INTRODUCTION

1. The Fourteenth Session of the Codex Committee on Food Hygiene was held in the
Main Conference Room, Department of State, Washington, D.C. from 29 August to
2 September 1977. The session was attended by representatives and observers of 26
countries and observers from four international organizations (see Appendix I for list
of participants.

2. The participants were welcomed on behalf of the Government of the United States
by Mr. E. Kimbrell, U.S. Codex Coordinator who emphasized the value of the Committee
in providing expertise in the elaboration of Codes of Practice for consumer protection
and for the establishment of soundly based food laws for use both within countries and
in international trade.

ADOPTION OF THE AGENDA

3. After a brief discussion the Committee adopted the Agenda with some changes in
the order of the items to be discussed.

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

4. The representative of WHO reviewed recent WHO activities relating to the work of
the Codex Committee on Food Hygiene. He referred to recent publications and develop-
ments concerning food irradiation, microbiological specifications, the WHO Food Virology
Programme, the Joint FAO/WHO Food and Animal Food Contamination Monitoring Programme,
the WHO/UNEP Environmental Health Criteria Programme, surveillance of food-borne
causes and postgraduate training in food microbiology.

5. He also referred to the following meetings to be held in the comparatively near
Nairobi, the WHO/EURO Conference on the Organization and Methodology of Food Control
Laboratories, 24-28 October 1977 in Copenhagen, and the FAO/WHO Expert Committee on
Parasitic Zoonosis, 14-20 November 1978 in Geneva.

6. Mention was further made of the current reorientation within WHO directed towards
increased technical cooperation with member states and towards improvements in the
efficiency of national health services in health-related food and nutritional programmes.

7. The Committee noted that the Codex Committee on Food Additives at its 11th Session
(June 1977) had considered a Draft General Standard on Irradiated Foods which included
provisions for the irradiation of some individual food items and had also considered a
Draft Code of Practice for the Operation of Radiation Facilities Used for Treatment
of Foods. These drafts had been prepared by a Joint FAO/IAEA technical group on the basis
of the recommendations of the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness
of Irradiated Foods. Following extensive discussion, mainly on the irradiation aspects,
the Codex Committee on Food Additives advanced the Draft Standard and the Draft Code of
Practice to Step 5 for consideration by the 12th Session of the Commission in 1978.
8. It was drawn to the attention of the Committee that the Draft Standard for Irradiated Foods included provisions relating to microbiological aspects. In particular, the provisions for the irradiation of some individual food items contained specific microbiological criteria for some products such as chicken meat, strawberries, cod and redfish. In view of its extended terms of reference making it responsible for the endorsement of microbiological criteria in Codex standards and codes of practice, the Committee agreed that it be drawn to the attention of the Commission that these documents on irradiated foods contained provisions on hygiene such as microbiological requirements and that therefore they should be referred to this Committee for consideration and endorsement.

MATTERS RELEVANT TO THE CODEX COMMITTEE ON FOOD HYGIENE AS DISCUSSED BY CODEX COMMITTEES

Draft Standard for Canned Sardines and Sardine-type Products (ALINORM 78/18, Appendix II) and Draft Standard for Canned Mackerel (ALINORM 78/18, Appendix III)

9. The Committee endorsed the hygiene provisions of these standards.

Draft Standard for Quick Frozen Hake (ALINORM 78/18, Appendix IV)

10. The Committee agreed that the term "harmful to man" of the hygiene provisions in 5.3(a) and 5.3(b) should be replaced by that generally used in other provisions and 5.3 (c) "a hazard to health". The provision now reads: "5.3 When tested by appropriate methods of sampling and examination, the product:

   a. shall be free from microorganisms in amounts which may represent a hazard to health;
   b. shall be free from parasites which may represent a hazard to health; and
   c. shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health."

