

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

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

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

4.4 Sanitary Facilities

4.4.1 Water Supply

4.4.1.1 An ample supply of water, in compliance with Sub-Section 7.3 of the Recommended International Code of Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 1), under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination.

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

4.4.1.3 Steam used in direct contact with food or 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 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. 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 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. Canneries should have suitable conveyor systems to transport empty product containers to the filling stations. Their design, structure and installation should ensure that such containers do 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 eqipped with temperature measurement or recording devices.

4.5.2.4 Equipment identification

Eqipment 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. Sterile air, nitrogen or other appropriate gases used to form plastic containers, used for hot air knives to clear hydrogen peroxide from web material, used to maintain over-pressure or for other uses in a sterile zone should be filtered for removal of extraneous

material and properly incinerated and/or filtered to remove microorganisms. The delivery system should be designed to maintain commercial sterility. The system should also be designed to be sterilized from the air sterilization device (incinerator and/or filter) through the point of use. If a filter is used to sterilize air, the processor should be careful to change the filter according to the filter manufacturers guidelines. Filter should be visually examined before installation and after removal. The processor should also have assurances from the filter manufacturer that exposure to the sterilization medium used will not damage the filter or shorten the working life of the filter.

5.0 SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS

5.1 Maintenance

The buildings, equipment, utensils and all other physical facilities of the establishment, including drains, should be maintained in good repair and in an orderly condition. As far as practicable, rooms should be kept free from steam, 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 General Principles of Food Hygiene referred to in Sub-Section 4.4.1 of this Code.

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 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 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

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 tehcniques.

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, equipment and utensils from contamination. After application, contaminated equipment 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.

6.0 SECTION VI: PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene Training

Managers of establishments should arrange for adequate and continuing training of all food handlers in hygienic handling of food and 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 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 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 water in compliance with Sub-Section 7.3 of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1 of this Code. 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 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, and betel nuts, or unhygienic practices such as spitting, should be prohibited in food handling areas.

6.8 Gloves

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

6.9 Visitors

Precautions should be taken to prevent visitors to food handling areas from contaminating food. These may include the use of protective clothing. Visitors should observe the provisions recommended in Sub-Sections 5.9, 6.3, 6.4 and 6.7 of this Code.

6.10 Supervision

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

7.0 SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

7.1.1 No raw material or ingredient should be accepted by the establishment if known to contain parasites, microorganisms or toxic, decomposed or extraneous substances 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 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 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, 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 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 water in compliance with 4.4.1.1.

7.4 Packaging

7.4.1 Storage and characteristics of containers

7.4.1.1 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. 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 and should be stored and maintained in such a manner as to prevent contamination by insects, other animal pests, microorganisms, soil, grease, dust, etc., and noxious odours which may be absorbed by organic packaging materials. Soiled aseptic packaging material may be affected by damage or by changes in physical parameters such as relative humidity should be stored so as to minimize such changes.

7.4.2 Inspection of empty product containers

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

7.4.3 Cleaning of containers or container materials

7.4.3.1 Containers to be sterilized by superheated steam should be inverted for a dry, clean air blast to clean them immediately before passing into the

superheated steam tunnel. In no case should water be used or remain in the containers. (Water has been found to prevent sterilization if present in such a system).

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. Once such packaging has become soiled, chemical sterilization becomes very difficult.

7.4.4 Proper use of product containers

Product 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 accidentally 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 empty product containers during plant cleaning

Empty containers 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 may be shielded or located so they will not become contaminated or obstruct clean-up operations.

7.4.6 Filling of product containers

7.4.6.1 During filling of containers, contamination of seal or seam areas with product should be avoided unless equipment is specifically designed to seal through product. Seam or seal areas should be kept as clean and dry as necessary to obtain satisfactory closure. (Overfilling can lead to contamination of seams or seals and adversely affect container integrity.)

7.4.6.2 The mechanical filling of containers should be controlled in the aseptic zone so as to meet the filling and headspace requirements specified.

7.4.6.3 The filling temperature or mechanical handling equipment should be adjusted to give the package an appearance that does not indicate pressure within the package when it is held at room temperature. (This is a consumer safety-indicator practice.)

7.4.7 Closing operations

7.4.7.1 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 and cover used. Seams and other closures should be tight and secure and meet the requirements of the container manufacturer, the food processor and those of the agency having jurisdiction. The equipment manufacturer's or supplier's instructions should be followed meticulously.

