codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 87/13A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
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REPORT OF THE TWENTY-SECOND SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE
Washington, D.C., 20-24 October 1986

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W/Z 1842

INTRODUCTION

1. The 22nd Session of the Codex Committee on Food Hygiene (CCFH) was held in the Main Conference Room, Department of State, Washington, D.C. from 20th to 24th October 1986 by courtesy of the Government of the United States of America. Representatives and Observers from 28 countries and 5 international organizations were present. The Chairman of the Session was Dr. Douglas Archer, Director, Division of Microbiology, FDA. A list of participants is attached as Appendix I.

OPENING OF SESSION

2. Dr. Archer opened the session and introduced Dr. Walter Schlech (Victoria General Hospital, Halifax, Nova Scotia, Canada) who addressed participants on "New Concepts of Listeriosis" in which he presented the evidence for considering Listeria monocytogenes as a food borne pathogen, the characteristics of the micro-organism and the way in which it was transmitted.

3. The Committee noted that the comments of participants that experimental work on Listeria monocytogenes was in progress in several countries, particularly in relation to its persistence in milk after certain pasteurization processes.

4. The Committee expressed its appreciation to Dr. Schlech for an interesting and informative presentation, an abstract of which is attached as Appendix II.

ADOPTION OF THE AGENDA

5. The observer of the International Dairy Federation drew attention to the fact that the two documents under Item 11 - CX/FH 86/10A "Code of Hygienic Practice for Soft Cheeses", CX/FH 86/10B "Code of Hygienic Practice for Raw Milk Preservation using the Lactoperoxidase System" had only been made available to delegates on their arrival at the meeting. The first of them had been prepared specially for this meeting of CCFH and the work of the authors Dr. E. G. McGarrahan and Dr. J. Nelson (U.S.A.) was submitted to IDF in September 1986 and was subsequently transmitted to CCFH. The second had been presented in a previous version to the Committee of Government Experts concerning the Code of Principles for Milk and Milk Products (the Milk Committee) at its meeting in Rome in June 1986 and subsequently revised by Swedish experts under IDF auspices. Both documents had been examined at IDF's annual session in The Hague in September 1986 and were now due for circulation to IDF member committees for comment. New versions prepared in the light of the comments received will be submitted to IDF's next annual session, in Helsinki in August 1987, and then passed on to the CCFH secretariat for consideration at this committee's next meeting. IDF would welcome preliminary comments from delegates on the documents and would be prepared to participate in a working group set up during the session. Any remarks made would be reported to the IDF experts responsible and taken into consideration alongside those of IDF member committees in the preparation of the new drafts.

6. The Committee noted that under Agenda Item 12, "Consideration of Microbiological Criteria for Freeze-dried Food", the document listed as CX/FH 86/11 was not available.

7. Several delegations, including France and the Netherlands, pointed out that many of the documents, including those containing Government comments, had not been received in their countries and were only available the meeting. This made it difficult to make constructive comments on the Codes and other matters under consideration.

8. It was explained that many Government comments had arrived very late and were further delayed by the need for translation into the working languages of the Committee. The Chairman regretted the inconvenience and proposed the beginning of the afternoon session should be delayed to give participants an opportunity to study the documents further.

9. The Committee agreed to this proposal and adopted the agenda as amended.

INFORMATION ON ACTIVITIES WITHIN FAO OF INTEREST TO THE COMMITTEE

10. The representative of PAHO, Dr. Fernando Quevedo gave the following review of the activities of WHO and PAHO/WHO related to the work of the Committee:

1) During the XIII International Congress on Nutrition, Brighton, U.K., August 1985, WHO, jointly with the organizers of the congress, sponsored a colloquium on Food Safety and Health. The papers presented during the colloqium featured essentially on microbioligical food contamination hazards and their contribution to morbidity, mortality and mal(under)-nutrition.

2) Under the auspices of the FAO/WHO/IAEA sponsored International Consultative Group on Food Irradiation, a Task Force on the Use of Irradiation to Ensure Hygienic Quality of Food met in Vienna in July 1986. The Task Force concluded that at present, and in the foreseeable future, no technology is available to produce raw foods of animal origin, particularly poultry and pork, in which the absence of certain pathogenic microorganisms and parasites such as Salmonella, Campylobacter, Toxoplasma and Trichinella can be guaranteed. Where such foods are important in the epidemiology of foodborne diseases, irradiation decontamination/disinfection must be seriously considered. The report of this meeting will be published by WHO in early 1987.

3) Jointly with FAO, WHO is organizing a 2nd Conference on Mycotoxins tentatively scheduled to take place in Harare, Zimbabwe on 30.3.87 - 6.4.87.

4) Also jointly with FAO, WHO sponsored a Consultation on Food Protection (Food Safety) for Urban Consumers, scheduled to take place 1-5.12.86.

5) Considerable efforts are being made by WHO to encourage Member States to establish or strengthen national or sub-regional foodborne disease surveillance programmes. Several intercountry workshops have taken place during 1985/86. The Codex Coordinating Committee for Latin America and the Caribbean decided, during its session in 1985 to have this topic on the agenda of its forthcoming 5th Session in Havana, Cuba from 11-16 February 1987.

6) Considerable efforts are also being made by WHO to integrate food safety into Primary Health Care (PHC). To this end, preparations are underway for a WHO Consultation on Health Education in Food Safety, scheduled for 27.4.87 - 1.5.87 in WHO/HQ. In addition, studies on domestic and small scale commercial food processing, using the HACCP-approach, are sponsored jointly by WHO, food and related industries and other donors. A HACCP Guide has been prepared and will be published by WHO in 1987. The first HACCP training course will be held in February 1987 in the Dominican Republic.

7) A brochure containing examples of health education material on food safety is being prepared with financial and technical support from one food industry and is expected to be available in 1987. The final edition of an International Source List of Audiovisual material on food safety will also be available in 1987.

8) WHO still has a role to play concerning food irradiation, namely to reassure Member States that this technology can be used to the protection of food safety and the reduction of food losses. To this end WHO, co-sponsored by FAO, is in the process of preparing a book on food irradiation, the publication of which is expected during the second half of 1987.

9) In early 1986, WHO published a provisional edition of the FAO/WHO Guiding Principles for the Evaluation of Programme to Ensure Food Safety in English, French and Spanish. The objective of this publication is, amongst other things, to assist Member States in reviewing and analysing national needs in food safety and to determine appropriate measures necessary to meet those standards.

10) Guidelines for safe food handling in hotels, restaurants and similar establishments have been completed and are at present with the WHO editors. Their publication is expected in 1987. In addition, WHO has developed cartoons featuring

important food safety hints which are being sent to publishers of cookery books for inclusion in future cookery publications.

11) A WHO consultation on specific methods (immunisation) of prevention and control of salmonellosis in animals was held in Munich, Germany in October 1986.

ACTIVITIES OF ISO

11. Madame Gantois as representative of the ISO Secretariat reported on the progress in ISO work in the field of microbiology.

12. Sub-Committee 9 "Microbiology" of Technical Committee 34 for food and agricultural products (ISO/TC 34/SC9) would hold its next meeting in Lisbon, Portugal from 18-20 November 1986 at the same time as SC 6 "Meat and Meat Products" mainly to discuss microbiological questions.

13. There had been no new publications since the 20th Session of the Codex Committee on Food Hygiene. However, three standards were published in 1985 as final texts. These were:

ISO 7042 - General Guidance for enumeration of Enterobacteriaceae without resuscitation.

ISO 7937 - General Guidance for enumeration of Clostridium perfringens.

ISO 7218 General Guidance for microbiological analysis.

14. The last mentioned standard was of particular importance. It was in fact a basic document which would allow a better measurement of the validity of analysis, an assurance that the general techniques were common to all laboratories and would also ensure that the health of laboratory personnel was better protected.

Drafts for discussion at the next SC 9 Meeting

15. Two draft international standards one for Bacillus cereus (DIS 7932) and another concerning yeasts and moulds (DIS 7954) had completed the voting procedure and should be finished next month.

Only the section "Expression of results" required further work and should in fact be brought into line with that included in the microbiological standards of the International Dairy Federation.

16. Two first proposed draft standards DP 8914 - General Guidance for the detection of Vibrio parahaemolyticus and DP 8523-General Guidance for the detection of Enterobacteriaceae with resuscitation will be examined at Lisbon in the light of government comments.

17. Two working documents:

- Precision tests for standard microbiological methods and

- Reference material for the evaluation of the standard method for the detection of Salmonella, were included in the agenda for the next SC 9 Meeting.

18. SC 9 had also been requested to give some attention to interlaboratory microbiological tests. Such tests could not follow the parameters adopted for chemical methods since the essential problem lay in the preparation of stable samples.

ISO 4831-78 - General guidance for the enumeration of coliforms - most probable number technique at 30°C

ISO 4832-78 - General guidance for the enumeration of coliforms - Colony count technique at 30°C

ISO 4833-78 - General guidance for the enumeration of micro-organisms - Colony count technique at 30°C

19. The above standards were under revision. No fundamental changes had been requested and they would therefore be re-issued after editorial changes had been made to take into account the standard ISO layout (ISO 7667) and to harmonize the expression of results if required.

20. In addition, the draft revision of ISO 6579-81 - General guidance on methods for the detection of Salmonella providing for the replacement of tetrathionate broth with Rappaport-Vassiliadis medium and including the rehydration required for dry food products would be discussed at Lisbon. Methods for Campylobacter spp. and Yersinia enterocolitica were still in the work programme but so far no working documents had been circulated.

REVIEW OF MATTERS RELEVANT TO THE COMMITTEE AS DISCUSSED BY THE EXECUTIVE COMMITTEE AND OTHER CODEX COMMITTEES

(A) THE EXECUTIVE COMMITTEE (33RD SESSION ALINORM 87/3)

Future Direction of the work of the Joint FAO/WHO Food Standards Programme

21. The Committee noted that the above subject had been discussed at the 33rd Session of the Executive Committee in the light of a document prepared by a consultant (Mr. G.O. Kermode).

22. The document reviewed the current state of the work of the Commission and its subsidiary bodies and indicated the changed situation likely to be facing the Commission by the end of 1989, when most of the activity on the elaboration of standards by the Codex Commodity Committees would probably have been completed. The document considered food groups not previously standardized under the Programme and other matters which might be given attention by the CAC, in order to fill lacunae in the Codex Alimentarius.

23. Among the points made by individual members of the Executive Committee the following were of particular interest:

- There was a need to investigate the problems of contamination by mycotoxins of internationally traded foods. To deal with these and with environmental contaminants a special Codex Committee on Contaminants might be required.

- The establishment of a Codex Committee on Tropical Fruits and Vegetables appeared to be a possibility at the next session of the Commission.

- The establishment of an "Omnibus" Commodity Committee which would deal with outstanding items from Committees which had wound up their main work programme and with any matters which would not justify the convening of a full Commodity Committee session should be considered.

- The proposal by the Consultant to undertake work on the standardization of alcoholic beverages should be considered in view of the enormous international trade in such products and the necessity to protect the consumer from abusive practices.

Recent North American National Conferences on Codex had stressed:

i) the importance of maintaining a high priority for the work of the Codex General Subject Committees and of placing more importance on the work of Regional Coordinating Committees;

ii) more emphasis on acceptance and implementation of Codex Standards;

iii) the need to better inform governments, international organizations, UN agencies, the food industry and consumers on the role anad impact of Codex activities;

- The hygienic aspects of the handling of street vended foods should be covered by the elaboration of a Codex Code of Practice.

