CODEX ALIMENTARIUS COMMISSION

FOOD AND AGRICULTURE ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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CODEX ALIMENTARIUS COMMISSION

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REPORT OF THE

TWENTY-FIRST SESSION OF THE

CODEX COMMITTEE ON FOOD HYGIENE

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REPORT OF THE TWENTY-FIRST SESSION
OF THE CODEX COMMITTEE ON FOOD HYGIENE
WASHINGTON, D.C., 23-27 SEPTEMBER 1985

Introduction

1. The 21st Session of the Codex Committee on Food Hygiene (CCFH) was held in the Main Conference Room, Department of State, Washington, D.C. from the 23 to 27 September 1985 by courtesy of the Government of the United States of America. Representatives and Observers from 29 countries and 3 international organizations were present. The Chairman of the Session was Dr. R.B. Read, Director, Division of Microbiology, FDA. A list of participants is attached as Appendix I.

Opening of the Session

2. Dr. Read opened the session and introduced Dr. Frank E. Young, Commissioner of the Food and Drug Administration, who made a statement on the present and future applications of biotechnology and genetic engineering to food preparation and food processing. The full text of Dr. Young's speech is attached as Appendix II.

Adoption of the Agenda

3. The Committee noted that as a result of a decision made at the 16th Session of the Commission (see also paras. 93-94) item 5 "Consideration of the Draft Code of Practice for Processed Meat and Poultry Products", had been deleted from the agenda. Item 12, End Product Specifications for Freeze Dried Foods was also deleted since no background paper was available. The Committee adopted the agenda with the above modifications.

Information on Activities within WHO of Interest to the Committee

4. 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:

5. A document on histamine poisoning had been issued by the Organization. This paper contains valuable information on the epidemiology of this poisoning in different countries of the world, foods incriminated in histamine poisoning, mechanisms of formation of histamine, prevention and control measures including a detailed methodology for the detection of histamine in foods, etc. Copies of this paper were available from WHO/HQ (Document No. VPH/FOS/85.1).

6. A Joint FAO/WHO Expert Consultation on Veterinary Drug Residues was convened in Rome (29 October - 5 November 1984) which recommended in particular that within the framework of the Codex Alimentarius Commission immediate consideration should be given to the establishment of a Codex Committee on Residues of Veterinary Drugs in Foods, to determine priorities in this area, recommend maximum residue levels and to develop codes of practice. The report has been published by FAO as No. 32 of the FAO Food and Nutrition Papers (Rome, 1985).

This question was considered by the last session of the Codex Alimentarius Commission in Geneva (1-12 July 1985) which decided to establish such a Committee. The USA will be the host country.

7. A WHO informal meeting on prevention and control of salmonellosis and other foodborne bacterial zoonoses was held in Geneva from 4-6 March 1985. The meeting assessed the global situation with this infection and concluded that non-typical salmonellosis, much of which is derived from animal sources, is an important cause of diarrhoea in man in the industrialized countries. The situation in the developing countries is not clear but there are indications that it may be of considerable importance.
Experts underlined that "because of the important role of animals as reservoirs of salmonellosis, veterinary public health activities may contribute usefully to the control of diarrhoeal diseases caused by these organisms and other related zoonotic agents".

At the present time, the Organization is preparing a working group which will deal with the consideration of the veterinary public health contribution to prevention of salmonellosis and other zoonotic diarrhoeal diseases.

8. The third report of the WHO surveillance programme for control of foodborne infections and intoxications in Europe was published by the WHO Collaborating Centre for Research and Training in Food Hygiene and Zoonoses in Berlin (West). This report contains information on the epidemiology of foodborne diseases in 21 European countries, gives an explanation of the work of the "Early Warning (Alert) System" as well as general principles of organization and management of the WHO surveillance programme for control of foodborne infections and intoxications in Europe. This report is available from the above Centre in Berlin (West).

Guiding Principles on Food Safety Evaluation

9. Illness due to contaminated food is perhaps the most widespread health problem in the contemporary world and an important cause of reduced economic productivity. Many countries are becoming increasingly aware of this situation and have established, or are in the process of establishing and strengthening, national programmes to respond to this challenge. Programme development requires continuous re-examination and evaluation to ensure that the activities which are being undertaken are those that bring substantial improvements. Nowhere is this more true than in situations where the task at hand is diverse and where resources are limited and fragmented. Such is the case of food safety, where so many areas need to be tackled, problem awareness is frequently low, and responsibility may be fragmented among various ministries. For these reasons, FAO and WHO are developing a document on food safety evaluation to be used in conjunction with the existing Guidelines for Developing an Effective National Food Control System as well as Guidelines for Establishing or Strengthening National Food Contamination Monitoring Programmes. The decision to develop such a document on food safety evaluation also follows recommendations of a meeting of the Joint FAO/WHO Expert Committee on Food Safety (Geneva 1983).

For preparation of this document, the two organizations held a Consultation on Food Safety Evaluation in October 1984 in Chapel Hill, USA. It is anticipated that the document will be available in late 1985.

Informal consultation on WHO/Food Industry cooperation for the improvement of Food Safety, Geneva, 1-2 May 1984

10. The recent Joint FAO/WHO Expert Committee on Food Safety (Geneva, 1983) concluded that illness due to contaminated food is perhaps the most widespread health problem in the contemporary world and an important cause of reduced economic productivity. There is also now a consensus among food safety experts that in order to prevent foodborne illness, the safety of food should be guaranteed not only at the retail level but that responsibility should be extended to the consumer, especially to those responsible for storage, handling and preparation of food in the home. The Expert Committee therefore felt that public education is probably the single most important measure to prevent foodborne disease and unnecessary food losses, especially for rural populations which are largely independent of foods moving in trade, and therefore also of any form of control. However, although the principles for the prevention of foodborne diseases are technically the same all over the world, specific problems and appropriate modes of intervention will vary from one country to another, depending on environmental, economic, political, technological and socio-cultural factors. Consequently, in making recommendations to consumers, local needs and circumstances have to be considered.

This is a vast undertaking far beyond the scope of WHO alone. In seeking support for such a far-reaching operation, WHO was therefore looking towards the food industry itself, as it should be in the interests of food producers, processors and distributors to raise the general level of food hygiene. An informal consultation was therefore organized to obtain the initial reactions of industries to these proposals.
Hazard Analysis of Domestic Food Preparation

11. As described in para. 10 above, health education forms a most important measure to prevent foodborne disease and food losses. But health education must be based on knowledge of prevailing food handling practices, prevailing beliefs, and the cultural values attached to these practices as well as the social and economic roles they fulfill.

WHO has commenced a pilot study in various locations in Peru to assess domestic food preparation, with particular emphasis on weaning food preparation, which will form the basis for the development of appropriate health education programmes. Similar studies are envisaged in various countries of all WHO regions.

List of Publications

12. WHO has produced a List of Selected WHO and Joint FAO/WHO Publications/Documents on Food Safety/Food Hygiene. (See Appendix III) This list is available from the Secretariat or FOS/WHO/HQ.

Nutritional value and safety of products specifically intended for infant and young child feeding - World Health Assembly Resolution WHA34.23

13. In accordance with Health Assembly Resolution WHA34.23, various steps have been taken to assess changes that occur with time under various climatic conditions, particularly in tropical conditions, in the quality, nutritional value and safety of products used specifically for infant and young child feeding.

In addition to the convening of an informal consultation in October 1981 to review information on the subject, a WHO consultant visited three countries -- India, the Philippines, and Trinidad and Tobago -- during the period October 1982 to January 1983. A summary of the consultant's main findings was presented to the Health Assembly in May 1983; the complete report was also presented to the Codex Committee on Foods for Special Dietary Uses at its 14th Session in January 1985. In the discussion that followed, the possible importance of storage-related deterioration in nutritional quality to the work of the Committee was pointed out.

The Government of Switzerland has expressed interest in making a voluntary contribution to help finance the launching of laboratory studies in collaboration with appropriate national research institutions. Final arrangements are being made for this purpose. The product samples necessary for testing are being provided by the infant-food industry, which also participated in the October 1981 meeting, provided relevant information on the basis of a questionnaire sent to individual manufacturers of infant formula, and commented on the technical aspects of the planned laboratory studies.

Health Legislation

14. WHO continues to publish the International Digest of Health Legislation in English and French editions. The journal, which appears quarterly, includes a section devoted to "Nutrition and Food Safety", covering national and international legal instruments in this sector. Every effort is made to avoid duplication with the FAO journal, Food and Agriculture Legislation. Material likely to be of interest to regulatory officials concerned with nutrition and food safety also appears, from time to time, in the "News and Views", "Food Reviews", and "In the Literature" sections of the Digest.

The information available to WHO's Health Legislation unit (including the 35 volumes of the Digest published to date) is used as the basis for responding to requests for documentation on particular aspects of health legislation.
Second Workshop on Food Standardization and Health

15. This Workshop was held in Havana, Cuba from 15 to 16 April 1985, in cooperation with the Codex Coordinating Committee for Latin America and the Caribbean (CCCLAC) (17-22 April 1985). Thirteen countries and observers from international organizations participated in this very successful workshop, held in coordination with the Fourth Session of the CCCLAC.

Inter-American Conference on Food Protection

16. This Conference took place at the premises of PAHO's Headquarters in Washington, D.C., from 5 to 9 August 1985. It was organized by a Committee of the US National Academy of Sciences, under the auspices of US and Canadian agencies, FAO and PAHO.

The Conference approved by consensus a Plan of Action, asking FAO and PAHO to prepare a project for a Regional Program for Food Protection.

FAO/PAHO Latin American Workshop on Street Foods

17. This Workshop will be held in Lima, Peru from 21 to 25 October 1985. To date, all but three Latin American countries have designated delegates to participate in the Workshop.

Translation in Spanish, Editing and Distribution of Two Publications on Pesticides

18. Thanks to an Agreement with the Consortium for International Crop Protection, the documents: "An Agromedical Approach to Pesticide Management: Some Health and Environmental Considerations" (Book by J.E. Davies, V.H. Freed and F.W. Wittemore, U. of Miami) and "Pesticides Data Sheets" (FAO/WHO) have been translated, printed and will be distributed to authorities and specialists of the Latin American countries.

ACTIVITIES OF ISO

19. Madame Gantois as representative of the ISO Secretariat gave the Committee a progress report on the work of ISO in the field of microbiology.

ISO Technical Committee 34/SubCommittee 9 (ISO/TC34/SC9) Food Microbiology

20. SC9 had not met since 1984 (Helsinki). Documents in preparation had made good progress by correspondence. Three international standards were completed in 1985 and two drafts have been forwarded for voting.

21. In addition two first draft proposals are at the experimental stage in member countries. These are D.P. 8523, a study of the detection of Enterobacteracea with resuscitation and D.P. 8914 in which the detection of Vibrio parahaemolyticus (using selective media TCBS and TSAT) was being studied.

22. Two new documents proposed by the Netherlands were now in circulation, one concerning precision tests for standard microbiological methods and the other on reference material for the evaluation of the standard method for detection of Salmonella.

23. ISO 6579-81 on methods for the detection of Salmonella was under revision and would include the rehydration step required for dried food products and a proposal to replace tetraithionate enrichment medium with Rappaport-Vassiliadis medium.

24. Campylobacter spp. and Yersinia enterocolitica have been included in the work programme but no working documents are yet available in spite of the interest shown in these organisms.
In view of studies in progress on several methods (Vibrio parahaemolyticus and Enterobacteriaceae spp with resuscitation) and the recent distribution of new working documents, it was decided to defer the meeting of SC9 for a year. It is expected that the meeting will take place in November 1986, probably in Portugal.

A summary of the work of ISO/TC34/SC9 is given in Appendix IV.

ISO/TC147/SC9 - Water Microbiology

The above Subcommittee met in Tokyo in September 1985.

The following documents have already been published.


Other work. The following will be registered as DIS in 1986 and submitted to the voting procedure - D.P. 8199 water quality - general guidance for the enumeration of microorganisms and documents concerning detection and enumeration of coliforms, thermotolerant coliforms and presumptive Escherichia coli. - Part 1: Enrichment method in liquid medium and Part 2: membrane filtration method.


D.P. 8360 (pseudomonas) and D.P. 6341 (Salmonella) were not discussed at the Tokyo meeting.

Future Work. In the absence of a candidate the Secretariat will continue the work in progress. No new work has been proposed for the moment.

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

The Executive Committee (32nd Session ALINORM 85/4)

Utilization of Codex Codes of Practice in Member Countries

The Committee noted that in discussing the future work programme of the Commission at its 31st Session, the Executive Committee had stressed the need for an intensified campaign for the acceptance, implementation and utilization of Codex standards and had also noted the importance of Codes of Practice and in particular Codes of Hygienic Practice in furthering the goal of protecting the health of the consumers.

Unlike Codex Standards, Codes of Practice/Hygienic Practice were voluntary texts and were not subject to acceptance. It was therefore difficult to assess the result of the intended purposes, that is, to assist governments to ensure that foods are prepared under conditions of good manufacturing practice in particular under sound hygienic conditions and to facilitate international trade.

In CL 1985/11 (February 1985) governments were invited to supply information on the ways in which the Codex Codes of Practice were used in their countries both by regulatory authorities and by industry.

To date replies had been received from the following countries - Argentina, Cuba, Greece, Ireland, New Zealand, Netherlands, Norway and Thailand.
The Executive Committee had noted that in general the replies showed that countries attached great importance to the Codes of Practice/Hygienic Practice for use in industry, by government regulatory authorities and in the drafting of new laws on foods. Where necessary some countries were translating the Codex into the national language before using them as instructions to Quality Control Services and Industry.

Other countries reported that they had fully accepted a large number of Codes of Practice.

The Executive Committee expressed its satisfaction with the positive reaction of governments to the usefulness of Codex Codes of Practice/Hygienic Practice in their countries. It was however regretted that comparatively few countries had so far replied to the Circular Letter.

The Executive Committee further recommended that reports on the utilization of the Codes be regularly reviewed through the Regional Coordinating Committees and requested in particular that countries be encouraged to make some case studies on the effect of the Codes on improving their commodity distribution systems.

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

In consideration of the Executive Committee's report on the utilization of Codex Codes of Practice in member countries the Commission took note of further information from member countries.

The delegation of Mexico informed the Commission that many of the Codes were of great interest, particularly those concerning meat and meat products: it was considered that all codes were invaluable reference documents and to a great extent their texts were reflected in the food legislation of the country.

The delegation of the USA stated that the Codes were widely used in the voluntary fish-inspection services in the USA to improve processing efficiency and quality control. They were also of great service in adapting US Federal Regulations in the interests of international harmonization of food regulations as, for instance, processed meat products.

The Commission agreed that the Codes of Practice were valuable sources of information both to the developed and developing countries. The Commission agreed with the suggestion of the Executive Committee that countries be encouraged to embark on some case studies on the effect of the Codes on improving their commodity distribution systems. Reports on the utilization of the Codes should be reviewed by the Regional Coordinating Committees.

Codex Committee on Food Hygiene

The reports of the 19th and 20th Sessions of the above Committee (ALINORM 85/13 and 85/13A) were introduced by the rapporteur Dr. R.W. Weik (USA). The rapporteur, with the concurrence of the delegation of Switzerland, reminded the Commission that the Draft Code of Hygienic Practice for the Collection, Processing and Marketing of Natural Mineral Waters which the Committee proposed for adoption at Step 8 of the Procedure would be considered in conjunction with the European Standard for Natural Mineral Water since the End Product Specifications, which had been reviewed by an ad hoc Working Group of the Committee, were identical in both documents and could usefully be discussed together.