7.4.7.2 For heat sealing, heads or jaws should be adjusted such that pressure is distributed uniformly across the sealing surface. The temperature utilized during sealing should be maintained within the specified range for the packaging material, and delivered uniformly over the whole seal area.

Pressure build-up on sealing heads or jaws should be fast enough and final pressure high enough to allow product to be squeezed away from the seals before bonding commences.

7.4.8 Inspection of closures

7.4.8.1 Inspection for external defects

During production runs, regular observation should be made for external container defects. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other person competent to inspect container closures should visually examine the container and its seal and should make a record of the observations. Additional visual closure inspections should be made immediately following a machine malfunction, adjustment or startup following a prolonged shut down. Seals should be visually examined for defects or product leakage.

The equipment manufacturer's recommendations for examining each container should be followed exactly.

All pertinent observations should be recorded. Where irregularities are found, corrective action should be taken and recorded.

7.4.8.1.1 Inspection of glass container closures

Glass containers consist of two pieces, viz., a glass container and lid (closure) usually metal, which can be twisted or pried off according to the closure design. 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.

7.4.8.1.2 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-Acid and Acidified Low-Acid Canned Foods.

For plastic containers with metal ends, consult the container manufacturer's guidance manual.

7.4.8.1.3 Inspection of heat seals

Appropriate visual 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 should include some physical testing of the uniformity of strength of heat 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 manfacturers of these containers or materials.

7.4.8.1.4 Closure defects

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

7.4.9 Handling of containers after closure

7.4.9.1 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. Generally, flexible plastic and paperboard containers should be overwrapped. They should be kept dry and clean prior to overwrapping.

The risk of micro leakage may be increased if by inadequately designed container conveyor, handling, labelling and packaging equipment which can result in increased container abuse. Conveying systems and equipment should be designed to minimize abuse, and conveyor and equipment surfaces must be effectively cleaned and disinfected. Containers of food should not be manually handled while still wet. 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.

7.4.9.2 If metal cans are used in an aseptic system and they are washed after closing, can dryers if used should not cause damage to or contaminate containers and should be readily accessible for routine cleaning and disinfection.

7.4.9.3 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.

7.4.10 Coding

7.4.10.1 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.

7.4.10.2 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.

7.4.10.3 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.

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

7.4.11 Washing

7.4.11.1 Washing of empty containers to be used in aseptic canning should not be done. (See 7.4.3 "Cleaning of Containers or Container Materials.")

7.4.11.2 Washing of closed metal containers of food in aseptic canning is acceptable if washed in water of the microbiological quality of drinking water.

7.4.11.3 Closed plastic containers usually should not be washed due to a possibly enhanced risk of postprocessing contamination. If plastic containers are washed in water after sealing, the water should be of the microbiological quality of drinking water.

7.5 Sterilization of equipment, containers and food

7.5.1 General considerations

7.5.1.1 Scheduled thermal 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 consist of the following elements:

1. The heat process needed by the food to render the food commercially sterile;

2. The heat and/or chemical process necessary to bring all product contact surfaces (including aseptic surge tanks and fillers) down stream from the hold tube and that area of the packaging machine defined as the aseptic zone, to a condition of commercial sterility;

3. The combination of physical (heat or irradiation) and/or chemical treatments necessary to produce the condition of commercial sterility on all product contact surfaces of the container or container material.

7.5.2.2 The required heat 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 micro-organisms;

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;

Innoculated pack incubation results;

Product incubation results.

Traditionally, process establishment for low-acid foods involves the marriage of the heating characteristics of the product with the bacterial resistance of certain target microorganisms. A mathematical model is used to develop thermal processes which are confirmed by bacterial inoculated pack studies. The use of a mathematical model allows maximum flexibility concerning process alternatives while minimizing the amount of process testing necessary. The Ball formula method essentially serves this purpose for traditional in-can retort processing. The conventional approach for aseptic processing of homogeneous products is that the thermal process includes only that lethality accumulated in the product as it passes through the hold tube. A mathematical model is used to determine the minimum residence time and minimum product terperature necessary to produce a desired lethality. The flow rate, physical dimensions of the hold tube and the rheological properties of the fluid are used to calculate a residence time for the fastest fluid particle. The minimum temperature is verified by physically measuring the temperature at the end of the hold tube. Since no heat is applied to the hold tube, this represents the minimum temperature for the product flowing through the hold tube.