24. The Executive Committee had agreed as follows:

i) The future work programme should be given high priority for further discussion at the Codex Committee on General Principles and at the next Session of the Executive Committee and the Commission.

ii) There was strong support for the continuation of the work of the General Subject Committees and for giving greater importance to the activities of the Regional Coordinating Committees.

iii) The Secretariat should provide information to the Codex Committee on General Principles concerning the possibility of establishing new Committees, such as the "Omnibus" Commodity Committee and a Committee on Environmental Contaminants.

iv) The establishment of a Codex Committee on Environmental Contaminants (including mycotoxins and radio nuclides) was considered to have very high priority and this was recommended to the Commission by the Executive Committee.

v) The formation of a "Codex Task Force" for direct contact with Codex Member Countries should be given consideration.

vi) The periodic publications of a Codex Activities bulletin should be investigated.

vii) The Codex Committee on General Principals should look into the Codex working mechanisms, and, if necessary, make recommendations for improvements.

25. The Committee noted that during the discussion at the Executive Committee it had been suggested that the hygienic aspects of the handling of street-vended foods should be covered by the elaboration of a code of practice.

26. The Committee also noted the opinions of delegates at the present session that the problems of street-vending were already a point of discussion in regional fora and that since practices and control regulations varied widely in different regions it would be impracticable to embark on an international code of practice. A better approach would be to deal with the establishment of proper practices through educational programmes aimed at consumers rather than to attempt to elaborate an international code.

27. The Committee agreed with this point of view and decided to bring it to the attention of the Executive Committee and the Commission.

(B) OTHER CODEX COMMITTEES

CODEX COORDINATING COMMITTEE FOR ASIA (CCA) (5TH SESSION, ALINORM 87/15)

Status of the Microbiological Criteria for Pre-Cooked Frozen Shrimps and Prawns

28. CCA had noted that microbiological criteria for pre-cooked frozen shrimps and prawns as end product specifications were adopted by the Commission. The end-product specifications were considered important to the region since there was a considerable international trade in these commodities. The delegations of Indonesia and Malaysia, however, had pointed out that specifications for salmonella should be expressed on the basis of quantity of sample analyzed (for example per 25g or 50g).

29. The Committee noted that the microbiological criteria had been included in the code of practice for shrimps and prawns (CAC/RCP 17-1978) and the method had been given by reference only. In the case of the determination of salmonella, the method referenced specified a sample size of 25g.

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (18TH SESSION, ALINORM 87/20)

Consideration of the Draft International Standard for Honey

Section 5 - Hygiene

30. The delegation of the Federal Republic of Germany was of the opinion that honey should be practically free from mould at all stages in the distribution chain and not only when the product was offered for sale in retail trade as required in Section 5.2.

On the recommendation of the Delegation of the Federal Republic of Germany the Committee agreed to require in Secion 5.3 that honey shall not contain any toxic substances arising from plants, which may constitute a hazard to health. (See also Section (c) - Provisions for Endorsement).

CODEX COMMITTEE ON CEREALS, PULSES AND LEGUMES (5TH SESSION, ALINORM (87/29)

Consideration at Step 7 of Draft Standard for Certain Pulses

Food Hygiene - Section 5

31. The Committee noted that Section 5 followed the same pattern as the other standards developed by the Committee. The delegation of Poland informed the Committee that its country's Sanitary Inspection Services required a maximum limit for aflatoxins of 0.005 mg/kg subject to the sensitivity of the method applied. (See also Section (c) - Provisions for Endorsement).

JOINT FAO/WHO COMMITTEE OF GOVERNMENT EXPERTS ON THE CODE OF PRINCIPLES CONCERNING MILK PRODUCTS (21ST SESSION, CX 5/90)

Definition of Heat Treatments of Milk

32. At its 20th Session the Milk Committee had considered definitions proposed by the Governments and by the International Dairy Federation (IDF) for pasteurization, UHT and sterilization of milk and fluid milk products and decided that governments be invited to comment on the proposals of IDF and on the comments and definitions provided by governments as given in Appendix II of the Milk Committee's Report of the 20th Session.

33. The Milk Committee had noted the comments received from governments and definitions proposed by the IDF as given in document MDS 86/10.

34. Following a proposal by the Chairman, the Milk Committee discussed a definition for Pasteurization proposed by the delegate of the United States which took into account the definition prepared by the IDF. After a brief discussion the Milk Committee adopted the following definition:

> "Pasteurization is a heat treatment process applied to a product with the aim of avoiding public health hazards arising from pathogenic microorganisms associated with milk. Pasteurization as a heat treatment process is intended to result in only minimal chemical, physical and organoleptic changes.
>
> NOTE:
>
> Pasteurization is intended to avoid public health hazards in the sense that, although it may not destroy all the pathogenic micro-organisms which may be present, it reduces the number of harmful micro-organisms 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 micro-organisms in the product."

35. The Committee noted that at its 18th Session it had considered the Draft Code of Hygienic Practice for Dried Milk at Step 7 at which time the following discussion on the definition of pasteurization had taken place (ALINORM 83/13, para 67).

"Sub-section 2.9: The Swiss delegation stated that industrial heat treatment of dried milk was generally carried out at higher temperatures than those indicated in this section. The time/temperature relationship did not cover the requirements for all microorganisms nor did it make allowance for different requirements in different countries. These views were supported by several delegations. The delegation of Canada pointed out that the Code did not include reference to the phosphatase test which would

be useful in verifying proper pasteurization. The Committee recalled that this section had been thoroughly discussed at its previous session (paras 108-110 of ALINORM 81/13) and noted, moreover, that the Milk Committee at its forthcoming session would give consideration to definitions including that of pasteurization. The outcome of the discussions by the Milk Committee would also provide advice for this Committee. The Committee offered to introduce in the meantime the following, more general, text of Section 2.9: Pasteurization: heating at a time/temperature relationship to ensure an adequate reduction in the number of pathogenic microorganisms of concern" and to reconsider this section in the light of the Milk Committee's discussion."

36. The Committee also noted that the "Dried Milk Code" had subsequently been adopted by the Commission at Step 8 but the question of an agreed definition of pasteurization was still pending.

37. The IDF observer pointed out that definition of pasteurization quoted from the report of the Milk Committee's 21st Session (Rome, June 1986) gave the text as modified and adopted at that meeting but did not include the supplementary information on time/temperature relationships that had featured in the earlier draft. This information was essential for a full appreciation of the Milk Committee's agreement. Furthermore, the implications of this definition should be considered in relation to the Recommended Code of Hygienic Practice for Dried Milk (CAC/RCP 31-1983) which, he recalled, had been approved with a very concise definition of "pasteurization" pending further work in the Milk Committee. The clauses in CAC/RCP 31-1983 concerning equipment (4.5.2.3, 4.5.2.4), thermometers and recording devices (4.5.3) and processing (7.4.4, 7.4.6, 7.4.7) were also relevant to the application of the word pasteurization in the Code.

38. After some discussion the Committee decided to establish a Working Group to examine the question and to propose a definition to the plenary session at a later stage. The Committee also requested the Working Group to give some consideration to items 11A, Draft Code of Hygienic Practice for Soft Cheeses and 11B Draft Code of Hygienic Practice for Raw Milk Preservation by use of the Lactoperoxidase System.

CODEX COORDINATING COMMITTEE FOR EUROPE (CCE) (15TH SESSION, ALINORM 87/19)

(2) Amendment to the Codex European Regional Standard for Natural Mineral Waters - Codex Stan. 108-1981)

39. The Committee was informed that the Codex Committee on Food Hygiene had advanced the Code of Hygienic Practice for the Collecting, Processing and Marketing of Natural Mineral Waters (Appendix VII to ALINORM 85/13A) to Step 8 of the Procedure. The Code included provisions for microbiological end product specifications identical to those proposed for inclusion in Section 5.4 in the Regional European Standard for Natural Mineral Waters at Step 5.

40. The Commission had agreed with the Coordinator for Europe to adopt the specifications at Steps 5 and 8 as an amendment to the Regional Standard consequential to the adoption of the same provisions in the Code of Practice. Steps 6 and 7 were omitted.

41. The Committee was informed that CCFH had confirmed that the methods of analysis for these microbiological requirements would be available in the near future. The Committee noted that a detailed report on methods of analysis prepared by GESEM would be considered later.

Report by the Representative of GESEM on Methods of Analysis for Natural Mineral Waters

42. The representative of GESEM, Dr. Paul Bordier, presented to the Codex Committee for Europe an extensive report of the work undertaken by GESEM concerning the development of appropriate Microbiological and Chemical Methods. Dr. Bordier informed the Committee that the report would be made available in English and French for inclusion in the report of the CCE for comment.

43. He outlined the salient points of the collaborative studies which had been carried out by a number of Working Groups and Laboratories under the guidance of a GESEM Coordinating Committee.

44. The CCE recognized the immense amount of work undertaken on its behalf by GESEM and asked Dr. Bordier to convey its deep appreciation to all concerned.

45. The Codex Committee for Europe agreed to request comments on the GESEM report as contained in Appendix VII and to study the document in depth at its next session.

46. The Committee at its present session noted that so far neither methods of analysis nor numerical values for the organisms concerned had been examined although both the Code of Hygienic Practice for the collecting, processing and marketing of Natural Mineral Waters and the Codex European Regional Standard for Natural Mineral Waters had been adopted by the Commission at Step 8.

47. The Committee reiterated its opinion that such a procedure was a departure from the General Principle for the Establishment and Application of Microbiological Criteria for Foods which had already been adopted by the Commission. It was emphasized that any further microbiological specifications proposed for inclusion in the Code and the Standard should be examined by the Committee.

Proposal for Amendment of the Code of Hygienic Practice for the Collecting, Processing and Marketing of Natural Mineral Waters

48. The delegation of Norway, referring to its written comments had proposed to amend Section 3.7 by deleting reference to numerical values for the radius of protection of the extraction area. The delegation of Portugal had pointed out that a numerical requirement was controversial because of the wide variation in mineral water sources.

49. The Secretariat pointed out that the Code had only recently been adopted, but that it might be appropriate to submit the proposals to CCFH for an opinion and subsequently to agree on an amendment procedure. This was agreed by the Codex Committee for Europe.

50. At the present session the delegation of Norway proposed that the amendment could be accepted as non-controversial and was basically of an editorial nature since removal of the numerical value did not change the essence of the provision.

51. The Committee concurred with this point of view and agreed to recommend to the Commission that section 3.7 of the Code, "Protection of the extraction area" be amended as proposed by Norway as follows:

"3.7 Protection of the extraction area
In the immediate surroundings of springs and wells, precautionary measures should be taken to guarantee that no pollutant whatsoever can enter the extraction area. The extraction area should be inaccessible to non-authorized people by providing adequate devices (e.g. enclosure). Any use of not aiming at the collection of natural mineral water should be forbidden in this area."

(c) Endorsement of Hygiene Provisions in Codex Standards

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES

Draft International Standard for Honey (ALINORM 87/20, App. IV)

52. The following text was endorsed by the Committee (see also para 30).

5. 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).