The Commission noted that the Committee had endorsed the hygiene provisions for the following:

- Draft General Standard for Vegetable Protein Products
- Draft Standard for Soy Protein Products
- Draft Standard for Wheat Gluten
- Draft Standard for Certain Pulses
- Standard for Pulpy Mango Products
- Standard for Guava Nectars
- Standard for Whole Maize Meal
- Standard for Degermed Maize Meal and Grits

Amendment of the General Principles of Food Hygiene at Step 8

48. The Commission was informed that at its 19th Session the Committee had agreed to amend the General Principles to include certain provisions for "lot" and for building facilities.

49. At its 20th Session the delegation of The Netherlands had proposed a further series of amendments which the Committee agreed to consider. The agreed amendments were attached to ALINORM 85/13A as Appendix VI and were submitted to the Commission for adoption at Step 8.

Status of the Amendments to the General Principles of Food Hygiene

50. The Commission noted that the amendments were not extensive and adopted them at Step 8 of the Procedure.

Microbiological Criteria for Pre-Cooked Frozen Shrimps and Prawns at Step 5

51. The Commission noted that the above had been prepared for addition to the Code of Hygienic Practice for Pre-Cooked Frozen Shrimps and Prawns as end product specifications. The criteria had been discussed and agreed by both the Committee on Food Hygiene and the Committee on Fish and Fishery Products and the Committee now recommended that Steps 6 and 7 be omitted and the provisions adopted at Step 8.

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

52. The Commission agreed with the Committee's recommendation and adopted the microbiological Criteria at Step 8.

53. The delegation of Poland had been of the opinion that the Criteria should stay at Step 6 for further comment by governments.

Amendment to Section V of the International Code of Hygienic Practice for Dessicated Coconut to include Microbiological Specifications as End Product Specifications

54. The Commission noted that at its 31st Session, the Executive Committee had agreed to the amendments proposed by the Committee on Food Hygiene (ALINORM 85/3 paras. 143-149) and that subsequently the Committee had recommended that the microbiological specifications be advanced to Step 5 and that Steps 6 and 7 be omitted. (ALINORM 85/13A paras 47-50).

Status of Amendment

55. The Commission agreed to the measures recommended by the Committee and adopted the end product specifications to the Code of Hygienic Practice for Dessicated Coconut at Step 8.

Amendment to Code of Hygienic Practice for Egg Products to include Melange

56. The Commission noted that the above amendments had been issued at Step 3 of the Procedure at the 19th Session of the Committee had received no government comments and had concluded that the proposed amendment was acceptable.

57. It had therefore recommended to the Commission that the amended text should be advanced to Step 5 of the Procedure and that Steps 6 and 7 be omitted.
58. Status of the Amendment of the Code of Hygienic Practice for Egg Products to include Melange

59. The Commission agreed with the recommendation of the Committee and adopted the amended text at Step 8 of the Procedure.

Initiation of the Amendment of the Code of Hygienic Practice for Low Acid and Acidified Low Acid Canned Foods

60. The Commission was informed that a Working Group on Low Acid and Acidified Low Acid Canned Foods had met in Chipping Campden in April 1984 and had proposed a series of amendments to the Code which modified the introduction, the table of contents and sections 7, 8, 9 and 10 (see ALINORM 85/13A Appendix V Annex I). The Committee had agreed that the amendments should be incorporated in the Code and requested approval to initiate the amendment procedure.

61. The Commission approved the Committee's proposal.

Statement by the Delegation of China

62. The delegation of China, as a new member of the Commission, expressed its wish to participate fully in the work of the Commission in the interests of consumers and the promotion of international trade.

63. The delegation gave a brief account of developments in food hygiene and food control in China.

64. China recognized that there was still room for future improvement on food hygiene and was willing to exchange experience with colleagues and friends from different countries at the session.

65. It expressed its support of the aims of the Codex Alimentarius Commission and was ready to share efforts with all members of the Commission to protect the interests of the consumers and to promote international trade.

66. The Commission noted with interest the above statement of the delegation of China.

Concluding Part of Rapporteur's Report

67. In concluding his report Dr. Weik informed the Commission that the Sub-Committee on Microbiological Criteria of the Committee on Food Protection, Food and Nutrition Board, National Research Council, USA had recently issued a publication entitled "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients" (National Academy of Press, Washington, D.C., 1985) which he thought could provide useful background material for many of the subjects considered by the Codex Committee on Food Hygiene.

68. The Committee noted that pertinent recommendations from the above publication would be considered at a later stage when discussing the Proposed Draft Code of Hygienic Practice for Spices and Herbs. (See paras 124-137).

DRAFT CODE OF PRACTICE FOR THE COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS (Appendix VII to ALINORM 85/13A)

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

Microbiological Requirements, Section 5.4 (Annex I to Appendix IV to ALINORM 85/19)

69. The Commission recalled that it had agreed earlier in the Session that the above draft code at Step 8, being elaborated by the CCFH, and the proposed draft amendment on microbiological requirements at Step 5, being elaborated by this Committee, be considered together.
70. The Coordinator for Europe indicated that the Coordinating Committee for Europe had advanced the proposed draft amendment on microbiological requirements to Step 5 of the Procedure. He also pointed out that subsequently the 20th Session of the CCFH on Food Hygiene had, after extensive consideration within a special working group, been able to endorse the proposed draft amendment. CCFH had also included identical provisions in the form of microbiological end product specifications in the Code of Practice which it had advanced to Step 8.

71. The Coordinator expressed the view that the action taken by CCFH on the Code of Practice justified omission of Steps 6 and 7 and advancement to Step 8 of the proposed draft amendment to the regional standard on microbiological requirements and recommended to the Commission to adopt at Step 8 the identical provisions as contained in Section VIII of the Draft Code and Section 5.4 - Microbiological Requirements in the Regional European Standard.

72. The Coordinator for Europe thanked the representatives of GESEM (Groupement Européen Des Sources D'Eaux Minérales) for their consistent support in drawing up the highly technical provisions in the Codex documents concerning natural mineral waters and for providing technological and scientific expertise on this matter.

73. Several delegations drew attention to a footnote in the text of the end product specifications which indicated that methods of analysis still needed to be developed. They felt that the numerical values in the specifications were closely linked to the relevant methods and that the microbiological requirements in both texts should not be adopted at Step 8.

74. Attention was drawn to a paragraph in the report of the Working Group on Natural Mineral Waters of CCFH which confirmed that the methods of analysis for the microbiological requirements would be available in the very near future.

Status of the Amendment

75. The Commission adopted at Step 8 the Amendment to the Regional European Standard for Natural Mineral Waters - Microbiological Requirements (Section 5.4).

Status of the Code of Practice

76. The Commission was informed by the rapporteur of the CCFH, Dr. R.W. Weik of USA, that CCFH had finalized the Code and recommended its adoption at Step 8.

77. The Commission adopted at Step 8 the Code of Practice for the Collecting, Processing and Marketing of Natural Mineral Waters.

78. The Committee at its present session noted the decision of the Commission and supported the points of view expressed by some delegations concerning the adoption of the microbiological requirements in both texts without providing relevant analytical methods.

79. It was noted that ISO had not yet developed a method for the detection of Pseudomonas aeruginosa and in such circumstances it was premature to give numerical values to the microbiological requirements in the standard. Such a measure was, in the opinion of the Committee, a departure from the "General Principles for the Establishment and Application of Microbiological Criteria for Foods" which had already been adopted by the Commission.

OTHER COMMITTEES

CODEX COORDINATING COMMITTEE FOR LATIN AMERICA AND THE CARIBBEAN (CCCLAC) (4TH SESSION - ALINORM 85/36A)
Consideration of the need to elaborate a Codex Code of Hygienic Practice for Aquaculture

80. The CCCLAC had before it Document CX/LA 85/6 Part III – Add. 1 relating to the proposal to elaborate a code of technological and hygienic practice for aquaculture. The Secretariat pointed out the importance of the cultivation of marine and freshwater species of fish as a food source, as well as the interest of many countries of the Region in developing this activity.

81. It was noted that at the last Session of the CCCLAC it had been agreed to forward these proposals to the Codex Committee on Fish and Fishery Products (CCFFP). (See ALINORM 85/36, para 169). That Committee took note and proposed to submit it to the Commission at its 16th Session.

82. Several Delegations (Argentina, Brazil, Mexico, Peru and Venezuela) had expressed their support for the document and considered it desirable for the Coordinating Committee to begin work in this direction.

83. The Secretariat pointed out that in the elaboration of this Code, participation by the Codex Committee on Food Hygiene and the Codex Committee on Fish and Fishery Products would be required, since it would entail both technological and hygienic aspects.

84. It was pointed out to the CCCLAC that if it were not possible for the above-mentioned Codex Committees to undertake this work immediately, they could request support from the Fisheries Department of FAO, given the fact that the scope of the Code surpassed regional boundaries.

85. The CCCLAC agreed to begin work on the elaboration of this Code in coordination with the above-mentioned Committees and with the support of the Fisheries Department of FAO.

86. The Committee noted that the Commission at its 16th Session, had been informed by the delegation of Norway that the item would be included for consideration at the next session of the Codex Committee on Fish and Fishery Products (CCFFP).

Should the CCFFP agree with the need for such a code a first draft would probably be prepared by the FAO Fisheries Department and at a later stage, this Committee would examine the hygienic requirements as had been the case for other Codes elaborated by CCFFP.

Other Activities of Interest to the Committee

Irradiated Foods

87. The Committee was informed that as a result of the invitation of the Directors-General of FAO, WHO and IAEA, an International Consultative Group on Food Irradiation had been established in 1984 in order to:

(i) evaluate global developments in the field of food irradiation,

(ii) provide a focal point of advice on the application of food irradiation to member states and the organization, and

(iii) furnish information through the organizations to the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Foods and the Codex Alimentarius Commission.

88. At its first meeting in December 1984, the Group decided that priority should be given to the promotion of international trade in irradiated food and to this end a Task Force, consisting of food control officials, consumer organizations and irradiation control authorities, had been established to advise the group on the appropriate means to promote trade in irradiated foods. The Task Force would meet in October 1985.
89. The Committee was also informed of specific activities relating to cooperation with member governments particularly those of developing countries, carried out by the FAO Food Quality and Consumer Protection Group in the Food Quality and Standards Service.

(i) Food Control Assistance to Developing Countries including promotion of coherent national food quality control systems and the organization of national food control strategy workshops. It had been proposed that the FAO Committee on Agriculture discuss in detail at its next session in early 1987 the "role of food quality control and standards in food security, health and trade."

(ii) Food Contamination Surveys and Training in Food Contamination Control were carried out within the overall efforts to strengthen food control systems in developing countries. They also supported the activities of the FAO/WHO Food Contamination Monitoring Programme. Regional activities in Asia and Africa were supplemented by additional activities in specific developing countries.

(iii) Training to include a course in maintenance and repair of laboratory equipment for technicians from Francophone Africa, and a training course on mycotoxin analysis and control for countries in the sub-region of Central America. A regional training course for food inspectors would be held in Sri Lanka and approaches had been made to funding agencies to establish a regional network of food control training centres in South and South East Asia. Training at a specialized level for persons working with mycotoxins had been carried out with UNEP support in the USSR in 1984 and 1985.

(iv) Food handling activities were directed at ensuring safety, quality and wholesomeness of food at the village and household levels thereby improving nutritional status of the population and promoting consumer protection and reducing food losses. Workshops were held in Asia and Africa to direct governments attention to the priorities needed for action. Some projects have been initiated in Asia and Africa.

(v) Publication of guidelines and manuals covering different aspects of food control and food safety continued. Distribution included Codex Contact Points.

ENDORSEMENT OF HYGIENIC PROVISIONS IN CODEX STANDARDS

Codex Committee on Foods for Special Dietary Uses

Draft Standard for follow-up food for Older Infants And Young Children at Step 5

90. The following text was endorsed by the Committee.

6. HYGIENE

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

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

(a) shall be free from pathogenic microorganisms;

(b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and

(c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

6.3 The product shall be prepared, packed and held under sanitary conditions and should comply with the relevant provisions of the Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).
Codex Coordinating Committee for Africa

Draft African Regional Standards for Pearl Millet and Pearl Millet Flour at Step 5

The following provisions are common to both standards and are submitted for endorsement.

91.

6. **HYGIENE**

6.1 It is recommended that the product covered by the provisions of this standard should be prepared in accordance with the International Code of Hygienic Practice entitled "Recommended International Code of Practice, General Principles of Food Hygiene" (CAC/RCP 1 - 1969, Rev. 1).

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

(a) shall be substantially free from pathogenic microorganisms;
(b) shall be substantially free from substances originating from microorganisms in amounts which may represent a hazard to health; and
(c) shall not contain any other poisonous or deleterious substances which may represent a hazard to health.

92. The delegation of the United Kingdom pointed out that the above provisions differed from those in the African Regional Standards for Gari and for Maize. It thought that the expression "substantially free from pathogenic microorganisms" was confusing and preferred the hygienic provisions endorsed for the Gari standard as being appropriate to the standards for Pearl Millet and Pearl Millet Flour.

The Committee agreed with this point of view and recommended the following text to the Regional Coordinating Committee for Africa.

6.1 Unchanged.

6.2 When tested by appropriate methods of sampling and examination the Pearl Millet/Pearl Millet Flour shall be:

6.2.1 to the extent possible in Good Manufacturing Practice, free from objectionable matter,

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

**RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR PROCESSED MEAT AND POULTRY PRODUCTS**

93. The Committee noted that the above Code which was elaborated by the Codex Committee on Processed Meat and Poultry Products (CCPMPP) had been adopted at Step 8 at the 16th Session of the Commission. At its previous session (ALINORM 85/13A para 30) the Committee had agreed that in view of the importance of this Code and the changes made throughout the text at the last session of the CCPMPP, it should be reviewed by this Committee before submission to the Commission.

94. The attention of the Commission had been drawn however, to a decision taken at its 8th Session in 1971 (ALINORM 71/31) that Codes of Practice elaborated by the Codex Committees on Meat Hygiene and the CCPMPP would not have to be endorsed by this Committee. The Commission had reconfirmed this decision and the item had therefore been deleted from the present agenda (see also para 3).
CONSIDERATION OF PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE SALVAGING OF DAMAGED CANNED FOODS AT STEP 4

ITEM 6

95. The Committee had before it the revised Code as contained in CX/FH 85/4 entitled "Code of Hygienic Practice for the Salvaging of Canned Foods Suspected of Having Been Contaminated" and comments thereon from the Federal Republic of Germany, Australia, Argentina, Finland and the United Kingdom. It was noted that these comments related to the above Code as well as to the proposed revision of the Code of Hygienic Practice for Low Acid and Acidified Low Acid Canned Foods (see Item 7).

96. The revised text of the "Salvaging" Code had been prepared by the Delegation of Canada as a result of comments made by the 20th Session of the Committee. The Delegation of Canada informed the Committee that among other amendments the ones made to the sections on scope and definitions were of importance.

97. Some delegations sought clarification on whether the Code applied to foods damaged in accidents as well as to those which had undergone faulty processing, e.g., under-processing. The Committee noted that the scope section of the Code covered could be interpreted to apply to both these types of foods, i.e. in the factory as well as to the inspection of damaged foods outside the direct control of the processor. The question was referred to the Working Group for clarification.

98. Some concern was expressed that circumstances could arise where unsuitable foods could be released for consumption because of the lack of adequate sampling plans and laboratory control. It was suggested that guidelines, rather than a Code of Practice would be more appropriate.

99. It was also suggested that such guidelines should contain a statement that a decision on the fate of the damaged foods should be made by experts, especially the decision on re-processing or repacking of the damaged food.

100. Several delegations questioned whether it was possible to establish criteria concerning all of the possible circumstances which might result in damaged canned foods.