Any changes in the product specifications should be evaluated as to their effect on the adequacy of the process. If the scheduled heat process is found to be inadequate, it should be reestablished.

7.5.2.3 Reproduction Equipment Sterilization

7.5.2.3.1 Processing, holding and filling equipment

Before production begins, all piping, values, 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. This is usually accomplished by hot water and/or saturated steam at temperatures in excess of 121°C (250°F) for at least 30 minutes in the coldest part of the system. Surge tanks and/or fillers are sometimes sterilized separately from the rest of the system; however, these sterilization cycles should be conducted simultaneously. Temperatures reached during the sterilization cycles should be verified by accurate temperature measuring devices such as thermocouples located in the slowest heating part of the system. For product systems sterilized by hot water, this will normally mean a location within the piping beyond the valve which interfaces the filler with the processing system. Ideal sensor locations must also be determined for surge tanks and complex valving such as that which may be used for flow diversion devices. Special

considerations for surge tank sterilization are discussed in sub-section 7.6.1.7 and sterilization of flow diversion devices is discussed in sub-section 7.6.1.6.

7.5.2.3.2 Packaging equipment

The "aseptic zone" of filling and sealing equipment must be brought to a condition of commercial sterility prior to the initiation of product filling and must be maintained in a condition of commercial sterility until the completion of 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 those systems which utilize super-heated steam, or by chemicals such as those systems which employ hydrogen peroxide for this purpose. For those systems using heat, the time and temperature at the coldest locations within the aseptic zone will be critical factors and should be recorded. For hydrogen peroxide systems the quantity 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 based on the biological effectiveness of the process in terms of reducing potentially resistant pathogenic microorganisms such as Clostridium botulinum to scientifically acceptable probabilities of survival. This will involve sometimes considerable testing with appropriate test organisms and procedures. Once the sterilization treatment of the aseptic zone is completed, this area is maintained under a positive pressure with sterile air or other gas until the end of production. Special considerations for gas sterilization are found in sub-section 4.7 and sterilization of packaging equipment is also discussed in sub-section 8.1.6.

7.5.2.4 Package Sterilization

The sterilization of packaging material to be used in aseptic processing is typically sterilized either inside the packaging machine or is sterilized off site and 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 be based on the biological effectiveness of the process in terms of reducing pathogens which are resistant to that particular sterilization treatment, to scientifically acceptable probabilities of survival. To establish this process, may involve considerable challenge testing using appropriate test organisms and methods. Further discussion of container sterilization and record keeping requirements can be found in sub-sections 8.1.6, 8.1.7 and 8.1.8.

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

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.

7.6.3 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) That 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, sterilant bath levels, sterilant concentration, sterilant temperature, temperatures of incinerators, zone temperatures, fogging times and all other factors identified as critical to the production of a commercially sterile product;

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

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 pre-sterilization 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.

7.6.4.2 Timing method(s)

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.

7.7 Deviations in Aseptic Operations

7.7.1 Loss of sterility

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

7.7.2 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 commerical 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 re-sterilized 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 improper pressure relationship has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

8.0 SECTION VIII - QUALITY ASSURANCE

It is important that scheduled processes be properly established, correctly applied, sufficiently supervised and documented to provide positive

assurance that the requirements have been met. These assurances apply also to the seaming and sealing operations. For practical and statistical reasons, an end-product analysis by itself is not sufficient to monitor the adequacy of the scheduled process.

8.1 Processing and Production Records

8.1.1 Commercial sterility processing of foods 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 the holding tube outlet;

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

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

(e) Product flow rate (in liters or gallons per minute, can per minute, etc.);

(f) Aseptic surge tank sterile air overpressure;

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

(h) The sterilization of equipment during the "pre-sterilization" cycle;

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

(j) The code mark of the containers;

(k) Records of each diversion;

(l) 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 reachs 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 up of machines following a prolonged shutdown. All seals and seams should be visually examined for product leadage. All pertinent observations should be recorded. Teardown and inspection of cans should be conducted at in 7.4.1.2 of the Draft Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods.

8.1.4 Metal cans or rigid container/sterilization systems employing super-heated steam

The coolest temperature in the super-heated 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 required in Sub-Section 7.4.8.1. 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 steriliant 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 suggested in 7.4.8.1 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 sterilant is approved for contact with the container material,

and that any maximum or minimum concentration and residual limits imposed by regulatory agencies are adhered to.