5.2 Honey should be free from visible mould and, as far as practicable, be free from inorganic or organic matters foreign to its composition such as, insects, insect debris, blood or grains of sand, when the honey appears in retail trade or is used in any product for human consumption.

5.3 Honey shall not contain toxic substances arising from microorganisms or plants

in an amount which may constitute a hazard to health.

The delegation of Brazil expressed its disagreement with the changes in section 5.3.

CODEX COMMITTEE FOR CEREALS, PULSES AND LEGUMES (5TH SESSION, ALINORM 87/29, Appendix II)

Draft Standard for Certain Pulses

53. The following provisions were submitted for endorsement (see also para 31).

5.1 It is recommended that the product covered by the provisions of the standard be in accordance with the appropriate sections of the Code of Hygienic Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev.1)

5.2 When tested by appropriate methods of sampling and examination the pulses shall be:

5.2.1 To the extent possible in good manufacturing practice, free from objectionable matter, having regard to the tolerances indicated in Section 3.4 where applicable.

5.2.2 Shall be free from microorganisms, or other poisonous or deleterious substances, in amounts which may reasonably represent a hazard to health.

54. The Committee noted that the reference in 5.1 required up-dating and made the necessary corrections.

55. It was pointed out that the reference to Good Manufacturing Practice in capitals might give the impression that there was a Code of Practice for Cereals. Since this was not the case the phrase was put into lower case (good manufacturing practice).

56. With regard to 5.2.2. it was noted that at its last session the Committee had agreed when examining the hygiene provisions for Pearl Millet and Pearl Millet Flour to the following wording (see ALINORM 87/13 para 92).

"Free from microorganisms, substances originating from microorganisms or other poisonous substances in amounts which may reasonably represent a hazard to health."

57. The delegation of Brazil was of the opinion that the term "reasonably" did not contribute to the intention of the provision. The Committee agreed with this point of view. The provision as endorsed now read:

5.1 It is recommended that the product covered by the provisions of the standard be in accordance with the appropriate sections of the Code of Hygienic Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969 Rev. 1) (1979)

5.2 When tested by appropriate methods of sampling and examination the pulses shall be:

5.2.1 To the extent possible in good manufacturing practice, free from objectionable matter, having regard to the tolerances indicated in Section 3.4 where applicable.

5.2.2 Free from microorganisms, substances originating from microorganisms or other poisonous substances in amounts which may represent a hazard to health.

- CONSIDERATION OF DRAFT CODE OF PRACTICE FOR THE SALVAGING OF CANNED FOODS SUSPECTED OF HAVING BEEN CONTAMINATED (Agenda item 5a)

- GUIDELINE PROCEDURES TO ESTABLISH MICROBIOLOGICAL CAUSES OF SPOILAGE IN CANNED FOODS (Agenda item 5b)

- DEFECT CLASSIFICATION; REPORT OF THE WORKING GROUP FOR THE VISUAL EXAMINATION OF CANNED FOODS: (Agenda Item 7)

A. Categories of Visual Can Defects

B. Manual of Visual Can Defects

58. The Committee noted the Verbal Report of the "Canned Food" Working Group which had considered the above items.

59. The Chairman of the Working Group Mr. I. Erdman (Canada) informed the Committee that two meetings had been held during the past year and presented the following report of these transactions.

60. A meeting of the Working Group was held at the Campden Food Preservation Research Association, Chipping-Campden, England from 28 April to 2 May 1986, inclusive. There were 26 delegates from 7 countries in attendance. A list of those attending is attached as Appendix III to this report.

61. The following documents were considered and revised by the Working Group during this meeting:

1. Guidelines for the Salvaging of Canned Foods exposed to Adverse Conditions.

2. FAO/WHO Working Group Report on Guideline Procedures to establish microbiological causes of Spoilage in Canned Foods. (ALINORM 85/13A)

3. Defect Classification and Manual

4. Visual Examination of Lots of Canned Foods

5. Review of government comments on amendments to the Code of Hygienic Practice for Low-acid and Acidified Low-acid Canned Foods.

Draft Code of Practice for the Salvage of Canned Foods

62. This Code was re-drafted following the instructions recorded during the 21st session of the Codex Committee on Food Hygiene. It should be noted that the title has been changed to "Guidelines for the Salvage of Canned Foods Exposed to Adverse Conditions". Since it was the recommendation of the Committee that this document should be appended to the present Code of hygienic practice for canned foods, it would not be in itself a code. The result of the revision of this document has been subbmitted for consideration by the Committee at this meeting. (CX/FH 86/3).

2. FAO/WHO Working Group Report on Microbiological Specifications and Examination of Canned Foods

63. This document required extensive editorial amendments in order that its contents could be appended to the Code of hygienic practice for Low-Acid and Acidified Low-Acid canned foods. This had been completed by the Working Group plus some amendments to the text which clarified some questions raised by various governments. It should be noted that this document was now entitled "Guideline Procedures to Establish Microbiological Causes of Spoilage in Canned Foods." This document had been circulated for comment at this meeting. Unfortunately the distribution of the revised document to the Working Group was delayed and additional editorial changes were requested. These were received too late to permit a re-draft of the document to be carried out and distributed before this meeting. It was hoped that these could be discussed first in a working group meeting.

3. Defect Manual and Classification

64. Amendment of the defect manual had been delayed pending the attainment of a consensus with respect to the classification of defects in metal containers. The actual pictures and diagrams in the manual were reviewed in this year's Working Group meeting as it was in last year's (1985). Recommendations for better illustrations had been noted but had not been acted upon. Therefore, substantially the Manual existed as presented to the Committee in 1984.

65. No consensus was reached as to the two-category versus the three-category systems of classification of defects. The data requested to permit a comparison of the two systems was not available at the time of the Working Group meeting; the defects depicted in the manual were reviewed and classified according to each system. The USA delegation reported that the results of an examination of about 6×10^6 cans of canned foods for visible defects, representing 6 styles of containers, could soon be available. To assist the USA in using this data to compare the two systems of classification, sample size and acceptance/retention criteria for inspection of lots using both classification systems were agreed upon. The USA delegation would endeavour to give their report prior to the meeting of the Committee and permit further comment by the Working Group.

66. Commenting on the above Summary of the Working Group meeting, the delegation of the USA pointed out that in fact a comparison of the two- and three-category systems of judging visual can defects was sent to members of the Working Group prior to its second meeting. The reasons why this 6×10^6 can data could not be used in the comparison were given to the Working Group at its second meeting. It was pointed out that the basis for the proposed comparison was supported by import inspection data.

4. Inspection of Lots of Canned Foods for Visual Defects

67. In the past working group there had been considerable discussion on various specific sampling plans and guidelines with respect to their application to the visual inspection of lots of canned foods. It was generally concluded that attribute sampling plans were appropriate. A document recently published by ISO, Guidance for Selection of an Acceptance Sampling Plan was reviewed as an excellent document. It was decided to reference this document with some specific cautionary statements when such plans were applied to visual inspection. While more work was required, this had to wait until the question of defect classification was settled.

5. Review of Government Comments on Amendments to the Code of Hygienic Practice for Low-acid and Acidified Low-acid Canned Foods

68. At the time of the meeting no government comments had been received. The Code was not, therefore, examined, and would be considered by the Committee at its present session in the light of comments since received.

2nd Working Group Meeting

69. The working group met again in Washington from October 15 - 17 1986. Sixteen delegates representing 7 countries attended, in an attempt to resolve the defect classification difficulty. A list of those attending is attached as Appendix III to this report.

70. It was concluded that since the matter of defect classification was tied to lot acceptance criteria the issue was not resolvable at that time. Acceptance of certain defects depended primarily on external but associated factors and individual judgements would be required on a case by case basis.

71. The Working Group thus offered the following objectives to resolve this issue.

1. Prepare a pictorial manual identifying those external defects which show visual evidence that a metal container is without a hermetic seal or that microbical growth has occured in the container's contents.

2. Provide guidance for the visual inspection of lots of canned food for the above defects.

3. Consider the feasibility of preparing a complete defect manual with such classifications as may be possible.

4. Provide guidance for inspections of lots of canned food for visual defects.

72. The working group stressed the importance of considering these objectives only in the order in which they were presented.

73. In summary:

1. The working group would like the committee to endorse or otherwise as they see fit the 4 point proposal offered for continuing the Working Group's activities on can defects.

2. The working group recommends that the documents on defects, salvage, and spoilage diagnosis not be considered as appendicies to the low-acid code, but that they be published as separate documents which may then be referenced in the code as required. The working group has no suggestions as to how this might be accomplished and will require guidance in this matter.

3. The working group requests that the salvage document as submitted at this meeting be submitted for government comments.

4. The working group recommends that following some editorial changes to be completed this week, the document on spoilage diagnosis also be submitted for a round of government comments.

74. In addition, the working group wished to thank delegates of Switzerland and France for preparation of a French copy of the spoilage document, Spain for a Spanish copy of a Salvage document and France for a French copy of the Low-Acid Canned Foods Codes. These will be provided to the Secretariat by the working groups, and will ensure that currently used scientific terminology will be used.

75. The Committee noted the four points in future action recommended by the Working Group and endorsed the proposals.

76. It noted that points 1 and 2 of the Working Group programme could be expected to advance rapidly and be ready for consideration by the Committee at its next session.

77. It was also noted that documents now being produced by the Working Group had originally been intended to be attached as appendices to the "Low-Acid" Code. The Working Group was now of the opinion that the documents would be better assembled in manual form as a separate publication for more general use. The Secretariat informed the Committee that he foresaw no problem in publishing the texts prepared by the Working Group in this way within the Codex system. The Secretariat also undertook to make further inquiries as to the publication of a visual defects manual and the availability of funds for such a publication when the Working Group was in a position to prepare a completed document for the Committee.

78. The Committee thanked the Chairman and participants of the Working Group for their sustained efforts in advancing the work of the Committee in this difficult area.

CONSIDERATION OF REVISED DRAFT CODE OF HYGIENIC PRACTICE FOR LOW-ACID AND ACIDIFIED LOW ACID CANNED FOODS

79. The Committee examined the above Code in the light of Government comments from Cuba, Hungary, New Zealand, Thailand, United Kingdom and the United States of America.

80. The Chairman of the Canned Foods Working Group, Mr. I. Erdman who led the discussion, reminded the Committee that comments were requested primarily on the new provisions introduced by the Working Group which were underlined in the text but that relevant comments on other sections of the text could also be considered.

81. There were also some problems that the Working Group had raised during its inter-session meetings which required further discussion.

GENERAL

82. It was noted that a method for the measurement of pH in Canned Foods was still required. The delegation of the United States proposed to communicate a study on the question to the Working Group. In addition the delegation of France offered to provide the Working Group with its national method. The delegation of Denmark pointed out that

at its 20th Session the Committee had agreed to some amendments to the Recommended International Code of Practice - General Principles of Food Hygiene (See ALINORM 85/13A, Appendix VI) which had been endorsed by the Commission. There were however some anomalies in the text adopted which required consequential amendments. The Secretariat agreed to look into the matter and to make the necessary changes.

83. The Committee then considered the comments in detail and agreed to a number of changes.

84. The Chairman of the Working Group undertook to reconvene the W.G. to incorporate the agreed changes and to complete work on other provisions in the Code.