101. The delegation of Nigeria was of the opinion that the Code was necessary so that importing countries could rely on canned foods being safe and adequately processed. The delegation felt that a note of caution should be included in the Code that damaged foods should be reprocessed only where appropriate expertise was available.

102. The Committee noted that a large number of detailed comments had been submitted and decided that the Working Group on the Code should be reconvened to consider those comments and to prepare a revised version of the Code for further consideration.

103. The delegation of New Zealand pointed out that governments had only little time to prepare comments on the present text of the Code and preferred to retain the present version of the Code for a further round of comments. The Committee decided however that the Working Group should meet during this session to improve the present draft.

104. The Committee had considerable discussions on whether the Code should be developed as a separate document or whether it should be part of the "Low-Acid" Code.

105. Some delegations thought that the "Salvaging" Code should be a separate document since it covered also provisions related to reprocessing while the "Low-Acid" Code dealt with in-plant processing. Other delegations pointed out that the "Salvaging" Code could be equally important to the canner and were of the opinion that the text should be issued as one package including the two above-mentioned Codes, provisions for microbiological specifications as well as visual examination of cans.
106. The Committee agreed with the latter point of view and consequently the Working Group was requested to deal with all matters related to Items 6 and 7. (See also paras. 157-162)

CONSIDERATION OF REVISED CODE OF HYGIENIC PRACTICE FOR LOW-ACID AND ACIDIFIED LOW ACID CANNED FOODS AT STEP 4

ITEM 7

107. The Committee had before it a report of the Working Group for the Visual Examination of Canned Foods which had met in April 1985 in Chipping Campden (UK) and the report of an earlier meeting of that Group which contained amendments to the above Code. The Committee noted that the 16th Session of the Commission had approved the Committee's request to initiate the amendment procedure. The amended text of the "Low-Acid" Code was contained in CX/FH 85/3.

108. The Committee recalled that it had already agreed on how to proceed with the further work on the Code (see para 106).

109. Attention was drawn to a footnote in Appendix II to the Code which indicated that the present provisions would be replaced by an ISO method as soon as it became available. Referring to the report of the ISO representative earlier at the session, it was agreed that ISO should be requested to proceed speedily with the development of a method for the pH determination.

110. The Chairman of the Working Group, Mr. I.E. Erdman of Canada, pointed out that provisions for aseptic packing should be removed from the Code and developed in the form of a separate code.

111. The delegation of the United Kingdom was of the opinion that the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods should include reference to HACCP.

112. The Delegation of the United States recognized that aseptic packaging was a matter of increasing importance; however, it should be taken up at a future meeting. The Committee agreed with this point of view.

113. The Committee also agreed that technical comments related to the document on visual examination of canned foods should be considered by the Working Group. The Committee, however, was of the opinion that matters related to the possible publication of a visual defects manual should be examined by the Plenary. It was noted that the publication of photographic material in the format of a book was rather costly. It was also noted that, as an alternative, sets of slides could be provided in a limited number to Codex Contact Points. The Committee decided to request advice from the Working Group whether the use of slide material was suitable and sufficient.

114. The Secretariat was requested to inquire about the availability of funds for the publication of either the book or sets of slides.

115. The Committee agreed that the Working Group should report back to the Plenary on Items 6 and 7.

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

ITEM 8

116. The Committee had before it the above Code as revised by the Delegation of The Netherlands (CX/FH 85/7).
117. The delegation of The Netherlands introduced the item and pointed out that the revised text was taking into account the comments made at the 20th Session of this Committee. However, it still needed to be amended to reflect the amendments made to the General Principles of Food Hygiene. The Committee noted that Section 2.4 should be editorially amended to include the term "cooked foods" as heading of Section 2.4(a). It was also noted that no written comments had been received on the revised Code as contained in CX/FH 85/7.

118. The delegation of France pointed out that in Section 2.11 in the French version "materiaux d'emballage" should be replaced by "materiaux de conditionnement". Concerning the period of time stipulated in Section 7.6.5, "three days" should be replaced by "five days" since under good conditions of preparation and storage much longer periods of time had been proved to be adequate.

119. The delegation of Sweden was of the opinion that reference to "reheating" should be included in the scope section. This was agreed to by the Committee.

120. The delegation of the United Kingdom proposed to include more detailed provisions in Section 3 on the nature and handling of raw materials. The delegation further drew attention to the fact that, while the Committee had agreed to include HACCP in the document, detailed critical control points had not been included. It was also proposed to include some flowsheets and diagrams as examples.

121. The delegation of Cuba pointed out that the temperature requirement of 21°C in Section 4.4.8 was not obtainable in countries with tropical climates and proposed, therefore, to raise the value to 24°C.

122. The delegation of Spain was of the opinion that the wording of several provisions was not clear and could be improved. This was the case in Sections 4.1, 4.4.5, and 4.4.8.

123. Several of the delegations indicated that they had detailed comments on the document. The Committee, therefore, decided that the working group on the Code should be reactivated in order to prepare a revised text of the Code for further consideration later during the session. (See paras 163-166).

CONSIDERATION OF A CODE OF HYGIENIC PRACTICE FOR SPICES AND HERBS

ITEM 9

124. The Committee had before it a working paper on "Spices and Herbs" (CX/FH 85/9) prepared by a consultant which consisted of two parts: Part I "Production, Processing and Microbiology" and Part II "Proposed Draft Code of Hygienic Practice for Spices". The extract of the relevant sections from a publication "An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients" published by the National Academy of Sciences of the United States was also available.

125. The Committee recalled that, at its 20th session, it had given consideration to a background paper on spices prepared by the delegation of The Netherlands (paras 125-141 of ALINORM 85/13A). At that session, the Committee had agreed in principle to develop a Code of Hygienic Practice for Spices and had also agreed that all spices should be covered independently whether they were used as such or as ingredients in foodstuffs.

126. It had also been agreed that the Code should cover production and processing and should include HACCP criteria. However, the Committee had recognized that in view of the complexity of the matter further background information was needed. It had therefore agreed to engage a consultant for the preparation of an additional paper and of the first draft of a Code.

127. The Secretariat introduced the above paper and outlined its salient points.
The Committee noted that definitions for spices as well as for herbs had been drawn up and that the nomenclature for these products had been established by ISO. The Committee also noted that spices and herbs were defined as dry or dried products characterized by a low water activity.

The paper indicated that the major organisms remaining in spices or herbs after physical cleaning were generally mixtures of aerobic spore forming bacteria and common moulds. Organisms of public health significance included *Clostridium perfringens* and *Bacillus cereus*. Low levels of aflatoxins had also been found. The paper stressed that the keeping quality of herbs and spices was directly related to the conditions of the products at harvest and on post harvest processing and storage.

The Committee noted that the paper also gave examples of processing procedures for different spices and herbs to indicate some of the types of processes which were used, depending on the part of the plant being processed.

Special attention was devoted to methods presently used to reduce the microbial flora of spices and to eliminate organisms of public health significance. These methods included treatments with ethylene oxide or propylene oxide, irradiation, heat treatment and extrusion. Detailed information was provided on the suggested sequence of such treatment.

In introducing Part II of the paper, the Secretariat informed the Committee that the present draft of the Code of Hygienic Practice for Spices had been based substantially on the Code of Hygienic Practice for Groundnuts (Peanuts), CAC/RCP 22-1979.

The Committee noted that the National Academy of Sciences of the United States had recently published a book on the "Evaluation of the Role of Microbiological Criteria for Food and Food Ingredients", which contained valuable data on spices and herbs. The Committee agreed that the publication was very useful for the establishment of microbiological specifications for inclusion in the Codex Code.

There was extensive discussion as to whether a Code of Hygienic Practice should be elaborated and if so, whether all spices and herbs and aspects concerning processing should be covered. It was pointed out by the Chairman of the Committee that these issues had already been discussed and decided on by the 20th Session of this Committee.

The delegations of India, Brazil and Rwanda, countries which were important producers of spices, were in favour of elaborating a comprehensive Codex Code for these products.

The Committee also recalled that several member countries of the Codex Alimentarius Commission had requested the elaboration of a code for spices and related aspects in view of public health problems which arose from the recent prohibition of the treatment of spices with fumigants and the reluctance of many countries to permit the use of irradiation treatment. It was also recalled that CCPMPP had requested the establishment of provisions for the treatment of spices used in meat products. The delegation of Denmark stated that Denmark had established limits for aerobic and anaerobic bacterial spores.

**Status of the Code**

The Committee agreed to accept at Step 2 the draft Code as contained in Part II of CX/FH 85/9 and to request comments at Step 3 thereon for consideration by the next session of this Committee. The Committee noted that Part I of the document had reached governments very late and decided therefore that the complete paper should be attached to the report of this session. (See Appendices VIII and IX).
CONSIDERATION OF MICROBIOLOGICAL SPECIFICATIONS FOR FROZEN COOKED CRABMEAT

ITEM 10

138. The Committee had before it Document CX/FH 85/10 which contained the draft report of an Ad Hoc Working Group on Microbiological Specifications for Frozen Cooked Crabmeat (extract from the 16th Session of the Codex Committee on Fish and Fishery Products).

139. The above Working Group had met during the 16th session of CCFFP to establish provisions for microbiological specifications for ready-to-eat crabmeat based on data collected from governments. It was noted that these data were derived from imported products only and that the views of producing countries were not available. The Committee was informed that the Working Group had, on advice of the delegations of Cuba and Denmark, decided to accept the following provisions which were identical to those elaborated for precooked shrimps and prawns:

Mesophilic aerobic bacteria
\[ n = 5, c = 2, m = 10^5, M = 10^6 \]

Staphylococcus aureus
\[ n = 5, c = 2, m = 500, M = 5000 \]

Salmonella
\[ n = 5, c = 0, m = 0 \]

140. The Committee recalled that the General Principles for the Establishment and Application of Microbiological Criteria for Foods required that an appropriate Code of Practice should accompany microbiological specifications. The Committee was informed that the specifications under consideration were intended to be attached to Code of Practice for Crabs (CAC/RCP 28-1983, Vol. B).

141. Several delegations held the view that it might not be feasible to apply to crabmeat the same microbiological specifications as for precooked shrimps and prawns since processing conditions for the two types of products could vary in some countries and restrictive values could have a negative effect on the production of crabmeat in those countries.

MESOPHILIC AEROBIC BACTERIA

142. The delegations of the United Kingdom and Canada pointed out that the value of \( m = 10^5 \) was suitable under GMP for products in their countries; however, they might create problems in other countries. Again it was pointed out that these data had been obtained from imported products and the Committee agreed that prior to their endorsement the deliberations of this Committee should be submitted to CCFFP, which in turn could request further comments from governments with a view to revising the present provisions.

SALMONELLA

143. The delegation of Canada drew attention to recent findings that outbreaks of salmonellosis could be provoked by a very small number of cells in such products as cheese, chocolate or products prepared with pepper and questioned whether the sample size was sufficient to assure a safe product. The delegation proposed to raise the value of \( n \) to 10 or 20.

144. The delegation of New Zealand informed the Committee that in order to obtain statistical confidence limits the number of samples would have to be increased to a very large extent. The delegations of the United Kingdom and Switzerland stated that several other factors contributed to the salmonella problem such as the type of food concerned and the type of salmonellae involved. They, therefore, proposed that more data on crabmeat should be obtained. This was supported by the delegation of Canada.
145. The delegation of Switzerland indicated that it was important to have appropriate requirements for processing of crabmeat and instructions as to how to avoid recontamination of the product.

146. It was proposed to refer the microbiological specifications for salmonellae back to CCFFP. This was supported by the delegation of India. The Committee decided to refer the above microbiological specifications back to CCFFP and to recommend to that Committee to consider (a) whether salmonella contamination was a problem in crabmeat specifically and, if so, (b) whether the sampling plan was adequate.

E. COLI

147. The delegation of Canada indicated that in Canada additional examinations for E. Coli were carried out. The Committee decided to recommend to CCFFP reconsideration of the need to include a microbiological specification for E. Coli and, if feasible, to establish an appropriate provision for endorsement by this Committee.

148. The Committee decided not to endorse the microbiological specifications in paragraph 257 of CX/FH 85/10 at this time and to request the Secretariat to inform CCFFP of its above recommendations for further action.

MICROBIOLOGICAL CRITERIA FOR CERTAIN CHEESES

ITEM 11

149. The Committee had before it document CX/FH 85/11, entitled "Microbiological Problems with Soft Cheeses" prepared by the delegation of the United States and Appendix 1 thereto containing views of governments. Furthermore, written comments were available from Argentina.

150. The delegation of the United States introduced the above papers and outlined the microbiological problems which were encountered with soft cheeses to an increasing degree. It was pointed out that most of the problems arose from the use of non-pasteurized milk which was added to improve the organoleptic properties of certain cheeses. Other problems arose in cheeses in which the growth of microorganisms occurred after improper storage and handling. Furthermore, a working group of IDF had recommended the establishment of microbiological specifications for "fresh" or "soft" cheeses and of a code of practice for these products.

151. The delegations which spoke expressed a favourable opinion on the establishment of a Code of Practice for soft cheeses and appropriate microbiological specifications for these products. They also pointed out that IDF and the Expert Committee on the General Principles on Milk and Milk Products (Milk Committee) should provide the technical expertise and be instrumental in the drafting of the above documents. It was also agreed that the Code should include HACCP criteria.

152. The Committee agreed that a Code of Hygienic Practice for Soft Cheeses should be elaborated and that the technical and technological experts of these products were already covered by Codex Standards.

153. The Committee was informed that IDF was meeting in October 1985 in New Zealand and that the documentation before this Committee was also submitted to the IDF meeting. It was noted that, according to the work procedures of the Milk Committee, IDF was in charge of drawing up working papers for that Committee.

154. The Chairman of the Milk Committee, Dr. R. Weik of the United States, stated that the question of a Code of Practice for soft cheeses had already been placed on the agenda of the next session of the Milk Committee to be held in June 1986.
The delegation of the United States informed the Committee that several meetings of an IDF Working Group on the Code of Practice were scheduled to be held before the meeting of the Milk Committee to improve the draft and that comments from Codex member countries could be submitted to these meetings.

The Committee expressed its appreciation to IDF as well as the Milk Committee for preparing the technical documents and agreed to review these documents in due course with a view to endorsing them.

REPORT OF THE AD HOC WORKING GROUP ON CODES FOR CANNED FOODS UNDER CONSIDERATION

ITEMS 6 AND 7

The Chairman of the Working Group, Mr. I.E. Erdman of Canada, introduced the report of the above group and informed the Committee that the following documents had been considered:

(a) Amended text of the Code of Hygienic Practice for Low Acid and Acidified Low Acid Canned Foods - CX/FH 85/3

(b) Defect Classification and Manual - Appendix D to the Report of the Working Group for the Visual Examination of Canned Foods - Item 7

(c) Proposed Draft Code of Hygienic Practice for Salvage of Canned Foods Suspected as Having Been Contaminated - CX/FH 85/4 and Comments thereon (See para 95)

The Committee was informed that the Working Group had decided that the Code should not be applicable for inplant use and needed to be amended accordingly. The Working Group had encountered difficulties with the present format of the Code. For these two reasons, and recalling also that the Code was to be appended to the "Low Acid" Code the Working Group had elaborated a new format and had recommended that the Working Group on Canned Foods should reconsider the Code.

The Committee also recommended that the two documents mentioned under (b) and (c) should be sent out at Step 3 for comments only after having been revised by the next meeting of the Working Group on Canned Foods.

The Committee adopted the Report of the Working Group and expressed its appreciation to the Group for the valuable work on the three documents. The Committee also agreed that the three documents should be placed at Step 3 of the procedure. The revised text of the Code of Hygienic Practice for Low Acid and Acidified Low Acid Canned Foods is contained in Appendix VI, and the full text of the report of the Working Group is contained in Appendix V to this report.