If sterile air or other sterile gas is necessary for the maintainance 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 the packaging.

8.1.7 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 provision 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 initialed by the processing system operator, or other designated person, at the time the specific condition or operation occurs. Prior to shipment or release for distribution, but not later than one working day after the actual process, a knowledgeable representative of plant management should review and ensure that all records suggested in 8.1.1 are complete and that the product should be commercially sterile based on these records. The records should be signed or initialed by the person conducting the review.

8.2.2 Container closure records

Written records of all container closure examinations should specify the code lot, the date and time of container closure inspections, the measurements obtained, and all corrective actions taken. Records should be signed or initialed by the container closure inspector and should be reviewed by a representative of plant management, who is competent, 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 the 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.

9.0 SECTION IX - STORAGE AND TRANSPORTATION OF FINISHED PRODUCT

Conditions of storage and transport should be such that the integrity of the product container and the safety and quality of the product are not adversely affected. 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 incubatory 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.

10.0 SECTION X - LABORATORY CONTROL PROCEDURES

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

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

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

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

10.5 Incubation tests of 10 days at 35°C ± 2.8 (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, initialed, and passed to management for final signature. These records should be retained.

11.0 SECTION XI - END-PRODUCT SPECIFICATIONS

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

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

11.2 The products should be commercially sterile, and not contain any substances originating from micro-organisms 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.

Draft Amendments to the Code of Hygienic Practice for Dried Milk (CAC/RCP 31-1983) (At Step 8 of the Codex Procedure)

Sections 2.9 and 7.7.3 are amended as follows:

2.9 "Pasteurization": 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.

Minimum Temperature/Time Combinations for Pasteurization

Pasteurized milk and skimmed milk	63°C for 30 mins 72°C for 15s
Pasteurized cream (18% fat)	75°C for 15s
(35% fat or more)	80°C for 15s
Pasteurized concentrated milk	80°C for 25s

NOTE: The temperature/time combinations given are typical examples of many combinations of temperature and time having an equivalent and minimum bactericidal effect necessary for pasteurization. The combinations depend on such factors as the nature of the product, solid content, viscosity, etc.

7.7.3 The following should be monitored by a laboratory:

(i) incoming milk and liquid milk products;
(ii) other ingredients;
(iii) processing and manufacturing stages, including pasteurization by means of phosphatase test;*
(iv) cleaning and disinfection in the plant;
(v) finished products;
(vi) water quality
(vii) calibration of instruments, for example, gauges, thermometers, etc.;
(viii) packaging materials;
(ix) air quality;
(x) steam quality; and
(xi) microbiological monitoring of the environment within and immediately outside the plant.

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* Methods IDF-63 Phosphatase activity - reference method for milk
ISO-3356: 1975. Milk and dried milk, buttermilk and buttermilk powder, whey and whey powder - Determination of phosphatase activity (Reference Method)
AOAC (1984) Official Methods of Analysis of the AOAC, Fourteenth ed., Phosphatase (residual) in milk. Final Action, Method II, 16.112 - 16.114.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-COOKED AND COOKED FOODS IN MASS CATERING
(At Step 5 of the Procedure)

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

This Code deals with the hygienic requirements for cooking raw foods and handling cooked and precooked 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/or delivery and serving of food.

2.2 Catering Establishment: a centralized kitchen where food is prepared for catering.

2.3 Cleaning: the removal of soil, food residues, dust, grease or other objectionable matter.

2.4 Contamination: the occurrence of any objectionable matter in the product.

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

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

2.6 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.

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

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

2.9 Food handling personnel: every person handling or coming into contact with food, or with any equipment or utensil used in food handling.

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

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

2.12 Mass Catering: the preparation, storage and/or delivery and serving of food on a massive scale.

2.13 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.

2.14 Pests: any animals capable of directly or indirectly contaminating food.

2.15 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.

2.16 Portioning: division of food immediately after cooking into single or multiple portions.

2.17 Potentially hazardous food: food capable of supporting rapid and progressive growth of infectious or toxigenic bacteria when improperly handled.

2.18 Rapid chilling: reduction of the temperature in the centre of the food from 60°C to 3°C or below within two hours.

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 somtimes from a food handler, but more 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. 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.