STATUS OF THE REVISED DRAFT CODE OF PRACTICE FOR LOW ACID AND ACIDIFIED LOW ACID CANNED FOODS

85. The Committee agreed with this course of action and decided to advance the revised Code to Step 5. (See Appendix VII).

86. The delegation of Australia agreed to re-submit its Government comments on the non-underlined provisions of the Code at Step 6 of the procedure.

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

87. The Committee had before it the above code as contained in Appendix VII, Alinorm 87/13 and comments thereon from Cuba, The Netherlands, New Zealand and the United Kingdom (CX/FH 86/6).

88. The documents were introduced by the delegation of The Netherlands. The Committee recalled the decision taken at its 21st Session to follow the Code of Hygienic Practice - General Principles of Food Hygiene as closely as possible while elaborating the Code for Pre-cooked Meals in Mass Catering. The Committee agreed to discuss the Code in the light of comments received, in plenary rather than in a working group in order to give an opportunity for full discussion with all participants.

General Comment

89. The delegation of U.K. was of the opinion that most of the requirements in the present draft code applied specifically to cook-chill and had been extended to cover cook-serve and cook-freeze systems. This resulted in unnecessarily strict requirements for, for example, low temperature rooms for portioning food for cook-serve and the need for rigorous separation of certain operations. Incorporating the three types of mass-catering in one code posed a dilemma which could be resolved by dividing the code into separate sections. Whether this was practical was debatable.

Explanatory Preface

90. Para B. The delegation of U.K. held the view that the present text presented a rather alarmist picture of mass catering. It was not correct to say that a large scale catering was particularly hazardous because of the nature of the food produced and the way in which it must be stored and handled. The following modified text put forward by the delegation of U.K. was agreed to by the Committee.

"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."

Para C: Hazard Analysis Critical Control Point (HACCP) System

91. Several delegations made the general comment that HACCP was a system that required an analysis of the microbiological hazards in a given operation before critical control points could be established and in most cases could only be applied to specific operations.

92. It was pointed out that the Mass Catering Code and Codex Codes of Practice and Hygienic Practice were general texts in which critical control points could not be readily identified. It was therefore better to replace reference to critical control points noted in the present code by explanatory notes.

93. The delegation of Norway pointed out that the CCFFP had responded to recommendations by the CAC and had already embarked on a consideration of applying the HACCP concept to the Codes of Practice for Fish and Fishery Products although these Codes already included comprehensive explanatory notes. The decision of the CCFH that it was inappropriate to include CCP noted in general codes of practice would have implications for the work of the CCFFP and other Codex Committees in this area.

94. The Committee accepted the offer of the delegation of the UK to prepare a general text on the "Application of HACCP to Codex Codes of Hygienic Practice" which dealt with i) Definition of HACCP, ii) Components of HACCP, iii) Specific Hazards and their risks related to particular operation systems, iv) Reasons for the non-applicability of hazard analysis to Codex Codes of hygienic practice and v) Need for explanatory notes in Codex codes of hygienic practice. The text would apply not only to the Code presently under examination but to Codex Codes of Hygienic Practice in general.

95. The Committee agreed with the provisions of the text prepared (see Appendix VI) and to bring it to the attention of the Commission with the recommendation that it be adopted and incorporated as an addendum to the General Principles for the establishment of Microbiological Criteria for Foods and included in the next edition of the Procedural Manual.

Scope:

96. The delegation of Australia reiterated its view that mass catered meals also included raw foods, which had been specifically excluded from the present scope of the code. It held the view that separate codes of hygienic practice might be needed for raw foods and precooked and cooked foods.

97. The delegation of The Netherlands recalled the decision of the Committee at its 20th Session to limit the code to cooked food, chilled or frozen. Handling of raw food if needed should be dealt with in a separate document.

98. The delegation of U.K. held the view that the present scope confined the code to centralized kitchens.

99. The following modified text was prepared by the delegation of The Netherlands for Section 1. Scope was agreed to by the Committee.

SECTION 1 - SCOPE

100. 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.

Definitions:

2.1 Catering Establishment

101. The delegation of Australia held the view that the present definition is limiting and needs to be expanded to include facilities available for chilling. Following the adoption of a definition for catering, the Committee subsequently agreed to the definition proposed by Australia that a catering establishment is a centralized kitchen where food is prepared for catering.

2.4 Cooked Food and Pre-cooked Food

102. A number of delegations expressed the view that maintenance of a minimum temperature of 60°C for cooked food is enough to prevent microbiological growth. The delegation of The Netherlands however expressed the view that the temperature should be at least 65°C since below that temperature the taste of the food was affected. In its view when fixing temperatures for holding of cooked food both microbiological as well as quality aspects should be taken into consideration.

103. Since specific temperature conditions were not needed in the definition, the Committee agreed to delete reference to them and to include them in a later section where such information might be needed.

104. The following definitions for cooked food and precooked food proposed by the delegation of The Netherlands were adopted by the Committee.

2.4 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.

The Committee agreed with the proposal of the delegation of France to change the translation of the expressions "cooked foods" and "precooked foods" in definition 2.4 of the text in french.

2.5 Disinfection:

105. The delegation of New Zealand proposed the definition be rewritten as follows:

"The reduction of micro-organisms by chemical agents or physical methods to a level that will not lead to harmful contamination of the food. Such methods should have no detrimental effect on the food or result in any undesirable residues".

In its view the rewording would be consistent with the definition in other codes.

106. The Committee agreed however that the definition should be as in Recommended International Code of Practice - the General Principles of Food Hygiene (CAC/RCP 1-1969 Rev.1 (1979)).

2.10 Catering and Mass Catering

107. The Committee agreed with the revised definition for catering and mass catering proposed by USA.

"Catering: the preparation, storage and/or delivery and serving of food.

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

2.11 Packaging Materials:

108. The delegation of Spain proposed that the definition of packaging materials should be reworded to include varnish and other materials used for some containers.

The Committee agreed that the definition should be as in the "General Principles of Food Hygiene".

2.13 Portioning: (old text)

109. The Committee agreed with the proposal of U.K. that the present definition of portioning was more apt for meal assembly and agreed that the text of 2.13 should read as follows:

2.13 Meal assembly:

110. Composing or placing food for one person in or on a suitable container, where it will be kept until delivery to the consumer.

The Committee preferred the use of the word "food" in the definition in place of "complete meal."

2.14 Portioning: (new text)

111. The Committee agreed with a definition for portioning proposed by UK.

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

2.15 Potentially hazardous food:

112. The Committee agreed with a rewording for the definition as proposed by U.K.

2.14 Potentially hazardous food is defined as food which when improperly handled is capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms.

While adopting the definition the Committee noted that microorganisms would include fungi in addition to bacteria.

2.16 Rapid chilling:

113. The Committee noted that the definition in the Spanish version of the report was inaccurate and asked the Secretariat to correct the text.

114. The Committee agreed to retain reference to time and temperature range in the definition since these parameters differentiated rapid chilling from chilling.

PRODUCTION OF PREPARATION ESTABLISHMENT, DESIGN AND FACILITIES:

4.2 Roadways and areas used by wheeled traffic:

115. The delegation of New Zealand proposed the replacement of "Hard Surface" by "Sealed Surface" since in its view hard surface in summer may not continue to maintain its hardness during other seasons of the year.

116. The Committee agreed to refer to a hard paved surface in line with the provisions of the General Principles of Food Hygiene.

4.3 Buildings and Facilities

4.3.5:

117. The delegation of Australia expressed the view that the design was important for proper storage and refrigeration of food and proposed insertion of "storage or refrigeration" in line 8 of the explanatory note after the word "unpacking". The Committee agreed to the changes proposed in the text.

4.3.7 - Walls:

118. The delegation of Cuba referred to the sanitary code in its country according to which the height of walls with sanitary tiles should be 1.80 metres. The Committee did not agree with specifying the height of walls with sanitary tiles since this could vary considerably. The word "appropriate" covered the different situations that could occur and the Committee did not change the text which was the same as in the General Principles of Food Hygiene.

4.3.12.2:

119. The delegation of Thailand expressed the view that many of the clauses in the code were such that they could not be put into practice in the developing countries. In its view adequate supply of hot potable water should be available only when needed but not at all times. The views of Thailand were supported by some delegations which referred to the use of chemical sanitizers that dispense with use of hot water for sanitization. Other delegations felt that hot water should be available at all times.

120. The Committee agreed to a modified text proposed by the delegation of Norway that read as "There should be a system to ensure an adequate supply of hot potable water" and deleted the explanatory note.

4.3.14 Refrigeration:

121. The Committee deleted reference to Section 7.6 which was not relevant and included references to Section 7.7, and 7.8.

122. The Committee held the view that the equipment should be under constant vigilance and changed the last sentence in the explanatory note to read as "The performance of the equipment should be monitored continuously with allowances for drifting outside specifications."

4.3.15 Changing facilities and toilets:

123. The delegation of Thailand expressed the view that in tropical regions tap water is usually warm and hence the need for hot water supply in hand washing facilities could be dispensed with. The Committee did not, however, change the text since it was similar to that in the General Principles of Food Hygiene.

4.3.19 Ventilation:

124. The delegation of The Netherlands proposed a temperature of a maximum of 18°C instead of 15°C. This proposal was not agreed to be the Committee.

4.3.20 Facilities for storage of waste and inedible material:

125. The Committee deleted the second sentence in the text since it did not convey any meaning.

126. In view of the lack of time that would be needed for discussion of the whole Code, the Committee agreed to discuss the remaining sections of the Code at its next Session.

STATUS OF THE CODE

127. The Committee returned the Code to Step 3. The Delegation of the Netherlands agreed to host a Working Group and to provide the Secretariat. The Committee agreed that the document as amended at this meeting would be sent for further comments by the Secretariat. The comments would be considered and the document re-drafted by the Working Group. The document as amended by the Working Group would again be sent for comments by the Secretariat before the next session of the Committee.

128. In addition to the delegation of The Netherlands, the following countries indicated their willingness to participate in the Working Group: Bahamas, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, Switzerland, Thailand, United

Kingdom and United States of America. The Committee agreed that the Secretariat would issue a circular letter asking for comments before 30 April 1987 to be sent directly to Mr. H.J. Beckers, National Institute of Public Health and Environmental Hygiene, P.O. Box 1, 3720 BA Bilthoven, The Netherlands.

129. The delegation of Cuba was of the opinion that provision for the control of frying oils and fats should be included in the code, since if not changed regularly they could form products harmful to man. The Committee noted that this point would be considered by the Working Group.

130. The Committee expressed its appreciation to the delegation of the Netherlands for its offer to host the Working Group.

CONSIDERATION OF PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR SPICES AND HERBS AT STEP 4

131. The Committee had before it the above code as contained in Appendices VIII and IX of ALINORM 87/13 and comments thereon from Cuba, Hungary, Netherlands, New Zealand, Thailand, UK and USA (CX/FH 86/7) and from the Chairperson of the Codex Committee on Processed Meat and Poultry Products (CCPMPP).

132. The Committee did not discuss the documentation but considered whether it would be feasible to develop a meaningful code of hygienic practice for all spices and herbs. After an extensive discussion it came to the conclusion that, based on exploratory work already completed, it was not feasible to develop such a code that could apply to all herbs and spices.