REPORT OF THE AD HOC WORKING GROUP ON THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-COOKED MEALS IN MASS CATERING

ITEM 8

The Chairman of the above Working Group, Mr. H.J. Beckers of The Netherlands introduced the Report of the Working Group and informed the Committee that a comprehensive review of the Code had been carried out. He also informed the Committee that critical
control points had been established throughout the Code and that, in general, good progress had been made in the drafting of the Code.

164. The delegation of Denmark pointed to some inconsistencies in the Code. These were corrected.

165. The Committee adopted the Report of the Working Group and expressed its appreciation to the Group for the fine work.

166. The revised Code is contained in Appendix VII to this Report. The Committee decided to retain the Code at Step 3 of the procedure for a further round of government comments.

OTHER BUSINESS

ITEM 13

167. None.

FUTURE WORK

ITEM 14

168. The Committee noted that the Agenda for its next session would include the following items:

(a) Activities of interest within FAO, WHO, and ISO,
(b) Matters arising from other Codex activities,
(c) Endorsements,
(d) Proposed draft code for Salvage of Canned Foods suspected as having been contaminated (Step 3),
(e) Revised text of Code of Hygienic Practice for Low Acid and Acidified Low Acid Canned Foods (Step 3),
(f) Defect classification and manual,
(g) Proposed Draft Code of Hygienic Practice for Pre-Cooked Meals in Mass Catering (Step 3),
(h) Proposed Draft Code of Practice for Spices and Herbs (Step 3),
(i) Microbiological Specifications for Frozen Cooked Crabmeat,
(j) Microbiological Criteria for Soft Cheeses,
(k) End-Product Specifications for Freeze Dried Foods.

169. The delegation of Canada referring to discussions earlier at the session was of the opinion that aseptic packaging became increasingly important for a large variety of foods. The delegation pointed out that the hygienic aspects of this type of packaging should be subject of a Code of Practice. This was supported by the delegations of the United States and the United Kingdom.

170. The delegation of the United States kindly agreed to prepare a basic document on the relevant aspects of aseptic packaging.

171. The Committee was informed that other Codex Committees, e.g. on fruit juices were requesting advice on this matter from this Committee.
DATE AND PLACE OF NEXT SESSION

ITEM 15

172. The Committee was informed that its 22nd Session was scheduled to be held from October 20-24, 1986 in Washington, D.C.

Envoi

173. The Committee was informed that Dr. R.B. Read would retire in early 1986 and that this was his last session as Chairman of the Committee.

The delegation of The Netherlands on behalf of the Committee expressed its warm appreciation to Dr. Read for the valuable contribution made to the work of the Committee during the five sessions in which he had been Chairman and extended its best wishes to him for the future.
APPENDIX I

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Good morning. It is a pleasure to welcome so many distinguished colleagues to Washington and to this important session. We come together at a time when the world has shown its extraordinary concern for the victims of the famine which is ravaging Africa, appreciating perhaps better than ever before how critical the issues of food supply are to us all. Biotechnology holds great promise for both the quality and quantity of our food supply, yet its unknown implications suggest that we must approach it with caution. In this work, I believe we represent not just our professions, organizations, or governments, but humanity itself.

We meet in a larger context of a technological explosion whose extent we at this time can only imagine. Biotechnology and bioengineering will revolutionize our food supply, raising unprecedented questions of hygiene. Yet, as your substantial agenda demonstrates, we have not fully disposed of all our current business.

As Commissioner of the United States Food and Drug Administration, I am well aware of the significance of foodborne diseases even in an industrialized society, although improvements in sanitation, personal hygiene, and refrigeration have reduced such serious foodborne diseases as typhoid fever, major outbreaks still occur on occasion. Less serious illnesses such as salmonellosis are still fairly common results of errors in food processing. FDA's Center for Food Safety and Applied Nutrition estimates that as many as 81 million cases of diarrhoea of foodborne origin still occur in the United States each year. Yet the answers still elude us. Just last week, the Washington Post reported that at least 22 people here in the Washington area had been stricken with salmonella food poisoning. The local health officer examined the restaurant where all had eaten but found no evidence of any contamination. He is quoted as concluding that, "people can be scrupulous about the way they prepare food, and sometimes it just happens".

When morbidity associated with food hygienic problems still attains large proportions in an industrialized nation like the United States, its magnitude and gravity in developing countries seems overwhelming. Diarrhoeal diseases, often caused by contaminated foods or water, are major causes of death in Latin America and the Caribbean. The reporting systems under which we all operate don't even begin to tell us the economic costs of such diseases, much less the costs in human suffering. How are we to prepare for future developments, then, when problems of the present command so much of our energy?

It is critical that we develop what Alfred North Whitehead termed "the integrative habit of mind" among scientific disciplines at least, as we look to the future. Fully to understand food-related disease, we must integrate data from nutrition, toxicology, microbiology, food technology, and all the other disciplines which can contribute. We know now, for example, that diet can modify the expression of carcinogenic activity, that microbial flora can modify the utilization of dietary components, and that environmental substances can modify flora. How much more can we learn if we integrate our learning? At this meeting, scientists from all over the world are communicating with one another findings critical to our common concerns; yet, in this age of specialization, how many of us can sustain a beneficial interdisciplinary communication on a day-to-day basis at home? Those who have worked in a university setting, as I have, realize that this sensible goal requires conscious effort and commitment to put into practice. Still, we must achieve this habit to face the avalanche of new food issues descending on us even now. For instance, we find that the 12th item on our agenda is "End Product Specifications for Freeze Dried Foods." It has not been too many years that freeze dried foods have been a public health concern; they are young products which our technology has popularized within the last 15 years. What will our agenda look like 15 years from now?
Clearly, it will reflect a revolution in the way we grow, process and distribute food. Every advance may be accompanied by unforeseen problems. Already the demand for new food sources and increased productivity has stimulated vigorous activity in plant cell and protoplast culture, plant regeneration, somatic hybridization, embryo transfer, and recombinant DNA techniques. A variety of microbes cultured on an assortment of substrates are appearing as possible sources of food or food ingredients. Aerobic and anaerobic liquid and solid state fermentations involving a wide range of yeasts, fungi and bacteria are all being explored. While traditional toxicological methods offer a basis for beginning to evaluate the health and safety implications of all these potential new foods, their innovative nature commands innovative methods in determining their health and safety implications. Our Center for Food Safety and Applied Nutrition has found detailed chemical analysis helpful for evaluating irradiated foods, and it is exploring development of analytical patterns and computer recognition techniques for traditional foods, which can be compared with those of the "new" ones. Thus in the future they may be able to define the nutritional quality of new products, while identifying any potentially toxic properties. Still, when a working group of the International Council of Scientific Unions concedes that the scientific community in general is, quote "profoundly ignorant of risks associated with traditional foods," we clearly have far to go before addressing the anticipated ones.

Yet we must begin, by acting on what we do know and, in the process, learning more about what we don't, to put present hygienic practices into effect on a world-wide scale will require another kind of integrative thinking. We are gratified that our efforts within this hemisphere at the Inter-American Conference on Food Protection last month to apply Codex Standards to our practices are moving ahead. At last the Americas have initiated a comprehensive approach to food protection, involving health promotion, food production, and increased trade.

That Regional Conference offers lessons for all. While evolving technologies like food irradiation offer means of improving food safety, we found that we must still stress the most basic principles of sanitation at each step in the production, processing and distribution of food. The food importing requirements which each country establishes in turn, constitute a trade barrier principally because importing and exporting countries have not harmonized their standards, although the Codex Alimentarius Commission is making major contributions towards that goal. The Conference underscores again the need to integrate not only the several disciplines touching food science, but also the policies among nations. I am very happy to say that the conferees returned to their homes throughout the Americas with a genuine commitment to implementing the recommendations they adopted, in a very practical way. I am certain that we here will achieve comparable results.

When a growing concern for nutrition has penetrated even the most prestigious cooking schools in our nation -- for instance, the Culinary Institute of America now includes nutritional instruction and dietary guidelines along with the mysteries of Haute Cuisine in its syllabus -- we have an excellent environment in which to promote healthy food practices as we develop new ones. Where will this lead?

Let me jump ahead to the year 2000, a millennium just 15 years away. Where we will find ourselves? Will farmlands, fisheries and food factories be displaced by the biotechnological laboratories?

Your general principles of food hygiene conceive that "Food will be safe, sound, wholesome and fit for human consumption". Biotechnology will certainly advance us toward this goal; how far in a decade and one-half remains to be seen. Yet the popular publications now beginning to herald the "exciting involvements of biotechnology in providing, securing, and improving the world's food supply" too often ignore a caution which should be apparent. Alteration of one food attribute in a positive, beneficial manner must not alter another attribute negatively. For instance, increasing the amount of an essential nutrient in a particular food may be beneficial in theory, but not in practice if it predisposes the food to growth of either pathogenic or spoilage bacteria, or if it interferes with another nutrient.
The Food Hygiene Committee has developed Codes of Hygienic Practice for foods that have long histories of use and economic importance. Now, the new biotechnology may force us to reconsider past practices. Instead of a traditional crop or meat, the new food may be the result of laboratory synthesis, never exposed to such common sources of contaminants as soil, water or wind.

The year 2000 will see new foods and new ways of food processing. Already, processes for genetically engineered and chemically synthesized foods have been patented, with more developing daily. These advances will improve the production and availability of food, and provide a greater variety of foods from which to choose. However, each presents us with new regulatory challenges and increased workloads.

In 1983, Dr. Jarvis of the United Kingdom published a Delphi forecast on biotechnology and the food industry. From his prediction of the specific years these events seem most likely to occur. It is clear that the food industry must already be applying new biotechnologies to food production and is planning future applications as well. Microbes, specifically tailored for certain tasks, will be principal sources of new, undegradable thickening agents, vitamins, antibiotics, colors, flavors, fertilizers, pesticides and herbicides, peptides, proteins and enzymes. Enhanced microbial enzyme production and new enzymes will be applied increasingly in food processes such as continuous, fixed-bed fermentations and effluent treatment. These advances will result in new types of fermented foods and wider availability of reliable starter cultures with specific attributes.

Microbes will not be the only targets of the new biotechnologies. As knowledge concerning eukaryotic genetics and genetic manipulation increases, totally new species of animals, plants and perhaps fusions of the two may emerge, permanently altering the ecology of our agriculture and mariculture. Plants may be reared in a smaller, more productive form such that hydroponic gardening could be profitable in climates presently unsuitable for growing. Possible new shapes and textures of fruits and vegetables could lend themselves to more efficient processing and packaging, yet retain more of their natural flavor, consistency and nutritive value.

Biotechnology may alter the chemical composition of foods for specific health purposes. Foods with even lower cholesterol or lower natural caloric content than our present diet products will become available. As the nutritional sciences advance, as we gain a greater understanding of chronic disease processes and the influence of diet on such processes, it may be possible to produce foods capable of altering the disease process itself. For example, if the benefits of the omega-3 polyunsaturated fatty acid eicosapentaenoic acid on clinical manifestations of rheumatoid arthritis are at some point proven scientifically, foods with increased levels of such fatty acids may be engineered for arthritis sufferers. Such accomplishments will need careful scrutiny, as beneficial changes to one organ system need not always be beneficial to the whole organism. Advances of this nature will rekindle the debate within regulatory agencies as to when a food becomes a drug. It is imperative that the regulators be prepared for these technological advances so the right questions can be asked.

Along these lines, the basic structure of the proteins of foods may be altered specifically to decrease their allergenicity. For instance, it may be possible to reduce the allergenicity of soybean protein by modifying the amino-acid composition of the three major allergenic proteins without substantially reducing their nutritive value. Custom-tailored enzymes may be capable of altering the allergenicity of cow's milk to the benefit of infants inflicted with intolerance to the responsible protein in the milk. If, then, biotechnology makes more and safer foods available, will it also help us to solve the new problems that will undoubtedly arise?

One of the products of the new biotechnology that will surely facilitate our work is the genetic probe. It detects pathogenic microorganisms in foods. The genus and species name of a microorganism is assuming less and less importance in judging pathogenic potential, while the harboring of genetic information capable of translation into harmful substances or traits is becoming the real issue. The development of genetic probes for specific microbial substances and traits applicable to foods has already commenced.
To date, the FDA's experience with such probes has been successful. The basic methodology has been tested collaboratively and accepted by the Association of Official Analytical Chemists, and we have trained our field personnel in these techniques. Our pathogen surveillance programs for several foods are already applying gene probes to differentiate non-hazardous Escherichia Coli in foods from those capable of causing human disease. Now we are expanding our capabilities in this area to include: Yersinia, Campylobacter, Listeria and other pathogens of concern. We hope that this technology will also enable us to regulate where our current methods do not work well, namely, in finding human viruses in foods.

In all this, we must consider the question of risk, the very idea of altering the genetic makeup of things considered natural, coupled with the complex jargon of the recombinant DNA technologist, has engendered fear and suspicion in many people. The fears that super-germs would be created have been somewhat allayed. Yet tampering with foods, something we all unavoidably encounter daily, is quite a different concern. The technology available now is generally capable of defining the exact changes that will occur. For example, duplicate genes for a specific, desired enzyme can be placed in bacteria or yeasts with no excess genetic material being incorporated into the recipient. In our Agency's limited experience thus far, genetic engineering companies have gone to extreme measures to assure us of the safety of the procedures they have followed and the safety of their product.

We must remember that the probability of harm will always be smaller than the probabilities of each possible negative event which leads to the final product. Yet, the potential benefits must always be considered along with the risks. The hazards originally conjectured for recombinant DNA technology have, by and large, failed to appear. Concern now, and rightly so, has shifted more towards issues regarding production technologies. Although demonstrable harm due to applications of new biotechnologies has not yet surfaced, we must be vigilant to ensure that it does not.

Even with this caution in mind, however, we cannot but marvel at the many possibilities which I have alluded to. Let us look at just one area for development, the application of recombinant DNA techniques to agriculture. We can realistically aspire to many specific R-DNA applications in such areas as forms of immunization, detection of contaminants both before and after harvest, decreasing the reliance upon conventional pesticides, reducing the need for irrigation, and improving the nutritiousness of many foodstuffs. Experiments with grains and legumes illustrate both the promise and the peril of these techniques. The amino acid deficiency which prevents the proteins in these foods from providing a balanced diet inspired experimental construction of a storage protein gene in corn (Zea Mays) which would supply this deficiency. It seems possible to modify the corn plant's protein composition beneficially to introduce sufficient lysine and methionine to supply the nutritional deficiency, and to do so without introducing any other effects, foreseen or unforeseen, yet we must certainly confirm that that will be the case.

Another exciting development is the process of ice-nucleation to prevent formation of ice on plant leaves during freezing weather. We find that Pseudomonas Syringae, Erwinia Herbicola, and other surface proteins of bacteria which permit ice to form may be counteracted by ice-nucleation negative bacteria. Such I-bacteria have not only been isolated and induced, but they have actually been produced by R-DNA techniques. In the future, perhaps the near future, we may hope to preserve citrus crops which are now so vulnerable to climate variations.

For this Committee, charged with the vital work of improving food hygiene in the commerce of the world, these are exciting developments. We will need all the enthusiasm such developments can inspire as we turn to the enormity of this task. Yet we can take comfort that these new techniques will produce new and improved foods to feed our world. Increased world trade in the new foods will surely follow, forcing us to reconsider the codes of hygienic practice which have served for their traditional counterparts. Certainly, some of the new foods and techniques will provide us with entirely novel challenges. Through your endeavours here, we will be prepared to meet them.