Draft Standard for Quick Frozen Lobsters (ALINORM 78/18, Appendix V)

11. The Committee noted that, as with the Standard for Quick Frozen Shrimps and Prawns (ALINORM 76/18A, Appendix III), there was a distinction to be made between the product which was heat treated before freezing and the product frozen in the raw state. For the raw product, the Committee agreed to the wording adopted for the Draft Standard for Quick Frozen Hake (see paragraph 10 above).

Draft Standard for Bouillons (ALINORM 76/9, Appendix II)

12. The Committee endorsed the hygiene provisions in the Proposed Draft Standard for Bouillons. It agreed to amend sub-section 6.4 by making reference to the provisions of the Code of Hygienic Practice for Low-acid Canned Foods (see Appendix VI to this Report).

RECONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PEANUTS (GROUNDNUTS) AT STEP 4

13. The Committee reconsidered the above-mentioned Proposed Draft Code as contained in ALINORM 78/13, Appendix III, in the light of comments received from governments (CX/FH 77/6).

14. The delegation of the USA acted as rapporteur to the Committee and reviewed the various comments. It was again noted with regret that no observations from developing producing countries had been forthcoming. The Secretariat was again requested to bring this matter to the attention of the Coordinating Committee for Africa. It was also thought that at the Joint FAO/WHO/UNEP Conference on Mycotoxins due to take place in September 1977 in Nairobi, Kenya, the Code should be drawn to the attention of the Conference.

15. The Committee considered the Code in great detail and a large number of changes, predominantly editorial, were made. It was agreed that where applicable the text of the Revised Code of Practice - General Principles of Food Hygiene would be incorporated into the present Code. In connection with the latter it was agreed to discuss later during the session the possibility and desirability of indicating in the "General Principles" that certain provisions applied specifically to perishable products.

16. The Committee discussed in some detail the usefulness of including a provision on refrigerated storage of peanuts in the Code. As such a procedure was not considered feasible in most producing countries - at least for the time being - it was agreed to include no reference to this in the Code.
17. Consideration was further given to a suggestion to include in the Code maximum levels for contaminants, in particular for aflatoxin. As the data available appeared to be insufficient, it was decided to leave this question as a matter of negotiation between buyer and seller. It was hoped, however, that at the next session of the Committee as a result of the Kenyan conference on mycotoxins, specific end product specifications related to contaminants could be placed on the Agenda. One delegation pointed out that the setting of any specific level depended largely on the sampling technique used.

Status of the Code

48. The Committee agreed to advance the Code to Step 5 of the Procedure and recommended that Steps 6 and 7 be omitted. The Revised Code is contained in Appendix II to this Report. The Committee expressed its appreciation for the work done by the delegation of the USA.

RECONSIDERATION OF THE DRAFT CODE OF HYGIENIC PRACTICE FOR MOLLUSCAN SHELLFISH

19. The Committee reconsidered the above-mentioned Draft Code as contained in ALINORM 76/13A, Appendix VI, in the light of government comments received (CX/FH 77/8). The delegation of the USA acted as rapporteur to the Committee.

20. The Committee agreed that in the panel at the head of the Code reference should be made to the "Guide to Shellfish Hygiene" (WHO Off-set Publication No. 31, 1976). In the Code a large number of editorial changes were made. It was agreed that where appropriate the text of the Revised General Principles would be inserted into the present Code. Those provisions specific to the Code were discussed in greater detail and are reported hereunder.

Scope (Section I)

21. The scope of the Code was broadened to include species not mentioned by name. The Committee noted that the Code was not intended to apply to products which would receive a thorough cooking and the scope was amended accordingly.

Definitions (Section II)

22. It was agreed that in addition to the definitions for purification (dépuration) and relaying, the term conditioning (dégorgement) should be defined.

Environmental Sanitation in Growing Areas (Subsections III.A.2-4)

23. The Committee discussed replacing the texts for Sanitary Quality of Water, Surveys of Shellfish Growing Areas and Animal, Pest and Disease Control (III.A.2-4) with a much more detailed text which had been proposed by the delegation of the USA. Some delegations thought that the proposed text was too lengthy and that it would be better attached as an annex to the Code. The Committee noted, however, that the proposal contained details which would be of especial value to those countries which were developing shellfish production and decided to include the text with some minor amendments in toto in the body of the Code.