133. The Committee noted that several delegations were of the opinion that because of the wide variety of factors involved with widely differing growing, harvesting and preparation techniques, any code which attempted to address all spices and herbs would be extremely difficult to prepare, and that general guidance on good practices could as well be obtained from the General Principles of Food Hygiene.

134. In addition, since it had not been established at which points in the production process microbial levels became elevated to unacceptable values, it was doubtful if a general code of hygienic practice could be expected to result in improved microbial quality.

135. Some opinions were expressed that, in order to respond to CCPMPP concerns, consideration could be given by the Committee to a code addressing the various treatments by which microbial levels of finished spices and herbs might be reduced to improve their suitability for inclusion in processed foods. This might involve the Codex Committee on Food Additives. However, a major difficulty associated with development of such a code would evolve around international agreement over the treatments which could be used.

136. It was also suggested that the development of a code of hygienic practice for commercially grown herbs or spices of importance in international trade, e.g. pepper, could be a better first step with the hope that the exercise would indicate if a meaningful code for this and other individual spices and herbs might be feasible.

137. In view of the difficulties involved in developing a General Code for the Harvesting/Handling and Processing of Spices and the wide variety of treatments required for the use of spices in various food products, the Codex Committee decided to recommend to the Commission that the CCPMPP develop a Code of Practice for its own specific needs. If required this Committee would be ready to advise the CCPMPP on specific provisions of such a proposed Code.

138. The delegation of Denmark, expressed its disagreement with the decision taken by the Committee. It expressed the view that the Code in its present form contained valuable information which could be further improved in the light of comments so far received and that CCFH had the expertise to elaborate a Code that would be generally applicable.

MICROBIOLOGICAL SPECIFICATIONS FOR FROZEN COOKED CRABMEAT

139. The Committee had before it document CX/FH 86/8 which gave the background to developments within this Committee and the Codex Committee on Fish and Fishery Products (CCFFP) with regard to the above microbiological criteria.

140. CCFFP had noted the discussion which took place at the 21st Session of the Committee (ALINORM 87/13, paras. 138-148) but did not further consider the matter in detail since no Government comments had been received. CCFFP had agreed to defer further discussion until its next session and had instructed the Secretariat to re-issue a circular letter and to emphasize that information or microbiological criteria would be required from producing countries.

141. Several delegations at CCFFP had re-stated that it was not possible to compare microbiological criteria for mechanically processed products (shrimps and prawns) with hand-peeled crabmeat.

142. The Committee was informed that the circular letter requested by CCFFP had already been issued and included the following points:

a. Whether it was appropriate to use the shrimps and prawns provisions for cooked crabmeat.

b. Whether the sampling plan for Salmonella was statistically significant.

c. Whether provision for E.coli should be added to the criteria.

143. The delegation of the United States of America informed the Committee that sanitation inspections and sample collections had been carried out in 47 crabmeat plants operating under Good Manufacturing Practice over a five-month period. The results of the study had been published and would be forwarded to the Chairman of the CCFFP.

144. The delegation of Cuba also undertook to forward data regarding microbiological inspection of crabmeat according to the Cuban Sanitary Code.

145. The Committee noted that the question of Microbiological Specification for Frozen Cooked Crabmeat would be re-examined by CCFFP at its next session based on information received from Governments and its recommendations for action would be sent for consideration by a future session of this Committee.

REPORT OF WORKING GROUP CONCERNING DEFINITION OF PASTEURIZATION (AGENDA ITEM 4), AND THE EXAMINATION OF THE CODE OF HYGIENIC PRACTICE FOR SOFT CHEESES (AGENDA 11A) AND THE CODE OF HYGIENIC PRACTICE FOR THE PRESERVATION OF RAW MILK USING THE LACTOPEROXIDASE SYSTEM (AGENDA ITEM 11B)

146. The report of the Working Group was presented by the Chairman, Dr. Robert W. Weik (USA) who gave the background to the development of the definition adopted by the Milk Committee at its 21st Session (Rome, June 1986).

147. In accordance with the rules of procedure of the Code of Principles an original proposal had been developed by the International Dairy Federation (IDF) and was discussed at both the 20th and the 21st sessions of the Milk Committee in addition to several annual sessions of the IDF. The definition quoted in the report before the present session of CCFH (CX/FH 86/2), taken from the report of the 21st session of the Milk Committee, did not incorporate the time/temperature combinations that had already been accepted by the Milk Committee at its previous session and were important for full application of the definition. These had now been added to the definitions by the Working Group (see Appendix IV, Annex 2).

148. The Chairman of the Working Group informed the Committee that the definition proposed by the Working Group had been thoroughly discussed at the Milk Committee and represented the best synthesis possible of divergent views.

149. Some delegations while agreeing with the definition itself and the time/temperature combinations which were given as an example, did not think it was necessary to extend the provision by references to practices under domestic legislation since this definition was intended to be included in an international Code of Practice.

150. The Committee agreed with this point of view and decided to delete the last paragraph of the definition referring to domestic legislation and requirements (i), (ii) and (iii). The Secretariat undertook to convey this decision to the Secretariat of the Milk Committee.

STATUS OF THE DEFINITION FOR "PASTEURIZATION"

151. The Committee agreed to recommend to the Commission that the above definition, as amended for inclusion in the Recommended Code of Hygienic Practice for Dried Milk (CAC/RCP 31-1983), should be adopted at Steps 5 and 8 of the procedure with the ommission of Steps 6 and 7.

DRAFT CODE OF HYGIENIC PRACTICE FOR SOFT CHEESES (CX/FH86/10A)

152. The Chairman of the Working Group informed the Committee that the matter had been raised at the previous session of CCFH by the USA delegation and had been referred to the Milk Committee. This Committee, in turn, had added the item to its future programme and thus, in accordance with its rules of procedure, had invited IDF to prepare a first draft. CCFH at its 1985 session had also been informed that IDF would be preparing a text for consideration at its 1986 annual session. The Committee noted that a draft document prepared by Dr. McGarrahan and Dr. Nelson (USA) had been presented for the first time at the annual meeting of IDF in the Hague in September 1986 (see also para 5).

153. The document was made available to CCFH for information and comment and it was not the intention to consider the document in detail in plenary session. The delegates present were, however, invited to submit shortly any comments they had either to FAO Secretariat with a copy to the IDF General Secretariat, or vice versa.

154. Within IDF, the text of CX/FH 86/10A would shortly be issued to member countries for comment, a revised text would be prepared in the light of comments received and discussed at the IDF annual session at Helsinki in August 1987. It was the intention to seek approval on that occasion for submission of the new text to CCFH for consideration at its next session.

155. The Committee noted that the Milk Committee had appointed an ad hoc Steering Group to act on its behalf in the interim between its 21st and 22nd Sessions (the latter to be held in 1990) and that it would thus be possible to submit comments for revision of the draft Code to the Steering Committee through the CCFH Secretariat. (See Appendix IV).

156. The Committee agreed to the recommendation of the Working Group to examine the new text at its next session.

DRAFT CODE OF HYGIENIC PRACTICE FOR PRESERVATION OF RAW MILK BY USE OF THE LACTOPEROXIDASE SYSTEM (CX/FH 86/10B)

157. The Working Group noted that text had already -

a) been the subject of a written consultation within IDF

b) been considered at the 21st Session of the Milk Committee (Rome, June 1986).

Subsequent to the Rome meeting a new revised version had been submitted to the IDF annual sessions in the Hague in September and was approved for submission to this Committee.

158. For the future the present text would be issued to IDF member countries for comment, and a further revised version prepared in the light of comments received to be submitted to the IDF annual session in Helsinki in August 1987. Approval to submit this text to the 1987 CCFH sessions would be sought.

159. The Committee agreed with the recommendations of the Working Group that delegates be invited to submit comments to the FAO Secretariat, as in the case of the code of hygienic practice for soft cheeses. (see para. 155).

160. The Committee thanked the Chairmen, the Rapporteur (Mr. E. Hopkin, IDF) and the members of the Working Group for their valuable contribution to the work of the Committee. The full report of the Working Group and list of participants is attached as Appendix IV to this report.

OTHER BUSINESS

Microbiological Criteria for Freeze-dried Foods

161. The Committee noted that no document had been available on this topic at the present session and enquired whether there was any interest in maintaining the item for consideration at its next session. This did not appear to be the case and the Committee decided not to pursue the matter at present.

Aseptic Processing and Packaging Systems

162. The Committee recalled that at its last session opinion had been expressed that the hygienic aspects of aseptic packaging were becoming increasingly important for a large variety of foods and that there was some support for the development of a Code of Practice on the subject.

The delegation of the United States of America informed the Commitee that an initial draft background document on the subject was in preparation, but required a good deal of further work before it could be made available to the Committee.

163. The Committee agreed to maintain the subject of Aseptic Processing and Packaging System on its future work programme and to review progress at its next session.

Code of Practice for Aquaculture

164. The Committee noted that the question had been examined by a Working Group at the 17th Session of the CCFFP (ALINORM 87/18, paras 220, 228) following a request by the Commission at its 16th Session that CCFFP consider the need and feasibility of developing a Code of Practice for Aguaculture. The Working Group had available background documents from Cuba and the United States of America and had made recommendations to CCFFP following which the Committee had agreed to the preparation of a Code of Practice.

The representative of the FAO Fisheries Department had offered to prepare a working document for consideration by CCFFP.

It was noted that the main aspects of the Code would be hygienic provisions related to the protection of the consumer.

165. The Committee noted, that, in line with other Codes of Practice developed by FAO Fisheries Department and CCFFP the hygienic provisions of a Code of Practice/Hygienic Practice would be examined by the Committee at a future date.

FUTURE WORK

166. The Committee noted that its future programme of work would include the following:

a. Code of Practice for the Salvaging of Canned Foods suspected of having been contaminated. (New title - "Guidelines for the Salvaging of Canned Foods exposed to Adverse Conditions"

b. Microbiological Specifications and Examination of Canned Foods - Guideline Procedures to establish Microbiological Causes of Spoilage in Canned Foods.

c. Defect classification and Manual.

d. Visual examination of lots of canned foods.

e. Consideration of Code of Hygienic Practice for Low-acid and Acidified Low-Acid Canned Foods.

f. Consideration of Code of Hygienic Practice for Mass Catering
g. Microbiological Specifications for frozen cooked crabmeat

h. Microbiological specifications for Natural Mineral Waters

i. Consideration of Code of Hygienic Practice for Soft Cheeses

j. Consideration of Code of Hygienic Practice for raw milk preservation by use of the Lactoperoxidase System.

k. Aseptic Processing and Packaging Systems.

l. Endorsement of Hygienic Provisions in Codes of Practice

DATE AND PLACE OF NEXT MEETING

167. The Committee was informed that the date and place of the next session had not yet been decided and would be communicated as soon as possible by circular letter when agreed by the Codex Secretariat and the appropriate authorities of the United States of America.

Envoi

168. The Committee noted that Dr. Klaas Buchli of the Netherlands delegation and Mr. Ilmer E. Erdman of the Canadian delegation were participating at their last session of the Codex Committee on Food Hygiene.

169. The Chairman thanked the two delegates, on behalf of the Committee, for their valuable contributions to the work of the Committee over many sessions and extended his and the Committee's best wishes to them for the future.

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CURRENT CONCEPTS OF LISTERIOSIS. Walter F. Schlech III, M.D., F.A.C.P., F.R.C.P.(C), Department of Medicine, Dalhousie University.