Thank you for your attention and time on this busy agenda.
LIST OF SELECTED WHO AND JOINT FAO/WHO PUBLICATIONS
ON FOOD SAFETY/FOOD-HYGIENE AND RELATED SUBJECTS

Each document or publication is followed by a number which identifies from
where it can be obtained. Please use this key to address your requests to the
right place within WHO or FAO. As there is no central despatch point for
unpriced documents, much time may be lost by addressing requests to the wrong
programme.

1. Distribution and Sales Unit, World Health Organization, Avenue Appia, 1211
Geneva 27, Switzerland. Please note that technical units are not permitted to
despatch priced publications directly. All requests for such publications
must be channelled through the Distribution and Sales Unit.

2. Food Safety Unit, Division of Environmental Health, World Health
Organization, Avenue Appia, 1211 Geneva 27, Switzerland.

3. Veterinary Public Health Unit, Division of Communicable Diseases, World
Health Organization, Avenue Appia, 1211 Geneva 27, Switzerland.

4. The Documents Officer, Joint FAO/WHO Food Standards Programme, Food and
Agriculture Organization of the United Nations, Via delle Terme di Caracalla,
I-00100 Rome, Italy.

5. The International Programme on Chemical Safety, World Health Organization,
Avenue Appia,
1211 Geneva 27, Switzerland.

6. WHO Regional Office for Europe, 8, Scherfigsvej, DK-2100 Copenhagen,
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Publications are usually available in French, and sometimes in Spanish,
Arabic and Russian. The majority of offset documents are available only in
English.

N.B. The WHO Library regularly issues a document known as WHODOC, which lists
all the significant technical documents produced by WHO/HQ which are not
priced publications. Anyone wishing to receive the WHODOC should write to the
Library, WHO/HQ, Avenue Appia, 1211 Geneva 27, Switzerland, and request to be
placed on the mailing list. The documents on this list are free of charge.
1. **Food Safety (general)**


2. **Food Microbiology**


Histamine Poisoning associated with Fish, Cheese, and other Foods. Prepared for WHO by S.L. Taylor. Document VPH/FOS/85.1

3. **Salmonellosis**


4. **Chemical Contamination of Food**


Analytical Quality Assurance II. Document EFP/83.54, Geneva, 1983.2


5. Individual Food Commodities

5.1 Meat hygiene

Meat hygiene. WHO Monograph Series No. 33, 1957.1

Guidelines on small slaughterhouses and meat hygiene for developing countries. Document VPH/83.56.3

5.2 Milk hygiene

Milk hygiene - WHO Monograph Series No. 48, 1962.1


5.3 Fish and shellfish hygiene


Halstead, B. Paralytic shellfish poisoning. WHO Offset Publication No. 79, 1984.1

6. Surveillance of foodborne disease/epidemiology


The Role of Food in the Epidemiology of Acute Enteric Infections and Intoxications, D. Barua & F.K. Käferstein. Document EFP/FOS/83.48 Rev.1.2


7. Food Technology


Summaries of Data referred to in TRS 659 - Document EHE/81/24.2

8. Food Control/Legislation


Guidelines for Developing an Effective National Food Control System. FAO Food Control Series No. 1, Rome, 1976 (UNEP/FAO publication)2,4

Food Safety Services (Public Health in Europe Series, No. 14). Edited by R. Johnson.6


Food Inspection - Report on a WHO Working Group, Copenhagen 1983. ICP/FSP 002.6

9. Food Catering

Mass Catering, by R.H.G. Charles. WHO Regional Publications, European Series No. 15, 1983.4

Food Hygiene in Catering Establishments. Legislation & Model Regulations. WHO Offset Publication No. 34, 1977.1

Guide to Hygiene and Sanitation in Aviation (2nd ed.), by J. Bailey. 1977.1
10. **Information/Education/Training**


Role, Functions and Training Requirements of Environmental Health Officers (Sanitarians) in Europe. Report on a consultation, Copenhagen 1977. ICP/BSM 004. 6

The Environmental Health Officer in an Industrial Society (Report on a WHO consultation - EURO Reports and Studies No. 29) Copenhagen, 1979. 6

11. **Socio-cultural aspects of food safety**

Socio-Cultural Aspects of Food Safety. Proceedings of an informal consultation, Bangkok, 1982. 2

12. **Food Additives**

Food Additives have been evaluated yearly by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) since 1956. Each report contains an annex listing all previous reports in this series. Only the name and number of the most recent report is therefore shown on this list.


13. **Pesticide Residues**

This subject has been covered by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) since 1961. The results of yearly meetings are published in the FAO Plant Production and Protection Paper Series, which again lists in each copy all previous reports on this subject. The last report is:

Pesticide Residues in Food - FAO Plant Production and Protection Paper No. 56, 1983. 1, 4

14. **Veterinary Drug Residues**


15. **Codex Alimentarius**

The Codex Alimentarius is a collection of internationally adopted food standards, codes of hygienic and technological practice and other advisory texts presented in a uniform manner and published by the Secretariat of the Joint FAO/WHO Food Standards Programme.
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<td>Codex Standards for Cocoa Products and Chocolate</td>
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<td>VIII</td>
<td>Codex Standards for Quick Frozen Fruits and Vegetables</td>
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<td>IX</td>
<td>Codex Standards for Foods for Special Dietary Uses Uses including Foods for Infants and Children and related Code of Hygienic Practice</td>
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<tr>
<td>X</td>
<td>Codex Standards for Fruit Juices, Concentrated Fruit Juices and Fruit Nectars</td>
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<td>XI</td>
<td>Codex Standards for Edible Fats and Oils</td>
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<td>XII</td>
<td>Codex Standard for Natural Mineral Waters (European Regional Standard), and Codex Standard for Edible Ices and Ice Mixes</td>
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<tr>
<td>XIII</td>
<td>Codex Maximum Limits for Pesticides in Food</td>
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<td>XIV</td>
<td>Food Additives (evaluated for their safety in use in food)</td>
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<td>XV</td>
<td>Codex Standard for the Irradiation of Food</td>
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<td>XVII</td>
<td>Food Contaminants</td>
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N.B. Supplements to the following volumes have been produced:

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<th>Volume</th>
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Recommended International Codes of Hygienic and/or Technological Practice

<table>
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<th>Volume</th>
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<tr>
<td>A</td>
<td>General Principles of Food Hygiene</td>
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<tr>
<td>B</td>
<td>Recommended International Codes of Practice for Fish and Fishery Products</td>
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<td>C</td>
<td>Recommended International Codes of Practice for Meat and Poultry Products</td>
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<tr>
<td>D</td>
<td>Recommended International Codes of Practice for Processed Fruits and Vegetables</td>
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<td>E</td>
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<td>F</td>
<td>Recommended International Code of Practice for Egg Products</td>
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<tr>
<td>G</td>
<td>Recommended International Code of Practice for Low-Acid and Acidified Low-Acid Canned Foods</td>
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</tbody>
</table>
Volume H
Recommended International Code of Practice for Dried Milk

Volume J
Code of Ethics for International Trade in Food (not yet available)

16. **Environmental Health Criteria documents of relevance to food safety**

The International Programme on Chemical Safety (IPCS) is producing a series of Environmental Health Criteria Documents, some of which are relevant to food safety. For a number of these documents, an Executive Summary has been prepared which summarizes the content of the document without going into scientific detail. These Executive Summaries, which are free of charge, can be obtained from the International Programme on Chemical Safety, WHO, which maintains a mailing list for this purpose. The Criteria Documents themselves are priced publications, and can be obtained from the Distribution and Sales Unit of WHO or from WHO booksellers in the normal way.

The following food-related Environmental Health Criteria Documents are currently available:

- Mercury
- Polychlorinated Biphenyls and Terphenyls
- Lead
- Nitrates, Nitrites and N-Nitroso Compounds
- DDT and its derivatives
- Mycotoxins
- Tin and Organotin Compounds
- Arsenic

(Executive Summaries in English and French are available for all the above-mentioned documents. Anyone wishing to be added to the mailing list for future summaries should contact IPCS directly).

17. **Zoonoses Control**


18. **Drinking Water**


N.B. The third and final volume in the series is expected to be published later in 1985.
REPORT ON THE STATE OF WORK OF
THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
IN THE FIELD OF MICROBIOLOGY OF FOOD PRODUCTS
(ISO/TC 34/SC 9)

NEW PUBLICATIONS

ISO 7218-85 - General guidance for microbiological analysis

ISO 7402-85 - General guidance for the enumeration of Enterobacteriaceae without resuscitation - Most probable number technique and colony count technique

ISO 7937-85 - General guidance for enumeration of Clostridium perfringens - Colony count technique

DRAFTS FORWARDED TO THE VOTING PROCEDURE

DIS 7932 - General guidance for enumeration of Bacillus cereus - Colony count technique

ISO 7954 - General guidance for detection and enumeration of yeasts and moulds

FIRST DRAFT PROPOSAL IN PROGRESS

The importance of having a method for Vibrio parahaemolyticus and a method with resuscitation for Enterobacteriaceae has been confirmed at the last meeting of SC 9.

A first draft has been circulated and is currently being studied by Members bodies:

DP 8523 - General guidance for detection of Enterobacteriaceae with resuscitation

Not long ago a first draft is just proposed by the French Member Body on the detection of Vibrio parahaemolyticus (DP 8914) and is currently being studied by Members bodies.

1985-09-18
QUINQUENNAL REVISION OF STANDARDS

Considering the progress of work in the field of microbiology, it has been decided to review the following standards:

- **ISC 4831-78** - General guidance for the enumeration of coliforms - Most probable number technique at 30 °C
- **ISO 4832-78** - General guidance for enumeration of coliforms - Colony count technique at 30 °C
- **ISO 4833-78** - General guidance for enumeration of micro-organisms - Colony count technique at 30 °C
- **ISO 6579-81** - General guidance on methods for the detection of Salmonella

FUTURE WORK

At Hungary's request, it has been decided to include in the programme of future work the production of a document on the procedure which is to be followed when carrying out microbiological interlaboratory tests. A document established by the Netherlands will be studied at the next meeting.

The SC 9 was requested to place "Campylobacter" and "Yersinia enterocolitica" on the agenda, therefore, the Secretariat requested to the member-bodies that it would be appreciable to have a first draft or working document for the next meeting.

Consequently, the Secretariat decided to postpone the meeting of SC 9 by one year for efficiency purposes.
REPORT OF THE WORKING GROUP ON CANNED FOODS

(Items 6 and 7)

1. The Working Group reviewed the Code of Practice for low-acid and acidified low-acid canned foods. The Code in general appeared satisfactory. A few changes were recommended and a copy of the revised Code, including the changes, is included in Appendix VI to this Report.

2. Defect Classification and Manual (Appendix B)

A number of delegates expressed the importance of this document and its application in a number of areas, such as: inplant inspection; port of entry inspection; salvage operations; and investigations of spoilage.

No consensus was reached as to the system to be used for the classification of defects, that is, whether there should be two categories for serious defects or one category for serious defects. Since the actual pictures depicting the various defects were not available their classification could not be reviewed by the delegates.

A. The defect manual and classification should be sent back to the Canned Food Working Group of the Committee with the following instructions:

1) Prepare an alternative classification of defects employing two categories as follows:

- Category I are serious defects which may indicate that the product should not, pending further investigation, be put into commercial distribution, and

- Category II are defects which are not considered to affect the soundness of the products.

B. Obtain data which compares the retention rates of lots using a three category system compared to a two category system. The U.S.A. has agreed to supply some data. It would be beneficial if other members of the LACF Working Group could also provide similar data.

C. Consider examples of samplings for various purposes such as might be required for other than port of entry inspections.

D. Visual Examination of Canned Foods.

1) Sampling for Visual Can Defects (Appendix A)

Dr. J.T. Peeler, Delegation of U.S.A. presented an appraisal of various statistical statements embodied in the report. He drew attention to random versus non-random sampling with example of the latter being stratified sampling. In comparing the performance of sampling plans the first consideration is to evaluate the vendor and consumer risks. The plans presented appeared to be based upon the consumer risk which is in keeping with the views of the Working Group. Comparisons of plans is clearer if defect levels at predetermined risks (probability of acceptance). He gave some examples using those in the report. He clarified some of the aspects of sampling small lots in which the sample size exceeds certain limits and reinforced the opinion of the Working Group that care should be exercised in the application of such plans. He drew attention to the fact that as the number of code lots in the lot to be inspected increased, the application of a plan becomes more difficult.
An error in the report was noted and corrected. The ISO reference on Pages 6 and 9 should read, ISO 2859-1974 and be entitled inspection by attributes, not variables as stated in the report.


Since this report will form the basis of a document to be appended to the Code of Hygienic Practice for Low-Acid and Acidified Low Acid Canned Foods, a number of delegates submitted suggestions to improve and strengthen the document. It was recommended that the report be given to the Canned Food Working Group for redrafting into a suitable format and incorporating all the suggestions submitted by the various delegates.

F. The Working Group reviewed the Code of Hygienic Practice for the Salvaging of Canned Foods suspected as having been contaminated. A number of changes were made including removal of salvage considerations for events which occur during processing. In its present form, a great deal of confusion was caused by separating the normally occurring time-sequence of events in an attempt to maintain the format used in Codex Codes of Practice. A suggested format is as follows:

I. Title
II. Scope
III. Definitions
IV. Procedures for Salvage
   A. Inventory
   B. Feasibility of Salvage
      1. Sorting-Primary
      2. Non-salvageable (Disposal)
      3. Salvageable
         Evaluation and Secondary Sort
            a. Non-salvageable - (Disposal)
            b. Reconditioning 1/
V. Reconditioning
   a. Requirements
   b. Procedures
VI. Recording and Identification

Much of the current text including modifications discussed can be incorporated directly but some new text will also have to be provided.

The Working Group recommends that the CCFH return the document to the Canned Foods Working Group for redrafting so that a clearer text can be considered at a future meeting.

1/ Definition was amended to include also reprocessing and re-packaging.
REVISED DRAFT CODE OF HYGIENIC PRACTICE
FOR LOW ACID AND ACIDIFIED LOW ACID CANNED FOODS

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. A holding period may follow the initial heating period.
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 "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.

2.16.1 "Rigid container" means that the shape or contours of the filled and sealed container are neither affected by the enclosed product nor deformed by an external mechanical pressure of up to 0.7 kg/cm² (10 psig), i.e., normal firm finger pressure.

2.16.2 "Semi-rigid container" means that the shape or contours of the filled, sealed container are not affected by the enclosed product under normal atmospheric temperature and pressure but can be deformed by an external mechanical pressure of less than 0.7 kg/cm² (10 psig), (i.e., normal firm finger pressure).

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

2.17 "Holding time", see sterilization time.

2.18 "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.

2.19 "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.

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

2.21 "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 "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).

2.23 "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
CAC/RCP 23-1979

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

3.2.4 Protection against contamination and damage

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

3.3 Storage at the Place of Production/Harvesting

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

3.4 Transportation

3.4.1 Conveyances

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

3.4.2 Handling procedures

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

4. SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

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

4.2 Roadways and Areas used by Wheeled Traffic

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

4.3 Buildings and Facilities

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

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

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

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

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

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

4.3.7 In food handling areas:

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

- **Walls**, where appropriate, should be of water-proof, non-absorbent, washable
  and non-toxic materials and should be light coloured. Up to a height
  appropriate for the operation they should be smooth and without crevices, and
  should be easy to clean and disinfect. Where appropriate, angles between
  walls, between walls and floors and between walls and ceilings should be
  sealed and 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 screens. Screens should
  be easily movable for cleaning and kept in good repair. Internal window
  sills, if present, should be sloped to prevent use as shelves.