Purification of Shellstock (IV.D.2(a))

24. The Committee noted that some contaminants accumulated in shellfish and could normally not be reduced by purification to acceptable levels. It was agreed to include a sentence to this effect in the provision, thus excluding such contaminated shellfish from the purification process.

End Product Specifications (Section V)

25. The Committee adopted a revised text proposed by WHO, amended to include mention of marine biotoxins. It also updated the terminology to refer to substances originating from microorganisms in amounts which may represent a hazard to health.

Current Laboratory Procedures and Standards (Annex I)

26. At its last session, the Committee had agreed to list in an Annex to the Code current laboratory procedures and standards in a number of countries. It was agreed to retain this information as an annex to the Code and to preface it with an introduction proposed by the delegation of the USA.
Status of the Code
27. The Committee agreed to advance the Code to Step 5 of the Procedure with the recommendation that Steps 6 and 7 be omitted. It also agreed to request the Secretariat to update the information on laboratory procedures and standards (Annex I) at such time as the Code was adopted by the Commission at Step 8. The revised Code is contained in Appendix III to this Report. The Committee thanked the delegation of the USA for its contribution to the elaboration of the Code.

REVISION OF CODE OF PRACTICE - GENERAL PRINCIPLES OF FOOD HYGIENE AT STEP 4

28. The Committee had before it the revision of the above Code of Practice which had been prepared by a small Working Group which met in Geneva in December 1976 (CX/FH 77/3) and which had been distributed to governments for comments. Prior to the present session of the Committee, the Working Group again met to reconsider the revised Code in the light of the observations received and submitted an amended text for further consideration by the Committee (CX/FH 77/3 Amended).

29. The Chairman of the Working Group, Dr. K. Büchli (Netherlands), gave a brief résumé of the history of the Code and presented the revised version for the Committee's consideration. He referred particularly to the observations made by the delegations of Australia and the Federal Republic of Germany which had been most helpful in preparing the first revision. He pointed out that the Code had been revised extensively.

Scope (Section I)
30. The Committee reviewed the revised document in some detail and agreed on several further amendments. Certain issues of particular interest are highlighted hereunder.

31. It was noted that not all provisions in the Code would be applicable to all food products and, bearing in mind the steadily increasing influence of Codex documents, it was agreed that the Code should recommend general rather than basic or minimum hygiene practices. Particular care was exercised to phrase the provisions of the Code in such a manner as to cover all essential hygienic requirements in general terms.

Definitions (Section II)
32. After a protracted discussion of the definition of "Food Handling", the Committee agreed to extend the definition to include transport, distribution and sale. It was also pointed out that the definition of "Establishment" could be interpreted to include harvesting and/or collection operations on the farm which, in the opinion of the Committee, should not be covered by the provisions in Sections IV and V of the Code relating to establishments. As a consequence, the Committee revised the definition for "Establishment" by restricting the term to buildings and areas in which food is handled after harvesting.

Environmental Hygiene in Areas from which Raw Materials are Derived (3.1)
33. The delegation of Japan proposed to include a provision on "unsuitable growing and harvesting areas" to cover areas where naturally occurring substances may result in the food being a potential hazard to the health of the consumer. The Committee agreed to this suggestion (new 3.1.1).

Buildings and Facilities — Windows (4.3.7)
34. After some discussion it was agreed to provide for apertures other than windows in the provision for windows.

Changing Facilities and Toilets (4.4.3)
35. It was pointed out that the extensive use of flushing water closets now represented an ecological problem and that research into alternative technology for dealing with waste matter was presently given high priority. The specific reference to flushing water closets was therefore deleted.

Personnel Hygiene and Health Requirements (Section VI)
36. Some delegations pointed out that "employee" used in relation to health requirements might be taken to exclude management from compliance with personnel hygiene and health requirements. To avoid misunderstanding it was agreed to use the term "food handler" instead.
Packaging (7.5)

37. The Committee agreed that if containers were used for other purposes than those for which they were intended they should not be re-used as product containers if this were to lead to contamination of the food. A provision to this effect was included in the subsection on packaging.