Listeria monocytogenes is a Gram positive, aerobic motile coccobacillary bacterium described first by E.G.D. Murray in 1926 (1). Murray described a disease of rabbits caused by this organism which was characterized by the development of a mononuclear leukocytosis. The organism remained of laboratory interest only until Gill in New Zealand in 1931 described a meningal encephalitis of sheep which he termed "circling disease" (2). Although Nyfeldt thought that L. monocytogenes was the cause of infectious mononucleosis (3), it was not until the early 1950's that Paiss and others in Germany described the most characteristic infection caused by this organism, "granulomatosis infantaseptica" (4). this disease was characterized by stillbirth or premature birth of seriously infected infants with granulomatous infection of the liver and spleen accompanied by sepsis with Listeria monocytogenes. Several years later the organism was described as causing meningoencephalitis, both in adults and humans similar to the disease found in sheep and cattle. Listeria monocytogenes is now the third most common cause of serious neonatal bacterial infection of the central nervous system, after Escherichia coli and Group B streptococcus.

Although the organism is ubiquitous within the environment and is capable of being isolated from soil, feces, water and various types of vegetation, the mode of transmission from this reservoir to humans was unknown until recently. Studies of small outbreaks of listeriosis in humans did not suggest a direct connection with an animal reservoir or person-to-person transmission within the hospital setting. In 1979 however, Ho et al (5) noted an outbreak of Listeria in 10 Boston area hospitals in immunosuppressed patients. During this outbreak a case-control study demonstrated a possible association between the ingestion of food and the development of infection but no specific food product was implicated. Following this outbreak Schlech et al (6) had the opportunity to study a larger outbreak of listeriosis in healthy adults and neonates in Nova Scotia. During this outbreak the first conclusive evidence that Listeria infection could be foodborne was developed. In that instance, the source of infection was raw cabbage contaminated by raw manure from a flock of sheep that had experienced an outbreak of "circling" disease in the previous year. Since that outbreak larger outbreaks of foodborne listeriosis have been documented in Massachusetts (7) and most recently in southern California (8). In the latter outbreaks dairy products, specifically pasteurized milk and soft cheese respectively appeared to be the sources of infection. This has prompted food hygienists to sample various pasteurized and unpasteurized dairy products both imported and locally produced for Listeria monocytogenes. The organism has been demonstrated in these products although no specific association with human disease has been found using selective techniques.

While food regulatory laws have been designed to prevent more traditional enteric infections such as salmonellosis or campylobacteriosis the concept of listeriosis as a foodborne disease is

relatively new and guidelines for the management of food products potentially contaminated with Listeria monoctyogenes are lacking. Because the organism is ubiquitous in the environment it is highly likely that individuals will be continually exposed to this organism in food products and that most endemic cases of listeriosis will be acquired from this source. However many individuals will ingest Listeria monocytogenes but disease will not develop. It is therefore extremely important that a study of this foodborne pathogen be undertaken to determine factors of organism virulence and host susceptibility that may fine the ratio between symptomatic and asymptomatic infection/colonization with this organism.

A newly developed animal model of foodborne listeriosis may be helpful in determining these factors. In our laboratory we have developed an animal model of foodborne listeriosis utilizing the juvenile female Sprague-Dawley rat. Using an isolate of Listeria monocytogenes serotype 4b isolated from the Nova Scotia outbreak, we have determined that infection by gastric intubation of these animals is clearly dose-dependent. Invasive infection develops in 90-100% of animals given a dose of 10 9 organisms. Fewer than 10% of animals are infected at a dose of 100 organisms. Gastric acidity modifies this dose response curve; animals pretreated with cimetidine to inhibit gastric acidity have a much lower infectious dose. this is consistent with knowledge about more traditional enteric pathogens such as salmonella and also consistent with the findings of ho et al (5) suggesting that antacid or cimetidine treatment in humans may predispose to infection in the immunocompromised host.

Additional work in our laboratory has determined that there are differences between virulent and avirulent Listeria monocytogenes (as determined by the animal model) in their ability to attach to and invade tissue cell monolayers. A fetal intestinal cell line (Intestine 407) has been used in these experiments and has suggested that virulent Listeria adhere to and invade these dedifferentiated mucosal cells to a greater extent than avirulent organisms. This work suggests that there may be specific surface components of L. monocytogenes that mediate virulence and that the phenotypic expression of these surface components may vary within and between species of Listeria and perhaps could be responsible for the development of invasive infection in susceptible hosts. Of particular interest would be the possibility that changes in such virulence factors may have contributed to recent outbreaks of listeriosis over and above the expected endemic rate of disease.

Both the animal model and the in vitro model of foodborne L. monocytogenes infection may yield important information that will allow public health sanitarians and food product regulators to develop sensible guidelines for the management of potentially contaminated food products. In turn thseguidelines wil assist in controlling both epidemic and endemic listeriosis, an increasingly important public health problem.

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ALINORM 87/13A
APPENDIX IV

REPORT OF WORKING GROUP CONCERNING DEFINITION OF "PASTEURIZATION" CODE OF HYGIENIC PRACTICE FOR SOFT CHEESES

CODE OF HYGIENIC PRACTICE FOR THE PRESERVATION OF RAW MILK USING THE LACTOPEROXIDASE SYSTEM

1. The group met on 21 October 1986 from 13:20 to 14:10 under the Chairmanship of Dr. Robert W. Weik (USA). Twenty five delegates and observers were present (see Appendix 1 for list of participants)

Terms of Reference

2. The group's terms of reference were identified as follows:

- Consideration of the definition of "pasteurization" adopted by the Committee of Government Experts on the Code of Principles concerning milk and milk products (the Milk Committee) (CX/FH 86/2)

- Consideration of the draft Code of hygienic practice for soft cheeses

- Consideration of the draft Code of hygienic practice for the preservation of raw milk using the lactoperoxidase system

Definition of "Pasteurization" in relation to the Recommended Code of Hygienic Practice for Dried Milk (CAC/RCP 31-1983)

4. The Chairman drew attention to the development of the definition adopted by the Milk Committee at its twenty-first session (Rome, June 1986). In accordance with the rules of procedure of the Code of principles an original proposal had been developed by the International Dairy Federation (IDF) and was discussed at both the 20th and the 21st sessions of the Milk Committee in addition to four or five annual sessions of the IDF. The definition quoted in the report before the present session of the CCFH (CX/FH 86/2), taken from the report of the 21st session of the Milk Committee, did not incorporate the time/temperature combinations that had already been accepted by the Milk Committee at its previous session and were important for full application of the definition.

5. Dr. Jackson (USA) suggested that the wording (in the note) ".....it reduces the number of harmful microorganisms to a level at which they do not constitute a significant health hazard." might be open to misinterpretation in view of the present uncertainty about the role of pasteurization in relation to recent outbreaks of food-borne pathogenic disease such as listeriosis and yersiniosis.

6. Dr. E. McGarrahan (IDF) said that it was implicit in the new wording of the definition that if the time/temperature relationships cited in connection with it were shown to be inadequate to eliminate significant health hazards they would have to be made more stringent, and this could readily be done.

7. The second, and more important, concern of the US delegation was the desire to have reference to every particle of the product being heated to the necessary degree. The fear was that, if this was not made explicit, an "average value" would be considered sufficient safeguard. The working group agreed that the average value concept would not be acceptable and noted that it was not mentioned in the text. It was pointed out that the other parts of the code of hygenic practice for dried milk effectively covered the heating of every particle.

8. Dr. H. Mrozek (Germany, Federal Republic) drew attention to the EEC directive which cited a temperature of 71.7°C for 15s as a satisfactory combination. The working group considered this to be not incompatible with the corresponding 72°C for 15s in the Milk Committee text.

9. The working group then agreed to the definition, notes and time and temperature combinations cited in Appendix 2 for inclusion in the Recommended Code of Hygienic Practice for Dried Milk (CAC/RCP 31-1983). (Thus deleting from the Milk Committee's text the reference to cooling of the product after heat treatment as being irrelevant in relation to dried milk.)

Draft Code of Hygienic Practice for Soft Cheeses (CX/FH 86/10A)

10. The working group noted that the matter had been raised at the previous session of CCFH by the USA delegation and had been referred to the Milk Committee. This Committee, in turn, had added the item to its future programme and thus, in accordance with its rules of procedure, had invited IDF to prepare a first draft. CCFH at its 1985 session had also been informed that IDF would be preparing a text for consideration at its 1986 annual sessions. (See paras 5 and 154 of the report).

11. The document was made available to CCFH for information and comment and it was not the intention to consider the document in detail in plenary session. The delegates present were, however, invited to submit shortly any comments they had either to FAO Secretariat with a copy to the IDF General Secretariat, 41 Square Vergote, 1040 Brussels, Belgium, or vice versa.

12. Within IDF, the text of CX/FH 86/10A would shortly be issued to member countries for comment, a revised text would be prepared in the light of comments received and discussed at the IDF annual sessions at Helsinki in August 1986. It was the intention to seek approval on that occassion for submission of the new text to CCFH for consideration at its 1987 session.

13. The delegate of France observed that the new text would thus be referred to CCFH before the Milk Committee had a chance to study it. This was acknowledged to be the case but the working group's attention was drawn to the fact that, at its 21st Session in June 1986, the Milk Committee had appointed a Steering Committee whose function was to take initiatives such as authorizing the circulation of papers to governments for comment. It would thus be possible for the Milk Committee to be consulted by correspondence in advance of its 22nd session which is, at present, scheduled to be held in 1990.

14. The working group therefore recommends that delegates be invited to submit comments to FAO Secretariat and IDF General Secretariat.

Draft Code of Hygienic Practice for Preservation of Raw Milk by Use of the Lactoperoxidase System (CX/FH 86/10B)

15. The working group noted that the text had already -

a) been the subject of a written consultation within IDF

b) been considered at the 21st Session of the Milk Committee (Rome, June 1986).

Subsequent to the Rome meeting a new revised version had been submitted to the IDF annual sessions in The Hague, September.

16. For the future the present text would be issued to IDF member countries for comment, a further revised version prepared in the light of comments received and submitted to the IDF annual session in Helsinki in August 1987. Approval to submit this text to the 1987 CCFH sessions would be sought.

17. The delegate of the Federal Republic of Germany requested that the text submitted to the next CCFH meeting should include the purity requirements for sodium percarbonate (Appendix II) which are currently omitted.

18. The working group recommends that delegates be invited to submit comments to FAO Secretariat and IDF General Secretariat as in the case of the code of hygienic practice for cheese.

APPENDIX 1 - LIST OF PARTICIPANTS

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Robert W. Weik	USA Chairman/President
Edward Hopkin	USA Secretary/Secretaire
Jorge H. Alonso	USA CPC International
Paolo Aureli	Italy/Italie
A. C. Baird-Parker	UK/Royaume-Uni
Lowry Beacham	USA
Harry F. Beckers	Netherlands/Pays BAs
Catherine Bouvier	France
Janet E. L. Corry	UK
Gloria E. S. Cox	USA
Jocelyne Gantois	France
Kaj Haaning	Denmark/Danemark
Jorma Hirn	Finland/Finlande
J. M. Hutchinson	FAO Secretariat
Haus Illi	Switzerland/Swisse
G. J. Jackson	USA
John E. Kvenberg	USA
E. T. McGarrahan	IDF/FIL
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Hinrich H. Mrozek	F. R. Germany/Allemagne R.F.
H. C. Murrell	UK/Royaume-Uni
Johnnie G. Nichols	USA
Mike van Schothorst	Switzerland/Swisse
Pierre Veit	France

APPENDIX 2

DEFINITION OF "PASTEURIZATION" IN RELATION TO THE CODE OF HYGIENIC PRACTICE FOR DRIED MILK (CAC/RCP 31-1983)

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 micro-organisms which may be present, it reduces the number of harmful micro-organisms 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 micro-organisms 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° for 15s

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.