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

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

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

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

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

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

4.4 Sanitary Facilities

4.4.1 Water supply

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

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

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

4.4.2 Effluent and waste disposal

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

4.4.3 Changing facilities and toilets

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

4.4.4 Hand washing facilities in processing areas

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

4.4.5 Disinfection facilities

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

4.4.6 Lighting

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

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

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

Adequate ventilation should be provided to prevent excessive heat, steam condensation and dust and to remove contaminated air. The direction of the air flow should never be from a dirty area to a clean area. Ventilation openings should be provided with a screen or other protecting enclosure of 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. **Maintenance**

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

5.2 **Cleaning and Disinfection**

5.2.1 Cleaning and disinfection should meet the requirements of this Code. For further information on cleaning and disinfection procedures see Appendix I of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1 of this Code.

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

5.2.3 Adequate precautions should be taken to prevent food from being contaminated during cleaning or disinfection of rooms, equipment or utensils by water and detergents or by disinfectants and their solutions. Detergents and disinfectants should be suitable for the purpose intended and should be acceptable to the official agency having jurisdiction. Any residues of these agents on a surface which may come into contact with food should be removed by thorough rinsing with water, in compliance with Sub-Section 7.3 of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1, before the area or equipment is again used for handling food.

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

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

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

5.3 **Hygiene Control Programme**

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

5.4 **By-Products**

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

5.5 **Storage and Disposal of Waste**

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

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

5.7 **Pest Control**

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

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

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

5.8 **Storage of Hazardous Substances**

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

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

5.9 **Personal Effects and Clothing**

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

6. **SECTION VI – PERSONNEL HYGIENE AND HEALTH REQUIREMENTS**

6.1 **Hygiene Training**

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

6.2 **Medical Examination**

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

6.3 **Communicable Diseases**

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

7.3 **Use of Water**

7.3.1 As a general principle only potable water, as defined in the latest edition of "International Standards of Drinking Water" (WHO), should be used in food handling.

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

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

7.4 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 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 Dirty containers should not be filled. Faulty rigid containers include those that have been pierced or severely dented, with defective side or bottom seams, with deformed flanges, with 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 or closure manufacturer.)

7.4.3 Proper use of product containers

Product containers must never be used within the cannery for any purpose other than packing food. They must never be used as ash trays, small waste containers, receptacles for small machine parts or for other purposes. This should be avoided because there is a considerable risk that such containers may accidentally find their way back onto the production line and result in the packing of food in the same container with very objectionable or 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 Air content of filled flexible and semi-rigid containers should be kept within specified limits to prevent excessive stressing of the seals during thermal processing.

7.4.6 Exhausting of containers

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

7.4.7 Closing operations

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

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

(Note: The italics for 7.4.7.2 have been removed and in 7.4.7.1 in addition to the changes noted there has been a change in the sentence order.)

7.4.8 Inspection of closures

7.4.8.1 Inspection for external defects

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

All pertinent observations should be recorded. Where irregularities are found, corrective action should be taken and recorded.
7.4.8.1.1 Inspection of glass container closures

Glass containers consist of two pieces, viz., a glass container and lid (closure) usually metal, which can be twisted or pried off according to the closure design. Appropriate detailed inspections and tests should be conducted by competent individuals.

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.)

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° apart around the double seam, (excluding the juncture with the side seam):

- Countersink depth - A
- Double seam length - W (Width, Length, Height)
- 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 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:

\[ \text{Free Space} = S - (2(Tb) + 3(Te)) \]

where Tb is the body plate thickness. The percent body hook butting can be calculated using the following formula:

\[ \text{Percent body hook butting} = \left( \frac{BH}{W} \right) \times 100 \]

Canada to provide Figure 2.
Optical measurements: overlap, body and coverhook lengths are directly visible in a cross-section of the double seam. Dimensions which cannot be optically measured should be measured by the micrometer. (See 7.4.8.1.2) (Wrinkling and other visual attributes can only be observed by stripping of the coverhook). The segments of the double seam to be examined should, for example, be taken at two or more places on the same double seam.

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 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 accumulation of stationary containers on moving conveyors should be kept to a minimum, as this may also damage containers.)

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

7.4.10 Coding

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

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

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

7.4.11.2 Washing containers after sterilization increases the risk of post-processing contamination and also it may be more difficult.

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 microorganisms including the heat resistant sporeforming pathogens such as Clostridium botulinum. It should be emphasized that the thermal processing of low-acid canned foods is a very critical operation, involving public health risks and appreciable losses of finished product if under-sterilization occurs.
7.5.2 Establishing scheduled process

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;
Air content, where applicable;
Minimum initial temperature;
Venting 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 processing room and times should be read from this instrument and not from wristwatches, etc. Where two or more clocks or other timing devices are used in a heat processing room they should be 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 initial temperature, sterilization time and temperature together with overpressure, where applicable, as specified in the scheduled process, other critical factors specified should be measured, controlled and recorded at intervals of sufficient frequency to ensure that these factors remain within the limits specified in the scheduled process. Some examples of critical factors are:

(i) Maximum fill-in or drained weight.
(ii) Minimum headspace of product containers;
(iii) Product consistency or viscosity as determined by objective measurement on product taken before processing.
(iv) Product and/or container type which may result in layering or stratification of the product, or in changes in the container dimensions hence requiring specific orientation and spacing of the containers in the retort.
(v) Percent solids.
(vi) Minimum net weight.
(vii) Minimum closing vacuum (in vacuum packed products).

7.6 Equipment and Procedures for Heat Processing Systems

7.6.1 Instruments and controls common to different heat processing systems

7.6.1.1 Indicating thermometer

Each retort and/or product sterilizer should be equipped with at least one indicating thermometer. The mercury-in-glass thermometer is recognized as the most reliable temperature indicating instrument at the present time. An alternative instrument having equal or better accuracy and reliability may be used subject to the approval of the official agency having jurisdiction. The mercury-in-glass thermometer should have divisions that are easily readable to 0.5°C (1°F) and whose scale contains not more than 4.0°C per cm. (17°F per inch) of graduated scale. Thermometers should be tested for accuracy against a known accurate standard thermometer. This should be done in steam or water as appropriate and in a similar position 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 120°C per cm (55°F per in.) within a range of 10°C (20°F) of the sterilizing temperature. The recording accuracy should be equal to or better than ± 0.5°C (1°F) at the sterilizing temperature. The recorder should agree as closely as possible (preferably within 0.5°C (1°F)) and should not be higher than the indicating thermometer at the sterilizing temperature. A means of preventing unauthorized changes in the adjustment should be provided. It is important that the chart should also be used to provide a permanent record of the sterilization temperature in relation to time. The chart timing device should be accurate and checked as often as necessary to maintain accuracy.
7.6.1.4 **Pressure gauges**

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

7.6.1.5 **Steam controller**

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

7.6.1.6 **Pressure relief valve**

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

7.6.1.7 **Timing devices**

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

7.6.2 **Pressure processing in steam**

7.6.2.1 **Batch (Still) retorts**

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

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

7.6.2.1.2 **Pressure gauges** (see Sub-Section 7.6.1.4).

7.6.2.1.3 **Steam controllers** (see Sub-Section 7.6.1.5)

7.6.2.1.4 **Pressure relief valve** (see Sub-Section 7.6.1.6).

7.6.2.1.5 **Steam inlet**

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

7.6.2.1.6 **Crate supports**

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

7.6.2.1.7 **Steam spreaders**

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

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

7.6.2.1.9 **Stacking equipment**

Crates, trays, gondolas, dividers, etc., for holding product containers should be so constructed that steam can adequately be circulated around the containers during the venting, coming-up and sterilization times.

7.6.2.1.10 **Vents**

Vents should be located in that portion of the retort opposite the steam inlet and should be designed, installed and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents should be fully opened to permit rapid removal of air from retorts during the venting period. Vents should not be connected directly to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single still retort, it should be controlled by a single suitable valve. The manifold should be of a size such that the cross-sectional area of the manifold is larger than the total cross-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.
7.6.2.8 **Stacking equipment** (see Sub-Section 7.6.2.1.9).

7.6.2.9 **Vents** (see Sub-Section 7.6.2.1.10).

7.6.2.10 **Air inlets** (see Sub-Section 7.6.2.1.11).

7.6.2.11 **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.

7.6.2.12 **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 7.6.2.1.11).

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 headscape**

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

7.6.3.1.17 **Water circulation**

- All water circulation 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.
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).

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.

Aseptic processing and packaging systems

Product sterilization equipment and operation

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 cm² (2 lbs per square in.) on a working scale of not more than 1.4 kg/cm²/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/cm² (1 lb per square in.) greater than the pressure of unsterilized product. Product flow should be directed either to waste or recirculated until the cause of the improper pressure relationship has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

7.6.5.2 Product container sterilization, filling and closing operations

7.6.5.2.1 Recording 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 container 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. The container and closure manufacturers' instructions should be followed. 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.

Air cooling alone may be used for products in which thermophilic spoilage is not a problem.

7.6.8.1 Cooling water quality

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

Therefore 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 provide suitable treatment for separation of impurities, prior to disinfection by chlorine thereby reducing excessive chlorine demand. Recirculated cooling water may gradually increase in organic load and it may be necessary to reduce this by separation or other means. If the pH of cooling water is greater than 7.0 or its temperature is above 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. Particular attention should be paid to positioning of inlet and outlet pipes to ensure all water follows a pre-determined flow pattern within the tank. Cooling tanks and systems should be drained, cleaned and refilled periodically to prevent excessive organic and microbial buildup. Records should be kept of such procedures.

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

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

7.7 Post Process Container Handling

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

1) cans are dried as soon as possible after processing;
2) conveying systems and equipment are designed to minimize abuse; 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, driers should be shown not to cause damage to or contaminate containers and should be readily accessible for routine cleaning and disinfection. Not all driers meet these requirements. The drying unit should be employed in the line as soon as practicable after cooling.

Driers do not remove all cooling water residues from container external surfaces but they reduce significantly the time containers are wet. This reduces the length of post-drier conveying equipment that becomes wet during production periods and which requires extra cleaning and disinfection measures.
The drying of batch processed containers may be accelerated by dipping the filled retort crates in a tank of a suitable surfactant solution. After immersion (15 seconds) the crates should be tipped and allowed to drain. It is essential that any dipping solution be kept at not less than 80°C to avoid microbial 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 26 cm² (4 w²). 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 post process container handling of each container.
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 involved.

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

8. SECTION VIII - QUALITY ASSURANCE

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

8.1 Processing and Production Records

Permanent and legible dated records of time, temperature, code mark and other pertinent details should be kept concerning each load. Such records are essential as a check on processing operations and will be invaluable if some question arises as to whether a particular lot has 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 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.
8.1.2 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).

8.1.3 Continuous agitating retorts (see Sub-Section 8.1.1.2)

8.1.4 Hydrostatic retorts

The temperature in the steam chamber or 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 or 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 product received the scheduled process. The records, including the recorder thermometer chart, should be signed or initiated by the person conducting the review.

8.2.2 Container closure records

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

8.2.3 Water quality records

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

8.2.4 Distribution of product

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

8.3 Retention of Records

The records specified in Sub-Sections 7.6, 7.7, 8.1 and 8.2 should be retained for a period of not less than 3 years to assist investigation of problems should they arise. 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 hygroscopic and therefore liable to promote rusting of tinplate should be avoided as should pastes and adhesives that contain acids or mineral salts.

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

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

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

9.5 The storage conditions, including temperature, should be such as to prevent deterioration or contamination of the product. 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

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

8.5 Retention of Records

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

9. 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

ANALYTICAL METHODOLOGY FOR pH MEASUREMENT

Methods that may be used to determine pH or acidity for acidified, fermented andpickled 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

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. Alternatively, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25°C and determine the equilibrated pH.

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

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

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

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

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

Explanatory Preface

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

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

1. Large-scale catering operations are particularly hazardous because of the nature of the food produced and the way it must be stored and handled. Epidemiological data showed that many outbreaks of food poisoning were caused by food produced in mass catering.

2. Mass catering provides food that is generally potentially hazardous and that is eaten at the same time by a large number of people.

3. The consumers for mass-catering may often be physically very vulnerable. For instance: children, elderly hospital patients and persons suffering from allergies or hyper-sensitivity.

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

The HACCP System consists of:

1. An assessment of hazards associated with growing, harvesting, processing/manufacturing, marketing, preparation and/or use of a given raw material or food product.
2. Determination of critical control points required to control any identified hazard(s).

3. Establishment of procedures to monitor critical control points.

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

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

SECTION I - SCOPE

This code of practice covers all techniques of handling of precooked and cooked foods in a centralized kitchen without prior consideration of each individual consumer. Foods, served raw to the consumer, are not included.

This centralized food production may lead to long delays between preparation and eating (time shift catering).

There may also be a considerable distance between the place where food is prepared and the place where it is served and eaten.

This code recommends specific hygienic requirements for the preparation, portioning, storage, reheating and possibly, transport, distribution and serving of precooked and cooked foods.

SECTION II - DEFINITIONS

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

2.1 catering establishment: a centralized kitchen where food is prepared in bulk and/or the place where the food is divided into portions.

2.2 cleaning: the removal of soil, food residues, dust, grease or other objectionable matter.

2.3 Contamination: the occurrence of any objectionable matter in the product.
2.4 a) cooked foods, foods cooked and immediately served to the consumer or, alternatively, kept or transported at a temperature of at least 65°C, before serving to the consumer.

b) precooked foods - precooked foods can be eaten hot, after reheating, or cold.

1) cooked-chilled: foods, cooked, rapidly chilled and stored between -10°C and + 30°C.

2) cooked-frozen: foods, cooked, rapidly chilled, frozen and stored at or below - 18°C

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

2.6 Establishment: Any building(s) or area(s) in which foods is handled after harvesting and the surroundings under the control of the same management.

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

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

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

2.10 mass-catering: the bulk preparation and/or cooking of food for a group without prior consideration of each individual consumer.

2.11 Packaging Material: any containers such as cans, bottles, cartons, boxes, cases and sacks, or wrapping and covering material such as foil, film, metal, paper, wax-paper and cloth.

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

2.13 Portioning: composing or placing complete meal for one person in or on a suitable container, where the meal will be kept until delivery to the consumer.
2.14 Potentially hazardous food: food capable of supporting rapid and progressive growth of infectious or toxigenic bacteria.

2.15 Rapid chilling: reduction of the temperature in the centre of the food from 60°C to 10°C or below within four hours.

SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA

are not covered in this Code.

For raw material Requirements: See Section VII.

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

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

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

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

4.3 Buildings and facilities

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

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

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

4.3.4 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.
CCP-Note: Cross-contamination is an important factor that contributes to foodborne outbreaks. Food can be contaminated with harmful organisms after cooking sometimes from a food handler, but more often directly or indirectly from raw food. Operations such as the cleaning and washing of vegetables, the washing up of equipment, utensils, crockery and cutlery, and the unpacking of raw materials should be performed in separate rooms or locations especially designed for that purpose. Managers and food inspectors should regularly check that the separation principle is properly applied. (See also CCP-Note in 4.4.1)

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

4.3.7 In food handling areas:

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

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

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

- Windows and other openings should be so constructed as to avoid accumulation of dirt and those which open should be fitted with insect-proof screens. Screens should be easily movable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.
Doors should have smooth, non-absorbent surfaces and, where appropriate, be self-closing and close fitting.

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

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

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

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

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

4.3.12 Water Supply

4.3.12.1 An ample supply of water, in compliance with the WHO "Guidelines for Drinking Water Quality", under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination.

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

4.3.12.2 An adequate supply of hot potable water should be available at all times during working hours.
CCP-Note: For cleaning knives, utensils etc. the temperature of the water used will depend upon the type of soil to be removed (for details see Annex 1 of the General Principles of Food Hygiene, CAC/V0LA-Ed.1). For disinfection of already cleaned utensils they should be immersed in potable water at 80°C for 30 seconds or other time/temperature combination of equivalent lethality for micro-organisms.