Product Coding (7.5.4)

38. There was some discussion on whether the Code should specify that production records should be retained during a certain minimum period. The Committee decided not to change the present provision which specified retention periods of production records up to a maximum of two years.

Instructions for Storage and Use

39. It was pointed out that the microbiological condition of a product might be intimately linked with the way the product was used at the consumer level, e.g. if a product was reconstituted and kept under unsatisfactory conditions it might represent a hazard to health. It was thought therefore that in certain cases it might be important to indicate on the label how a product should be handled by the consumer in order to help in assuring the safety of the product. The question was raised as to whether the Code should not contain some reference to informative labelling relevant to hygiene. The Committee agreed to discuss this matter at its next session. (See also para 56 of this Report).

Status of the Code

40. The Committee agreed to advance the Code to Step 5 of the Procedure with the recommendation to omit Steps 6 and 7 of the Procedure. The amended Code is attached as Appendix V to this Report. The Annex on cleaning and disinfection procedures prepared by the United Kingdom, which was at Step 3 of the Procedure, had not been discussed and was therefore not attached to the Code.

41. It was agreed that in the introduction to the document when published as a Recommended International Code of Practice it should be made clear that the Code was intended for advisory purposes and that the aim of the Code was to assist those concerned with food handling and was not to be construed as prescribing mandatory requirements.

RECONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR LOW ACID CANNED FOOD AT STEP 4

42. The Committee had before it the above mentioned Code (CX/PH 77/4) as revised by a Working Group under the chairmanship of the delegation of Canada who presented the substantive changes which had been made by the Working Group since the distribution of the document. He further took into account written comments received from the USA and the UK.

43. The Committee noted that the text of the Code as it stood could usefully be divided into recommendations and explanatory text, as was the case for Codes of Practice for Fishery Products. The delegation of Canada agreed to revise the document on these lines.

Status of the Code

44. The Committee advanced the Code to Step 5 of the Procedure and expressed its appreciation to the delegation of Canada and to the Working Group for the valuable work done. The revised Code is attached as Appendix VI to this Report.

RECONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN AT STEP 4

45. The Committee considered the above mentioned Code as contained in document CX/PH 77/8 in the light of government comments (CX/PH 77/5 and 77/13). The delegation of the Federal Republic of Germany acted as Rapporteur.
46. Several delegations held the view that the term "children" as used in the title was not sufficiently explicit even though the word was defined (for the purpose of the Code) in the Definition section. These delegations suggested that in the title an age limit should be included. The Committee agreed to this proposal.

Incorporation of amended text of "General Principles"

47. The Committee agreed that changes which had been made in the General Principles, and which were appropriate, would be incorporated in this Code.

Scope (I)

48. The Committee agreed to clarify that the Code covered only prepackaged food intended specifically for infants and children and amended the Scope section accordingly.

Water Supply (4.4.1) and Disinfection Facilities (4.4.5)

49. Some delegations expressed doubt about the need to specify in the Code the minimum temperature of hot water. Following some discussion it was decided to request governments to give their views on this matter.

Tanks and Vessels (4.5.4)

50. To avoid any misunderstanding, an amendment was made to the provision specifying that only fixed vessels were covered by the provision.

Storage of Raw Materials and Ingredients (7.1.3)

51. It was noted that a specific provision had been included in the Code for the storage of food liable to rapid deterioration. It was agreed that the term "liable to rapid deterioration" should be substituted by "perishable" for which a definition might be developed. A proposal was made to amend the storage temperature requirement for perishable foods. Following discussion it was agreed not to make any change.

Vacuum Checking (7.6.6)

52. The Rapporteur was requested to review the provision on vacuum checking. The opinion was expressed that only thermally processed containers need be checked for vacuum and that a single check sufficed.