ANNEX TO APPENDIX B - OTHER CLAUSES CONCERNED WITH PASTEURIZATION

4.5.2.3 The equipment for pasteurizing milk and liquid milk products should be provided with a thermometer and an automatic temperature recorder, a flow diversion valve or pump "cut-out" as well as a positive pump or timing device to ensure that the proper time/temperature combination is maintained.

4.5.2.4 Sensors of the temperature measuring devices should be so positioned as to measure the temperature of the milk or milk products on the completion of the holding section of pasteurizing process.

4.5.3 Thermometers and recording devices

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

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

7.4 Processing

7.4.4 Adequate heat-treatment facilities should be provided. All milk and liquid products should be pasteurized prior to concentrating.

7.4.6 Concentrated products may be transported to the drying plant, provided that, where necessary, they are pasteurized before drying. It should be recognized however that pasteurization reduces the number of viable micro-organisms, but may not destroy some toxins.

7.4.7 A continuous chart recording should be made of all pasteurization steps, and these charts should be dated and kept available for inspection for a period that exceeds the shelf life of the product, but unless a specific need exists they need not be kept for more than two years.

CODEX ALIMENTARIUS - LIST OF PUBLISHED VOLUMES

Food Standards

Volume I	Explanatory Notes on the Work of the Codex Alimentarius Commission
Volume II	Codex Standards for Processed Fruits and Vegetables and Edible Fungi
Volume III	Codex Standards for Sugars (including Honey)
Volume IV	Codex Standards for Processed Meat and Poultry Products and Soups and Broths
Volume V	Codex Standards for Fish and Fishery Products
Volume VI	Codex Standards and Guidelines for the Labelling of Foods and Food Additives
Volume VII	Codex Standards for Cocoa Products and Chocolate
Volume VIII	Codex Standards for Quick Frozen Fruits and Vegetables
Volume IX	Codex Standards for Foods for Special Dietary Uses including Foods for Infants and Children and related Code of Hygienic Practice
Volume X	Codex Standards for Fruit Juices, Concentrated Fruit Juices and Fruit Nectars
Volume XI	Codex Standards for Edible Fats and Oils
Volume XII	Codex Standard for Natural Mineral Waters (European Regional Standard) and Codex Standard for Edible Ices and Ice Mixes
Volume XIII	Codex Maximum Limits for Pesticide Residues in Foods
Volume XIV	Food Additives (evaluated for their safety in use in food)
Volume XV	Codex General Standard for the Irradiation of Food
Volume XVI	Codex Standards for Milk Products
Volume XVII	Food Contaminants

Recommended International Codes of Hygienic and/or Technological Practice

Volume A	General Principles of Food Hygiene
Volume B	Recommended International Codes of Practice for Fish and Fishery Products
Volume C	Recommended International Codes of Practice for Meat and Poultry Products
Volume D	Recommended International Codes of Practice for Processed Fruits and Vegetables
Volume E	Recommended International Codes of Practice for Quick Frozen Fruits and Vegetables
Volume F	Recommended International Code of Practice for Egg Products
Volume G	Recommended International Code of Practice for Low-Acid and Acidified Low-Acid Canned Foods
Volume H	Recommended International Code of Practice for Dried Milk
Volume J	Code of Ethics for International Trade in Food (Already issued in the three languages of the Commission, but also to be re-issued as Volume J)

APPLICATION OF HACCP TO CODEX CODES OF HYGIENIC PRACTICE

The HACCP (Hazard Analysis Critical Control Point) system is a means of identifying and specifying the key hygiene requirements that should be applied to a specific food operation to assure the microbiological safety and wholesomeness of a particular food or raw material.

It consists of:

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

2. Determining Critical Control Point(s) required to control identified hazards.

3. Specifying criteria that indicate whether an operation is under control at a particular Critical Control Point.

4. Establishing and implementing procedure(s) to monitor each Critical Control Point to check that it is under control.

5. Taking whatever corrective action is necessary when the monitoring results indicate that a particular Critical Control Point is not under control.

The assessment of hazards requires firstly the identification of the potential microbiological hazards (organisms and/or toxins) associated with a specific operation and a full evaluation of these hazards to assess their significance to the safety of the raw material or product. This is done by way of a hazard analysis which is a searching evaluation of the food operation for hazards, considering raw materials and equipment used, specific operating practice applied, as well as the layout of the operation and the intended system for distribution and use of the product. From this, specific Critical Control Points can be derived and control and monitoring requirements for each of these chosen on the basis of appropriateness and utility.

Codex Codes of Hygienic Practice by their nature and intended use are general codes usually covering a wide range of hygienic practices and procedures that can be used to produce a particular food or raw material with due regard to hygiene or public health requirements.

As stated above, HACCP can only be applied to a specific operation and therefore it cannot be applied to such codes.

Where HACCP should be applied is either when an actual operation is set up using Codex documents as guidance or when an existing operation is examined for conformity with a Codex Code or Standard. When this is done the full HACCP procedure should be applied using personnel knowledgeable of the technical aspects of the operation as well as microbiologists and hygienists with expertise on the microbiology of the particular food and procedures used in its manufacture or production.

EXPLANATORY NOTES

In the Codes of Hygienic Practice explanatory notes are included to emphasize and explain why certain practices, procedures or requirements are of particular hygienic significance. These are highlighted by way of example. The application of the HACCP system to an actual operation may lead to the conclusion that they are not significant for this operation and that other procedures or requirements may be more important.

ALINORM 87/13A
APPENDIX VII
Revised Draft

REVISED DRAFT CODE OF HYGIENIC PRACTICE FOR LOW ACID AND ACIDIFIED LOW ACID CANNED FOODS AT STEP 5

INTRODUCTION

The FAO/WHO Codex Alimentarius Commission was established to implement the Joint FAO/WHO Food Standards Programme. Membership of the Commission comprises those Member Nations and Associate Members of FAO and/or WHO which have notified the Organizations of their wish to be considered as Members. By 31 December 1979, 122 countries had become Members of the Commission. Other countries which participate in the work of the Commission or of its subsidiary bodies in an observer capacity are expected to become Members in the near future.

The purpose of the Joint FAO/WHO Food Standards Programme is to protect the health of consumers and to ensure fair practices in the food trade; to promote co-ordination of all food standards work undertaken by international governmental and non-governmental organizations; to determine priorities and initiate and guide the preparation of draft standards and codes of practice through and with the aid of appropriate organizations; to finalize standards and codes of practice and after acceptance of the standards by governments, publish them in a Codex Alimentarius either as regional or as world-wide standards.

At its Thirteenth Session, held in December 1979, the Commission adopted as a recommended code of practice to be sent to all Member Nations and Associate Members of FAO and/or WHO the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods contained in this document.

This Code of practice is to be regarded as being advisory in nature and it is for individual governments to decide what use they wish to make of the code. The Commission has expressed the view that codes of practice dealing with specific categories of foods might provide useful checklists of requirements for national enforcement authorities.

"Its application requires knowledge and experience of canning technology. It is not intended to be used as a complete operating manual. It primarily addresses hygienic critical control points. It should be used in conjunction with appropriate texts and manuals on the subject."

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 micro-organisms.

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 temperature.

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 micro-organisms 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 micro-organisms 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 micro-organisms 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 micro-organisms 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 "Pasteurization" means a heat process chosen to achieve commercial sterility, in which the temperature of the product generally does not exceed 100°C (212°F).

2.21 "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.

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

2.22.1 "Hermetically sealed containers" means containers which are designed and intended to protect the contents against the entry of micro-organisms during and after heat processing.

2.22.2 "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/cm^2 (10 psig), i.e., normal firm finger pressure).

2.22.3 "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/cm^2 (10 psig), (i.e., normal firm finger pressure).

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

2.23 "Retort" means a pressure vessel designed for thermal processing of food, packed in hermetically sealed containers, by an appropriate heating medium and where necessary with superimposed pressure.

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

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

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

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

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

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

2.30 "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.

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

3.1.3 Irrigation control

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

3.1.4 Pest and disease control

Control measures involving treatment with chemical, physical or biological agents should only be undertaken by or under direct supervision of personnel who have a thorough understanding of the potential hazards to health, particularly those which may arise from residues in the food. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

3.2 Harvesting and Production

3.2.1 Techniques

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

3.2.2 Equipment and containers

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

3.2.3 Removal of obviously unfit raw materials

Raw materials which are obviously unfit for human consumption should be

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

3.2.4 Protection against contamination and damage

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

3.3 Storage at the Place of Production/Harvesting

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

3.4 Transportation

3.4.1 Conveyances

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

3.4.2 Handling procedures

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

4. SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

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

4.2 Roadways and Areas used by Wheeled Traffic

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

4.3 Buildings and Facilities

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

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

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

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

4.3.5 Buildings and facilities should be designed to provide separation, by partition,

location or other effective means, between those operations which may cause cross-contamination.

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

4.3.7 In food handling areas:

- Floors, where appropriate, should be of water-proof, non-absorbent, washable, **non-slip 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 **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 coved to facilitate cleaning.

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

- **Windows and other openings should be so constructed as to avoid accumulation of dirt and those which open should be fitted with 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 shelve**

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

- Stairs, lift cages and auxiliary structures such as platforms, ladders, chutes, should be so situated and constructed as not to cause contamination to 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(1979)), under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination.

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

4.4.1.3 Steam used in direct contact with food 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 **not be less than:**

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

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

4.4.7 Ventilation

Adequate ventilation should be provided to prevent excessive heat, steam condensation and dust and to remove contaminated air. The direction of the air flow should never be from a dirty area to a clean area. Ventilation openings should be provided with a screen or other protecting enclosure of 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 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. 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 jursidiction. Any residues of these agents on a surface which may come into contact with food should be removed by thorough rinsing with water, in compliance with Sub-Section 7.3 of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1, before the area or equipment is again used for handling food.

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

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

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

5.3 Hygiene Control Programme

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

5.4 By-Products

By-products should be stored in such a manner as to avoid contamination of food. They should be removed from the working areas as often as necessary and at least daily.

5.5 Storage and Disposal of Waste

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

5.6 Exclusion of Domestic Animals

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

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 micro-organisms. 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 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, micro-organisms 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 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 micro-organisms 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-prducts.

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

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

distribution system which can be readily identified. The acceptance of the official agency having jurisdiction should be required for any treatment process and for the use of re-circulated water in any food process.

7.4 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 faulty 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 shut-down. 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 of 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 must never be used as ash trays, small waste containers, receptacles for small maching 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 they 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 meat 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 seal area should be free from product contamination.

7.4.8 Inspection of closures

7.4.8.1 Inspection of 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 shut down. Side seams should be visually examined for defects of 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 container external 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 shall be inserted here.) (Canada to provide references.)