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

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

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

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

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

Establishments should also have refrigerating and/or freezing cabinets or equipment (freeze tunnel) for rapid chilling methods, freezing methods and chilled and frozen storage of prepared food corresponding to the maximum daily activity of the establishment and in order to comply with the requirements of Section 7.6.

CCP-Note: Rapid chilling or freezing of large quantities of food requires proper equipment capable of extracting heat rapidly from the largest quantity of food likely to be produced. The method must ensure that foods are not held a long time in the temperature range between 10°C and 60°C where harmful microorganisms grow rapidly. The performance of the equipment should be checked regularly.
Cross contamination of pathogens from raw commodities to prepared foods frequently occurs in the refrigerator. Therefore, raw foods, particularly meat, poultry, liquid egg products, fish and shellfish, must be strictly separated from prepared foods, preferably by the use of different refrigerators.

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

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

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

4.3.18 Lighting
Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colours and the intensity should not be less than:
540 lux (50 foot candles) at all inspection points
220 lux (20 foot candles) in work rooms
110 lux (10 foot candles) in other areas

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

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

In rooms where food is being handled after chilling the temperature should not exceed 150°C. Ideally, the temperature in the kitchen should not exceed 260°C.

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

4.4 Equipment and Utensils

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

CCP-Note. Equipment and utensils constitute a source of potential cross-contamination. They must not be used for raw and cooked foods indiscriminately. In addition to regular routine cleaning, it is essential that all equipment and utensils used for raw foods be thoroughly disinfected before they are used for cooked and precooked foods.
4.4.2 Sanitary design, construction and installation

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

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

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

4.4.2.3 All refrigerated spaces should be equipped with temperature measurement or recording devices. They should be clearly visible and should be placed in such a way as to record the maximum temperature of the refrigerated space as accurately as possible.

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

4.4.3 Equipment identification

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

SECTION IV - B. SERVING ROOMS: DESIGN AND FACILITIES

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

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

SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS

5.1 Maintenance

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

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

For further information on cleaning and disinfection procedures, see Annex I of the General Principles of Food Hygiene (CAC/VOL. A-Ed. 1).

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

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

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

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

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

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

5.3 Hygiene Control Programme

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

5.4 Storage and Disposal of Wastes

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

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

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

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

5.5 Exclusion of Domestic Animals

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

5.6 Pest Control

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

CCP-Note: Insects and rodents are known carriers of pathogenic bacteria from areas of contamination to prepared foods and food contact surfaces therefore their presence in food preparation areas should be prevented.
5.6.2 Should pests gain entrance to the establishment, eradication measures should be instituted. Control measures involving treatment with chemical, physical or biological agents should only be undertaken under direct supervision of personnel who have a thorough understanding of the potential hazards to health resulting from the use of these agents including those hazards which may arise from residues retained in the product. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

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

5.7 Storage of Hazardous Substances

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

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

5.8 Personal Effects and Clothing

SECTION VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene Training

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

6.2 Medical Examination

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

6.3 Communicable Diseases

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

6.4 Injuries

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

6.5 Washing of Hands

Every person engaged in a food handling area should wash his hands frequently and thoroughly with a suitable cleaning preparation under running warm, potable water while on duty. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary.

After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 Personal Cleanliness

Every person engaged in food handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged.

Aprons and similar items should not be washed on the floor. During periods where food is manipulated by hand, any
jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in food handling.

6.7 Personal Behaviour

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

6.8 Gloves

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

CCP-Note: Gloves may be useful in protecting the food handler from the product and also may improve the sanitary handling of food. Torn or punctured gloves should be discarded to avoid leakage of any accumulated perspiration, which will contaminate food with high numbers of micro-organisms. Chain mail gloves are particularly difficult to clean and disinfect because of their construction: careful cleaning followed by heating or prolonged immersion in disinfectant is necessary.

6.9 Visitors

Precautions should be taken to prevent visitors to food handling areas from contaminating food. These may include the use of protective clothing. Visitors should observe the provisions recommended in paragraphs 5.8, 6.3, 6.4 and 6.7.

6.10 Supervision

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

SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

7.1.1 No raw materials or ingredient should be accepted by the establishment if known to contain parasites, microorganisms or toxic, decomposed or extraneous substances which will not be reduced to acceptable levels by normal plant procedures of sorting and/or preparation or processing.
7.1.7 Raw materials or ingredients should be inspected and sorted prior to the cooking process and where necessary laboratory tests should be made. Only clean sound raw materials or ingredients should be used in preparation of food.

7.1.3 Raw materials and ingredients stored on the premises of the establishment should be maintained under conditions that will prevent spoilage, protect against contamination and minimize damage. Stocks of raw materials and ingredients should be supplied frequently and regularly, and excessive quantities should not be stored.

7.1.4 Chilled raw materials which are not immediately used should be maintained or stored at a temperature between 1 and \(\theta\) C. Temperatures should be checked at least once daily.

**CCP-Note:** First in: First out is a good general principle. But age alone may be an imperfect indication of quality. The history of raw materials, in terms of intrinsic quality and temperature history also needs to be taken into account so that different batches can be used in proper sequence. For chilled raw materials the colder the storage temperature, without freezing, the better. Common human pathogens can grow, albeit slowly, at chill temperatures. Yersinia enterocolitica can grow very slowly at \(-1^\circ\) C., Clostridium botulinum type E at \(3.3^\circ\) C. and Listeria monocytogenes at \(4^\circ\) C.

7.1.5 Frozen raw materials which are not immediately used should be maintained or stored at or below \(-18^\circ\) C.

7.2 Prevention of Cross-contamination

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

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

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

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

CCP Note: Food handlers constitute a hazard. Cooked ingredients in potato salad, for instance, can be contaminated by persons during mixing operations in its preparation. Hazard analysis should therefore include observations of food handling and hand-washing practices of the kitchen staff.

7.2.4 Deboning and cutting carcasses should take place in separate rooms or at least on separate tables.

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

7.3 Use of water in the food process

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

7.4 Thawing

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

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

a) a refrigerator maintained at a temperature below 10° C. or
b) running potable water maintained at a temperature not above 21° C.

c) a microwave oven or
d) a purpose-built thawing cabinet.
CCP-Note: Hazards associated with thawing include cross-contamination from drip and growth of micro-organisms on the outside before the inside has thawed. Thawing times should be strictly controlled.

7.5 Cooking Process

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

CCP-Note: Boned rolled joints of meat are convenient for cooking, but the operation of removing the bone and rolling the meat will transfer microbes from the surface to the centre, where they are better protected from the heat of cooking. Recent studies have shown that for the safe production of rare cooked beef, the centre of joints must reach a minimum of 63°C in order to eliminate contaminating salmonellae.

For large poultry carcasses, where salmonellae are also a hazard, and which are not normally eaten rare, salmonellae will be killed if a temperature of 740 C is achieved in the deep thigh muscle. The body cavity of large poultry carcasses must not be stuffed (a) because the stuffing can be contaminated with salmonellae, and may not achieve a temperature high enough to kill them, and (b) because spores of *Clostridium perfringens* will survive cooking. Stuffed birds cool very slowly and *Clostridium perfringens* will germinate and multiply during this time. The effectiveness of the cooking process should be checked regularly by measuring the temperature in the relevant parts of the foods.

7.5.2 Frying fats and oils should be heated to appropriate temperatures not higher than 220°C. Used fats and oils should regularly be changed.

7.5.3 When products are grilled, roasted, browned, fried, blanched, poached or cooked the day before they are consumed, such treatment must be followed by rapid chilling.

NOTE: The cooking process should be designed to maintain the nutritional value of the food.

7.6 Portioning process

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

7.6.2 Only well cleaned and disinfected containers should be used.
7.6.3 Containers with lids are preferred so that the food is protected against contamination.

7.6.4 In large scale system the portioning process of cooked-chilled foods should take place in a separate area in which the ambient temperature should not exceed $15^\circ C$.

7.7 Chilling Process and Storage Conditions of chilled food

7.7.1 Immediately after preparation chilling should be carried out as quickly and efficiently as possible. A specially designed rapid chilling system is essential.

7.7.2 The performance required of the rapid chiller is to reduce the temperature in the center of the food from $60^\circ C$ to $+10^\circ C$ or below within four hours.

CCP-Note: Epidemiological information indicates the most important factors contributing to the occurrence of food-borne disease outbreaks are related to operations that follow cooking. For instance, if cooling is far too slow, so that any part of the food stays for a dangerously long (more than 4 hours) time in the temperature range between $60^\circ C$ and $10^\circ C$ where harmful microorganisms grow rapidly. Hazard analyses must assess conditions of rapid chilling.

7.7.3 As soon as the chilling is complete the products should be put into a refrigerator. The temperature should be less than or equal to $+3^\circ C$ throughout the product and should be maintained until final use. Regular control of the storage temperature is necessary.

CCP-Note: Seafood products should ideally be kept below $3^\circ C$ since the type of C, botulimum found in fish, type E, will grow slowly at temperatures over $3.3^\circ C$.

7.7.4 The storage period between the preparation of chilled food and consumption shall not be longer than five days including both the day of cooking and the day of consumption. This does not apply to food which has been subject to treatment for increased shelf life.

7.8 Freezing Process and Storage Conditions of frozen food

7.8.1 Immediately after preparation freezing should be carried out as quickly and efficiently as possible. A specially designed rapid freezing system is essential.
7.8.2 The performance required of the freezer is to rapidly chill the food and subsequently to freeze it to a temperature below -- 180 C.

**CCP-Note:** See CCP-Note in 7.7.2.

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

7.8.4 Cooked-frozen foods that have been thawed can be stored at or below 3° C but for not more than five days and should not be frozen again.

7.9 **Transport**

7.9.1 Hygienic requirements inside vehicles transporting cooked and precooked foods are also applicable.

7.9.2 During transport the food should be protected against dust and other pollution. The foods should be kept in an insulated container during transport.

7.9.3 Vehicles intended for transporting cooked-chilled food should be maintained at at least 65° C.

7.9.4 Vehicles intended for transporting cooked-chilled food should be appropriate for this transport. The temperature of the cooked-chilled food should be maintained below +3° C but may rise to 7° C for a short period of time during transport.

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

7.10 **Reheating and service**

7.10.1 Reheating the food should be carried out within at most two hours of being removed from chilling. The reheating process must be adequate: a temperature of at least 65° C should be reached in the centre of the food within one hour.

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

7.10.2 The reheated food should reach the consumer as soon as possible and at a temperature of at least 65° C.
NOTE: To minimize the loss of the nutritional value of the food it should be kept at or above 65°C for as short a time as possible.

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

7.10.4 In self service establishments the distribution system should be such that the foods offered are protected from direct contamination which could result in the proximity or the action of the consumer. The temperature of the food should be either below 7°C or above 65°C.

7.11 Identification and quality control system

7.11.1 Each container should be embossed or otherwise permanently marked in code or is clear to to identify the producing establishment and the lot. A lot means a definitive quantity of a cooked or pre-cooked food produced under essentially the same conditions.

CCP-Note: Lot identification is essential for implementing any product recall which may be required. It is also required to enable the "First-in/First-out Principle" to be implemented. For chilled foods a "Use before ...." date is appropriate.

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

CCP-Note: The control of temperature and time at critical control points is the key to producing a sound product. Access to a food microbiology laboratory is useful in establishing the validity of the procedures instituted. Occasional checking at critical control points serves to monitor the continuing efficacy of the management systems.

7.11.3 A sample of each item of food taken from each batch from each day’s production should be kept in a sterile container in chill or in freezer until at least two days after that whole batch has been consumed. These samples should be available for investigation in the event of any suspected food-borne disease or food poisoning.

7.11.4 The health authority will need for its own purposes a record of the catering establishments for which it is responsible and a registration scheme seems most appropriate.
INTRODUCTION

Spices are any of various aromatic vegetable (plant) products used primarily to season, flavor, or to impart an aroma or color to foods and beverages. Condiments are spices alone, or blends of spices which have been formulated with other flavor potentiators to enhance the flavor of foods. The International Organization for Standardization (ISO) has adopted "Spices and Condiments" as its official nomenclature. ISO has defined more than seventy spices and herbs (15). In the U.S. spice trade certain dehydrated vegetables (celery, garlic, onion, bell peppers) as well as some additional seeds (poppy, sesame) are included as spices. The characteristics and nomenclature of all recognized spices and condiments has been reviewed by PRUTHI (30), (31). Definitions and specifications for imported and domestic raw and processed spices can be found in various government publications (20), (32), (38) and trade association documents (1).

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Spice bearing plants are chiefly indigenous to the Asian tropics, approximately within 25 degrees of the equator (24), (25), (29), (31). Herbs, which are defined as the aromatic leaves and flowers of certain plants, are found in the more temperate climates of the Mediterranean, Middle East, North Africa and North America.

Spices represent various portions of the aromatic plants; cinnamon and cassia are barks, allspice and black pepper are berries, cloves represent floral parts, onion and garlic are bulbs, tumeric and ginger are roots or rhizomes, capsicum represents fruits, rosemary, thyme and sage are leaves, and poppy or mustard represent the seeds.

GENERAL CONSIDERATIONS

The physical and chemical diversity of spice materials presents problems in their analysis by chemists and microbiologists. Under normal dry storage conditions, spices are non-perishable items. Once ground, some spices may begin to lose certain characteristics such as color (paprika) flavor (dill 29) or pungency (black pepper, 10, 11). In some countries microbiical treatments of processed spices are permitted (8), (21), (31). The effectiveness of ethylene oxide (23), (39, 40, 42, 43, 44) propylene oxide (33, 41) gamma irradiation (42, 47) and microwave treatments have been reported.

In general, processed spices are examined with standard procedures for aerobic plate count, molds, yeasts and coliform bacteria (2). If coliforms are present, the presence and content of E. coli is determined. Where there is an indication of insanitary storage of spices,
the presence of Salmonella and Shigella must be determined (7). Certain other analyses may be requested by certain food processors and seasoning formulators. These include testing for coagulase-positive staphylococci, anaerobic sporeformers, enterococci, lactobacilli and Bacillus cereus.

**NORMAL FLORA**

Peppler and Guarino (26) summarize the normal microbial flora as follows: "Since they are raw agricultural commodities, spices accommodate mixed populations of bacteria and molds, normal to the growing area. The microbial load will vary with different production regions, harvest methods and post-harvest treatments. Celery seed, paprika, black and white pepper, and ginger will usually show total plate counts in the millions per gram (9), (18), (43, 45). Total plate counts ranging upward of a few hundred thousand per gram have been noted in cassia, mace and nutmeg (9), (18). Those spices whose essential oils exhibit antimicrobial effects generally show the lowest microbial populations (4, 29, 31, 36, 45, 46). Examples are cloves, mustard seed (12) onion and garlic (12), (13) oregano, sage (36).

During the cleaning and processing of spices there is a progressive reduction in the numbers and types of microorganisms (31). Those organisms remaining after physical cleaning operations are generally mixtures of aerobic sporeforming bacteria and common molds (9, 16, 29, 34). Other organisms found occasionally are coliform bacteria, yeasts, anaerobic spore formers, streptococci, and thermophiles. These are usually found in small numbers, when they are found at all (9, 18, 29, 27, 31).
Clostridium perfringens are present in processed spices, but seldom more than a few hundred per gram (13, 27). With the exception of Bacillus cereus, bacteria of public health importance have not been demonstrated in processed spices (17, 28).

A variety of molds can be found in spices. The numbers range from very few into the many millions per gram. Black and white pepper are normally found to carry an abundance of aspergilli (5, 16, 18). *Aspergillus flavus* and *A. niger* are generally the most prominent species (5, 6).