Establishments should also have refrigerating and/or freezing cabinet or equipment (freeze tunnel) for rapid chilling methods, freezing methods and chilled and frozen storage of prepared food corresponding to the maximum daily activity of the establishment and in order to comply with the requirements of Section 7.7 and 7.8.

Note: Rapid chilling or freezing of large quantities of food requires proper equipment capable of extracting heat rapidly from the largest quantity of food likely to be produced. The method must ensure that foods are not held a long time in the temperature range between 10°C and 60°C where harmful microorganisms grow rapidly. The performance of the equipment should be monitored continuously with allowances for drifting outside specifications.

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.

4.3.15 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 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 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 pipies 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.

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: Eqipment and utensils constitute a source of potential cross-contamination. They must not be used for raw and cooked foods indiscriminately. 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.

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.

4.4.2.3 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.

Note: The accuracy of the temperature-recording devices should be checked at regular intervals.

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.

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 1).

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 to prevent food from being contaminated during cleaning or disinfection of rooms, equipment or utensils by water and detergents and 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 potable water 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 Storage and Disposal of Wastes

In kitchen and food preparation rooms, offal and waste products should be collected in single-use bags or in 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.

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 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. Extreme care should be taken to avoid contamination of 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 Personnel Effects and Clothing

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 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

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 period 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.

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 Raw foods of animal origin should be stored between +1 and 3°C. Other chilled foods such as vegetables should be stored below 7°C. Temperatures should be checked at least once daily.

> 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. Common human pathogens can grow, albeit slowly, at chill temperatures. Yersinia enterocolitica can grow very slowly at -1°C, Clostridium botulinum type E at 3.30°C and Listeria moncytogenes at -1°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 If there is a likelihood of contamination hands should be washed thoroughly between handling products at different stages of processing.

Note: Food handlers constitute a hazard. Cooked ingredients in potato salad, for instance, can be contaminated by persons during mixing operations in its 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 maintained at at temperature below 10°C.
or
b) running potable water maintained at a temperature not above 21°C.
or
c) a 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.
or
d) a purpose-built thawing cabinet.

CCP-Note: Hazards associated with thawing include cross-contamination from drip and growth of micro-organisms on the outside before the inside has thawed. Thawing times should be strictly controlled.

7.5 Cooking Process

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

Note: Frying fats and oils should not be over-heated. Fats and oils should regularly be changed.

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. Recent studies have shown that 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.

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. The body cavity of large poultry carcasses must not be stuffed (a) because the stuffing can be contaminated with salmonellae, and may not achieve a temperature high enough to kill them and (b) because spores of Clostridium perfringens will survive cooking. 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 products are grilled roasted, browned, fried, blanched, poached or cooked the day before they are consumed, such treatment must be followed by rapid chilling.

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 the portioning process of cooked-chilled foods should take place in a separate area in which the ambient temperature should not exceed 15°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. A specially designed rapid chilling system is essential.

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 + 3°C or below within two hours.

Note: Epidemiological information indicates 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 micro-organisms grow rapidly. Hazard analyses must assess conditions of rapid chilling.

7.7.3 As soon as the chilling is complete the products should be put into a refrigerator. The temperature should not exceed +3°C in any part of the product and should be maintained until final use. Regular monitoring of the storage temperature is necessary.

CCP-Note: Seafood products should ideally be kept below 3°C since the type of C. botulinum found in fish, type E, will grow slowly at temperatures over 3.3°C.

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 +3°C. If storage temperatures between 3 and 7°C are used, the storage period should be reduced accordingly.

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. A specially designed rapid freezing system is essential.

7.8.2 The performance required of the freezer is to rapidly chill the food and subsequently to freeze it to a temperature below - 18°C.

Note: See CCP-Note in 7.7.2.

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

7.8.4 Cooked-frozen foods that have been thawed can be stored at or below 3°C but for not more than five days and should not be frozen again.

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. The foods should be kept in an insulated container during transport.

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 temperature of the cooked-chilled food should be maintained below + 3°C but may rise to 7°C for a short period of time 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 65°C should be reached in the centre of the food within one hour of removing the food from chilling.

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 65°C.

Note: To minimize the loss of the nutritional value of the food it should be kept at or above 65°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 distribution system should be such that the foods offered are protected from direct contamination which could result in the proximity or the action of the consumer. The temperature of the food should be either below 7°C or above 65°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 in chill or in freezer until at least three days after that whole lot has been consumed. The sample should be obtained from the lot just prior to the finish of portioning. 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.