7.4.8.1.2.1 Cylindrical cans

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

Micrometer measurement: measure and record the following dimensions (see figure 1) at, for example, three points approximately 120^{o} apart around the double seam, (excluding the juncture with the side seam):

Countersink depth - A
Double seam length (Width, Height) - w
Double seam thickness - S
Body hook length - BH
Cover hook length - CH
End plate thickness - Te
Body plate thickness - Tb

As well as measuring the seam thickness, the double seam should be stripped down and evaluated for tightness, pressure ridge (chuck impression) and for other visual characteristics, such as juncture rating, internal droop, etc. The overlap (OL) can be calculated by the following formula:

$$OL = (CH + BH + Te) - W$$

Other measurements useful in the evaluation of double seam quality are the free space and the percent body hook butting. The free space can be calculated using the following formula: Free Space = S - (2(Tb) + 3(Te)) where Tb is the body plate thickness. The percent body hook butting can be calculated using the following formula:

$$\text{Percent body hook butting} = (BH/W) \times 100$$

Canada to provide Figure 2

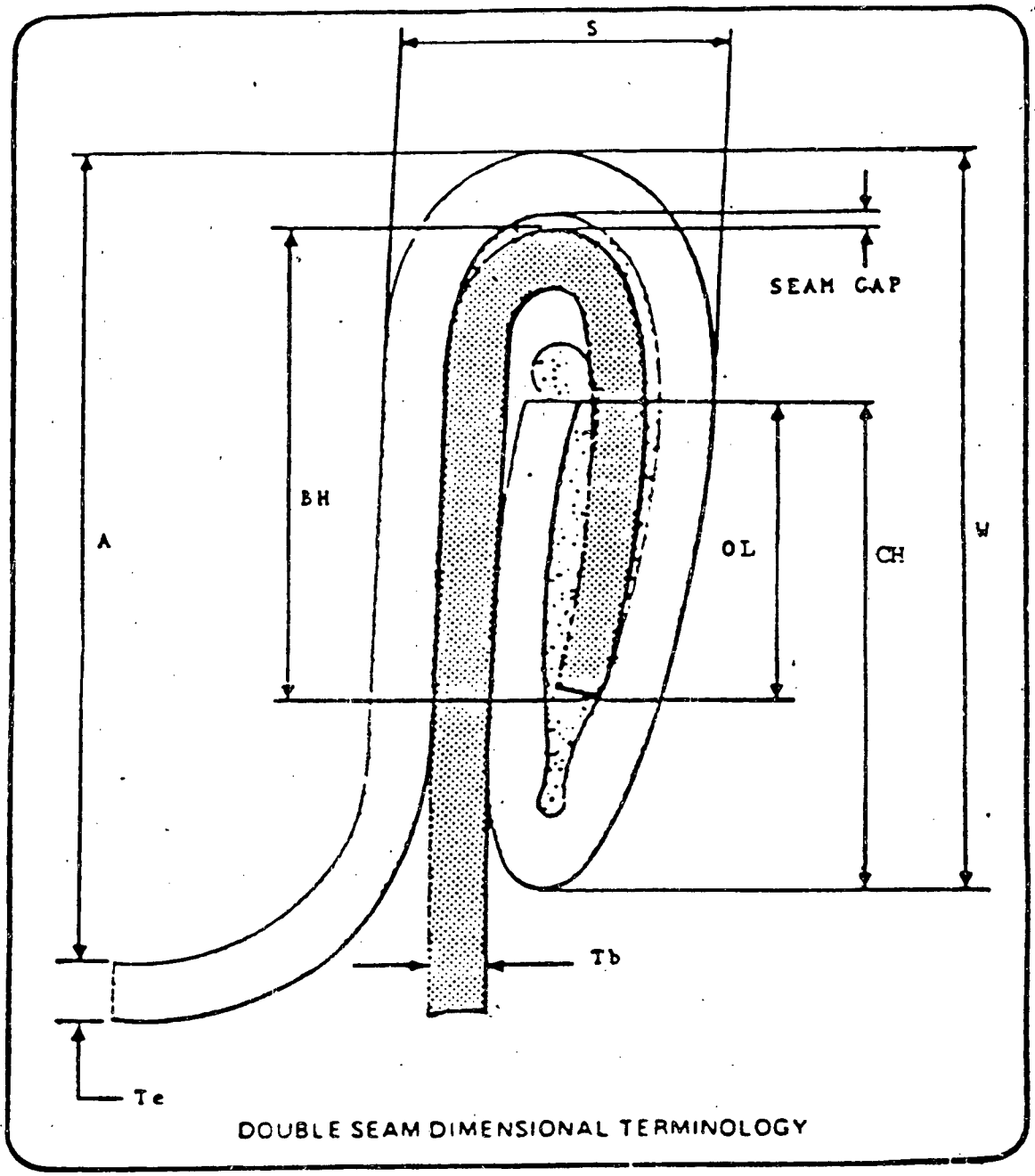

Figure 1

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.

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.

7.4.8.1.2.2 Other than cylindrical cans

Non-cylindrical 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. (Note: Figure 2 has been deleted.)

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.

7.4.8.1.4 (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.)

7.4.8.1.5 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 of container handling methods should be appropriate for the types of containers and materials 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 accumulatio 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.

7.4.10.3 *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.*

7.4.10.4 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 increases the risk of post-processing contamination.

7.5 Thermal Processing

7.5.1 General considerations

7.5.1.1 Scheduled process 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.

7.5.1.2 *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 micro-organisms 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 micro-organisms;
- 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 temperatures 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 specifications, 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;**
- **Vending procedures, 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.

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. *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.*

7.5.2.11 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 procesing 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 synchronised.

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 inital 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 or 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 columns 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/cm^2 (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 speaders 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-sectional 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-sectional 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 top 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 suitably 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-Sections 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 into 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 suitably screened to prevent blockage by floating containers or debris.

7.6.3.1.6 Pressure recorder

A pressure recording 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 described 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 filler.

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/cm^2 (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 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.

7.6.5.2.2 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 in 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 (105°F). In practice, water cooling is 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. The container and closure manufacturers' instructions should be followed.

7.6.8.1 Cooling water 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.)

Cooling water should consistently be of low microbial content. For example, an aerobic mesophilic total colony count of less than 100 c.f.u./ml. Records should be kept of cooling water treatment and of its microbiological quality.

7.6.8.2 To ensure effective disinfection, chlorine must be thoroughly mixed with the water to a level which will minimize the risk of contamination of the can contents during cooling: 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. are 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 provided 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 30°C 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 shold 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; 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, 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 food poisoning organisms 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 technically appropriate anti-corrosion agents may also be incorporated in dipping solutions. It is essential that any dipping solution be kept at not less than 80°C to avoid microbial infection and be changed at the end of each shift.

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. 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, 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 $25cm^2$ ($4in^2$). 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 overwrap 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 involed.

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 container headspace and critical factors such as in-going product consistency and/or viscosity, maximum drained weight, minimum net weight and percent solids (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 lots 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. 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 hydroscopic 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 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 prevei 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 corrosion.

9.6 Any of the above conditions may necessitate reference to the code of hygienic practice for salvage of distressed canned foods, (currently under preparation).

10. 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 micro-organisms 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 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.

APPENDIX I

APPENDIX I

ACIDIFIED LOW-ACID CANNED FOODS

1. 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. DEFINITIONS

(See definitions, SECTION II of the principle document).

3. HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA

As stated in SECTION III of the principle document.

4. ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

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

4.2 Roadways and Yards

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

4.3 Buildings and Facilities

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

4.4 Sanitary Facilities

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

4.5 Equipment and Utensils

As stated in Sub-Section 4.5 in the principle 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 pasteurizers, spray pasteurizers 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. ESTABLISHMENT: HYGIENIC REQUIREMENTS

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

6. PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

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

7. ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements and Preparation

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

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

7.1.3 As stated in Sub-Section 7.1.3 of the principle 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 micro-organisms of public health significance in the food product.

7.2 Prevention of Cross-Contamination

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

7.3 Use of Water

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

7.4 Packaging

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

7.4.1 Storage of containers

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

7.4.2 Inspection of empty product containers

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

7.4.3 Proper use of product containers

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

7.4.4 Protection of empty product containers during plant cleaning

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

7.4.5 Filling of product containers

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

7.4.6 Exhausting of containers

As stated in Sub-Section 7.4.6 of the principle document.

7.4.7 Closing operations

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

7.4.8.1.1 Inspection of glass container closures

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

7.4.8.1.2 Inspection of can seams

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

7.4.8.1.3 Inspection of seams for deep-drawn aluminium containers

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

7.4.9 Handling of containers after closure

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

7.4.10 Coding

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

7.4.11 Washing

As stated in Sub-Section 7.4.11 of the principle 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 micro-organisms 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 activity;
- microbial flora including *Clostridium botulinum* and spoilage micro-organisms;
- 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 and pasteurization is often adequate.

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 determinations 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 (or pasteurization) temperature;
- sterilization (or pasteurization) 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 recipe 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 or pasteurization 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 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 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 (or pasteurization) 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 products);
(viii) pH equilibrium time;
(ix) salt, sugar and/or preservative concentrations; and
(x) dimensional tolerances 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 of foods. The progress 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 progress 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 pasteurizer) 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 1°C (2°F) and whose scale contains not more than 4°C/cm (17°F 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 0.5°C (1°F) 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 pasteurizer 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 ± 1°C (±2°F) at the process temperature. The recorder should agree within 1°C (2°F) 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 or pasteurisation 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 principle 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 pasteurizer 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 principle document with the addition of the following sentence:

If a retort is only used 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 (or pasteurization) 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 principle document.

7.6.5 Aseptic processing and packaging systems

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

7.6.6 Flames sterilizers, equipment and procedures

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

7.6.7 Other systems

Systems for the 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 packing 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 principle document.

7.6.8.1 Cooling water quality

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

7.7 Post-Processing Contamination

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

7.8 Evaluation of Deviations in the Scheduled Process

Whenever any process operation deviates from the scheduled processes 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. QUALITY ASSURANCE

As stated in Section 8 of the principle document.

8.1 Processing and Production Records

Records should be maintained of examinations 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 inital distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaiminated 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. STORAGE AND TRANSPORT OF THE FINISHED PRODUCT

As stated in SECTION IX of the principle document.

10. LABORATORY CONTROL PROCEDURES

As stated in SECTION X of the principle document.

11. END-PRODUCT SPECIFICATIONS

As stated in SECTION XI in its entirety in the principle 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

APPENDIX II

1. ANALYTICAL METHODOLOGY FOR pH MEASUREMENT [1/]

Methods that may be used to determine pH or acidity for acidified, fermented and pickled foods 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 battery 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 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

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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).

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 determinations 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", 12th ed., 1975, section 50.007(c), page 943. 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 until 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", 12th ed., 1975, section 50.007(e), page 943. 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", 12th ed., 1975, section 50.007(f), page 943. 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 sample. These readings should be in agreement with one another to indicate 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 layers 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 milliters 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 determinations 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 colorimetric 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 milliter 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 colorimetric 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", 12th ed., 1975, sections 22.060-22.061, page 401. The procedure for preparing of standardizing the sodium hydroxide solution is described in ibid, sections 50.032-50.035, page 946.

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