The levels of aflatoxins detected in processed spices are quite low (35) although isolates of *A. flavus* obtained from spices have been shown to produce aflatoxins when grown on laboratory media (3, 6, 14, 35).

Inoculation of moistened ground spices and herbs with toxigenic strains of aspergilli results in aflatoxin production in the media prepared with ginger, rosemary, sesame, caraway seed and celery seed (14, 19).

Certain spices such as cinnamon, cloves, mustard and oregano show inhibition of mold growth and toxin formation.

Keeping quality of spices is directly related to the condition of the product at harvest and the post harvest processing and storage. Properly harvested, most seeds will require no further drying, whereas roots, barks and certain berries may require various drying times. When properly dried and stored, spices are generally immune to microbial spoilage. However, spices are raw agricultural materials and if the moisture content is too high molds may grow offering the opportunity for aflatoxin production.
A classic example of this occurred in the Cochin ginger crop of 1978. Two American Spice Trade Association Member Laboratories were conducting mycotoxin examination as a spice quality control measure. Independently, they started picking up aflatoxin B₁ in Cochin ginger at levels as high as 80 ppb. The ASTA office was apprised of the situation and the U.S. Food and Drug Administration was alerted to the problem. Through the cooperative efforts of trade association members, almost all of the U.S. Importation of the ginger in question was sampled and analyzed for aflatoxin, with lots in excess of the FDA administrative tolerance of 20 ppb removed from the market.

Subsequent investigation revealed that the crop had been harvested too early, had not been properly dried, and that mold growth had occurred sufficient to produce aflatoxin. External, visible mold had been removed, and the ginger had a normal appearance, but the damage had already been done.

METHODS OF HARVESTING, PROCESSING AND PRESERVATION

Quite varied methods of harvesting and immediate post-harvest processing are employed in handling spices. These have an influence on microbial content. The primary thrust is to dry the products as quickly as possible to prevent any kind of spoilage.

HARVESTING

Pivnick cites the following examples to detail the primitive aspects of harvesting and post-harvest treatment:
"A) Rhizomes (Douglas, 1973): ginger

Dried ginger for export is processed as either rough or unbleached ginger or as bleached ginger.

The methods used in Kerala are –

Rough or unbleached dry ginger. The harvested rhizomes are soaked overnight in water, on the next day they are rubbed in the hands and cleaned with water. The outer skin is peeled off delicately and carefully with split bamboos with pointed ends or with seashells which have sharp edges or glass pieces... The peeled rhizomes are washing in water and then spread out in the sun for 7 to 10 days. After that period, they are further cleaned with pieces of gunny or soaking to remove any loose skin. Finally, the rhizomes are packed in gunny bags.

Bleached ginger. The rhizomes are kept in broad open metal drums filled with water to a height of about 1 foot above the rhizomes. After a day's soaking, the water is drained off and the rhizomes are then peeled with the aid of glass pieces or split bamboos with pointed ends. The peeled rhizomes are soaked in 2% lime water which has been filtered through a cloth. They are then exposed to sulphur fumes for 12 hours, following which they are dried in sunlight for a day. This process is repeated until the bleaching is satisfactory. Finally, the rhizomes are spread out in the sun for 7 to 10 days for drying. When they are thoroughly dried, they are again checked for any loose skin and then packed in gunny bags."

B) Bark (Rosengarten, 1973): Cassia

"The first harvest takes place during the rainy season... shoots of 6 to 8 feet are cut close to the ground..."
With curved knives the bark is peeled off in strips and left to ferment in bundles for 24 hours. The corky outer layer of the bark is scraped off, leaving the clean, light colored bark. Drying - first in the shade, then in the sun - may require 3-4 days."

c) Berries (Rosengarten, 1973; Breag, et al., 1972):
Allspice (pimento).

"Allspice in Central America and Mexico is almost entirely from wild sources...from the natural virgin rain forests. Branches of large wild pimento trees are chopped off and the berries then picked off the ground...to dry the allspice berries for a few days in the sun on straw mats."

At collection centers they are boiled to combat mold growth and then dried and packed for export.

In Jamaica, allspice trees are cultivated. Nevertheless, an uncontrolled fermentation of the berries and drying in the sun is commonly practiced.

"The present method of sun-drying after the berries have been picked off the trees is to ferment them for four to five days in approximately 0.6 m high heaps. The fermentation is accompanied by a temperature rise and the berries brown. They are then spread out in thin layers on concrete barbecues and turned over several times in sun drying.

The time required for drying the berries down to a safe moisture content during dry weather conditions is approximately five days. At night and during downfalls of rain the berries are swept up into heaps and covered. Sudden downpours of rain are not uncommon during the pimento season and re-wetting of the partially dried berries during these times is inevitable."
This process, however, results in an estimated loss of about 10% of the harvested berries due to mechanical damage and mold growth. A shorter drying period using artificial drying produces a satisfactory product while reducing this loss (Breag, 1972).

D) Seeds (Rosengarten, 1973)

Although most seeds come from pods, and may be sterile in situ, the process of harvesting, threshing and winnowing offer ample opportunity for microbial contamination. Moreover, the smaller the particle the greater the surface per unit of mass. Thus, large surfaces are available for adherence of microorganisms on most seeds: caraway seeds number about 300,000 per kg and poppy seeds, about 2,000,000.

The four examples given above show that most spices, like other raw agricultural materials such as grains and hay, must be dried at harvest or quickly thereafter to prevent spoilage by molds. The sometimes primitive conditions of culture and harvest, small plots, vagaries of weather and often humid tropical climates may make drying difficult.

A much more detailed discussion of postharvest technology is presented by PRUTHI (31) who describes the pretreatments such as washing, peeling, pricking, blanching, and various chemical treatments; stressing also the importance of drying to reduce the moisture naturally present at the time of harvest to a safe limit of approximately 8-10%.

**PROCESSING METHODS**

To reduce the microbial flora of spices and to eliminate those organisms of public health significance it is desirable to employ one of several methods available.
A. ETHYLENE OXIDE. An excellent effective means of destroying bacteria, yeasts, and mold spores. The U.S. Environmental Protection Agency (1982) places a maximum tolerance of 50 ppm for Ethylene Oxide in or on whole spices. A similar maximum tolerance was also issued by FDA for ground spices (21 CFT 193.200). The most common reaction product from Ethylene Oxide treatment is Ethylene Chlorohydrin. The Canadian Food and Drugs Act of 1977 established a maximum tolerance of 1500 ppm for Ethylene Chlorohydrin in treated spices.

B. PROPYLENE OXIDE is substituted for Ethylene Oxide in some applications. Weight for weight it does not have the effectiveness of Ethylene Oxide. The U.S. Food and Drug Administration places a maximum permitted residue level of 300 ppm on spices treated with Propylene Oxide.

C. IRRADIATION. A very effective means of reducing microbial populations at dosage levels up to 1.0 mrad. Unfortunately, ionizing irradiation has limited legal acceptability in most countries at the present time. The U.S. Food and Drug Administration has approved the ionizing irradiation of spices at a maximum of 1 megarad.

D. HEAT TREATMENT. Various methods of heat treatment of spices have been proposed and discarded, primarily due to the high loss of spice volatiles as well as color loss and damage. A current process utilizing superheated steam (Kikkoman) is creating some interest in the treatment of spice seed, berries and roots or rhizomes.
E. EXTRUSION. United States Patent 4, 210, 678
(Bayusik et al.) describes how herbs and spices are sterilized for commercial sale purposes by extruding the products through a small orifice in a die, preferably while maintaining the products at a temperature above approximately 220°F. Prior to extrusion the spices or herbs are moistened and held in the presence of moisture until the moisture level has equilibrated to a range of about 16-20% by weight.

PRESERVATION

There are many areas where contamination of spices can occur - in the field, during processing, in storage and in transit. The spice trade is aware of the difficulty in improving spice handling techniques in remote areas of spice cultivation and harvesting.

Pruthi (31) offers the following suggestions for warehousing, shipping and fumigation of spices to insure freedom from insect and microbial infestation in spices:

1. Fumigation of the spices before storage is important, and also whitewashing of the godowns and prophylactic spraying before the onset of the monsoon.

2. Treated pestproof bags should be used for storage of spices to prevent reinfestation in the godowns.

3. Waterproof and lightproof packings may be used for susceptible spices. Polyethylene-lined double burlap bags or laminated pestproof bags are ideal for storage of spices if the moisture is reduced to a critical level before bagging.

4. Spices should be examined periodically and fumigated again if necessary. Old and fresh stocks should be stored separately to avoid cross-infestation and to protect against moisture absorption.
5. Ships' holds where the spices are to be stored should be cleaned and fumigated before the consignment is loaded.

6. The fumigants used should be effective against the particular pests attacking the spices.

7. To avoid any toxic residues of the fumigants being left after fumigation, it is necessary to use the right type of fumigants in optimum quantities.

The American Spice Trade Association (ASTA) has prepared a Warehouse Sanitation guide for spices. ASTA recognizes that in many parts of the world conditions are such that their recommendations could not be immediately implemented.

However, there is one area in the chain of distribution where the practice of proper sanitary controls will effectively help to reduce insect and rodent contamination; that is, in the processing and/or storage plant of the snipper.

Some hints from the Association in helping to control and eliminate insects and rodents are:

1. All insects begin as eggs, they require time and a warm temperature to develop. Examine all incoming lots for signs of infestation. Rotate stock (first in-first out) to avoid contamination of new parcels by older ones. Sweep up storage areas prior to receiving lots and discard the sweepings. Keep spices neatly stored in accessible lots, away from wall with rows between stacks. This will allow cleaners to keep areas free of refuse and spilled spices and to see where infestation may be occurring. Isolate any infested products from the rest of the stock to prevent spread of contamination to good stock.
2. Rodents are primarily active at night, and they can enter a storage area through holes as small as 5 mm. Keep them out by rodent proofing outer openings in walls, floor and ceiling with masonry and installing tight doors and screens. Starve them out by sweeping up spills as they occur. Destroy their hiding places. Rodents build nests in crowded storage areas, hollow walls, outside burrows, unused equipment and in unmoved lots of spices.

Keep outside premises neat and free from piles of trash, old equipment, ground burrows and store items away from walls to allow for inspection.

Examine stored lots for signs of excreta on bags, gnawing, urine smell and nesting material. Track the rodents down by following rub marks and runways caused by their traffic patterns. Trap them by using rodent traps regularly.

3. The use of pesticides can help support food sanitation, but they are not a replacement for a good clean-up program. Use pesticides only according to the manufacturer’s label instructions. Pesticides should be applied only by qualified personnel. Store pesticides in an area separate and apart from the spices to avoid accidental contamination.

Once a spice has been contaminated, proper cleaning processes must be followed to remove the contaminants. The refuse should be collected and removed from the area immediately to prevent further contamination.


SPICES AND HERBS

PART II - PROPOSED DRAFT CODE OF HYGIENIC PRACTICE
FOR SPICES AND HERBS AT STEP 3

1. Section I - Scope

1.1 This Code of Hygienic Practice applies to all spices, harvested wild, or cultivated.

It contains the minimum requirements of hygiene for harvesting, farm handling, cleaning, transportation, and storage. It covers all types and forms of raw and further processed spices.

2. Section II - Definitions

2.1 Spices are any of various aromatic vegetable (plant) products used primarily to season, flavor, or to impart an aroma or color to foods and beverages, as defined by the International Organization for Standardization (ISO) or as officially accepted by various governments.

2.2 "Curing" means drying to a safe moisture level.

2.3 "Safe water activity" means a water activity of spices that will prevent growth of micro-organisms normal to the spice harvesting, processing, and storage environment. Water activity ($a_w$) is a measure of free moisture in a product and is the water vapour pressure of the substance divided by the vapour pressure of pure water at the same temperature. An $a_w$ exceeding 0.07 at 25°C (77°F) is unsafe.

3. Section III - Hygiene Requirements in Production/ Harvesting Areas

3.1 Environmental Hygiene in Areas from which Raw Materials are derived - same*.

3.1.1 Unsuitable growing or harvesting areas - same.

3.1.2 Protection from contamination by wastes - same first sentence, then "Plant growth and spice material unsuitable for processing should not be permitted to accumulate in such a manner as to promote mold growth or to attract rodents or insects.

3.1.3 Irrigation control - same.

3.1.4 Pest and diseases control - same.

3.2 Harvesting and Production - same.

3.2.1 Curing (drying). After being harvested spices should be exposed for maximum rate of drying. Drying should be completed as rapidly as possible to a safe water activity so as to prevent growth of micro-organisms especially mycotoxin producing moulds. Excessive supplemental heat should be avoided where the general quality of the spice might be impaired.

3.2.2 Techniques - same.

3.2.3 Equipment and containers - same.

3.2.4 Removal of obviously unfit materials. Damaged or imperfect spices and lots that contain any obvious contamination with animal or human wastes, insect infestation, decomposition, or other defects to an extent which would render them unfit for human consumption, should be segregated during harvesting and production to the fullest extent practicable. Such segregated unfit spices should be disposed of in such a place and in such a manner as to avoid contamination of sound spices, water supplies and other crops.

3.2.5 Protection of ground spices from contamination. Paragraph can remain the same, substituting "spices" for "ground nuts." At line 9 omit the parenthetical statement "(e.g., pyramid stacking)."

3.3 Transportation - same.

3.3.1 Conveyances - same.

3.3.2 Handling procedures - same.

3.4 Shelling plant - this section not applicable.

Section IV - Establishment: Design and Facilities; Section V - Establishment: Hygiene Requirements; and Section VI - Personnel Hygiene and Health Requirements can be incorporated without any further wording changes.
7. **Section VII - Establishment: Hygienic Processing Requirements**

7.1 Raw Material Requirements - same.

7.1.1 Acceptance criteria. Substitute "spices" for ground nuts and stop the paragraph at the end of line 7. Drop the last two sentences. Also, drop the second paragraph referring to progressively more accurate decisions.

7.1.2 Storage - same, again with "spices" replacing "ground nuts."

7.2 Inspection and Sorting. Repeat 3 lines at bottom of page 11 only. Do not include the three paragraphs continuing on page 13.

7.3 Prevention of Cross-Contamination

7.3.1 Same.
7.3.2 Same.
7.3.3 Same.
7.3.4 Same.

7.4 Use of Water

7.4.1 Same.
7.4.2 Same.
7.4.3 Same.

7.5 Processing

7.5.1 Same.
7.5.2 Same.
7.5.3 Same.
7.5.4 Same.
7.6 Packaging

7.6.1 Same.
7.6.2 Same.
7.6.3 Same.
7.6.4 Lot identification - same.
7.6.5 Processing and production records - same.

7.7 Preservation of Product. Substitute "spices" for "ground nuts."

7.8 Storage and Transport of End-Product - same.

7.8.1 Same.
7.8.2 Controlled storage conditions - same.

7.8.2.1 Control of mould growth. An environment with a relative humidity between 55% and 65% should be maintained to protect quality and prevent mould growth.

7.8.2.2 Control of infestation by insects, mites and other arthropods. Spices should be stored in such a manner that infestation can be controlled by such methods as anaerobic or refrigerated storage or fumigation prior to storage. Stored spices should be inspected regularly and, if invested, fumigated by appropriate methods. If necessary they can be removed for fumigation. In this case the storage areas should be separately cleaned and disinfected.

7.9 Sampling and Laboratory Control Procedures

7.9.1 In addition to any control by the official agency having jurisdiction, it is desirable that each plant should have its own or contracted laboratory control of the hygienic quality of the spice products processed and of the pest control procedures. The amount and type of such control will vary with the different spice products as well as the needs of management. Such control should provide for rejection of all spices that are unfit for human consumption and monitoring of the quality of the finished products.