53. It was noted that this provision as well as several others dealing with the preservation of end products were also covered in the Code for Low Acid Canned Foods, and that there should be harmonization between the two Codes.

Microbiological Specifications

54. The Committee noted that a proposal for microbiological specifications for foods for infants and children which had been developed by an Ad Hoc Working Group which had met in Berlin (November 1976) had subsequently been discussed by the Second Joint FAO/WHO Expert Consultation.

55. The Committee agreed that the specifications as revised should be attached to the Code. Governments were specifically requested to comment on the specifications.

Instructions for Storage and Use

56. It was pointed out that for foods for infants and children it was important that the label should provide information on storage and use. This matter had also been discussed earlier during the session and it was agreed to reconsider the issue when the Code was discussed again. (See also para 39 of this Report.)

Status of the Code

57. The Committee agreed to advance the Code to Step 5 of the Procedure. The revised Code is attached as Appendix VII to this Report. The Chairman thanked the delegation of the Federal Republic of Germany and the members of the Ad Hoc Working Group for their valuable work. He made particular reference to the use that had been made of this Code in the preparation of the revision of the "General Principles". The delegation of the Federal Republic of Germany undertook to revise the Code in the light of the discussions.
GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF MICROBIOLOGICAL SPECIFICATIONS FOR FOODS

58. The Committee had before it the Report of the Second Joint Expert Consultation on Microbiological Specifications for Foods (EC/Microbiol/77/Report 2, page 3 and Annex II). This Committee (ALINORM 78/13, paras 84-85) at its last session had requested the Consultation to set out the guiding principles for the establishment and application of microbiological specifications for foods.

59. The Consultation was of the opinion that the question of relating microbiological criteria to mandatory and advisory provisions in Codex documents had yet to be resolved. It had therefore defined three types of microbiological criteria - standards, specifications and guidelines - as applying respectively to Codex Standards, Codes of Practice and to situations where neither provision existed. Consideration was also given to the need for and the purposes and application of microbiological criteria, their composition and the interpretation of the results obtained in applying the criteria. The conclusions of the Consultation were set out in Annex II to the above mentioned document.

60. The Committee expressed its appreciation to the Consultation for the excellence and value of the document. It was the opinion of the Committee that the criteria should be included in a future edition of the Procedural Manual of the Commission as General Principles governing the terms of reference of the Codex Committee on Food Hygiene. Governments should be asked to comment on this matter so that the Executive Committee could make suitable recommendations to the Commission in the light of government opinion. The General Principles are contained in Appendix VIII to this Report.

HARMONIZATION OF DEFINITIONS

61. At its 13th Session the Committee had considered the question of harmonization of definitions used in various Codex documents. It was noted that Codex Standards and Codes of Practice, and the Procedural Manual, contained definitions relating to foods and food hygiene, and that FAO and WHO had also included definitions for these terms in other documents.

62. The Committee took note of a document containing a glossary of definitions used in various Codex Codes of Practice (LIM/1/1977) compiled by the delegation of Australia. The Committee noted that the glossary demonstrated that there was considerable duplication of definitions at the international level with regard to food and food hygiene.

63. The Committee expressed its appreciation of the contribution of the delegation of Australia. This delegation undertook to prepare in collaboration with the various subsidiary bodies concerned and in consultation with the WHO Terminology Unit and FAO a glossary of definitions. It was agreed to request the Executive Committee to examine means whereby harmonization of Codex, FAO and WHO definitions could be achieved.

CONSIDERATION OF THE REVISED CODE OF PRACTICE FOR SMOKED FISH

64. The Committee considered the hygiene provisions contained in the above-mentioned Code (CX/FFP 77/6), which had been revised to bring it into line with the Recommended International Code of Practice for Fresh Fish. The delegation of the USA acted as rapporteur. In the discussion the comments received from governments and WHO were taken into account. Several minor changes to the text were made and a number of provisions from the revised General Principles of Food Hygiene were incorporated. Items considered in detail are reported hereunder.

Hygienic Procedures to Prevent Production of Toxin by Clostridium botulinum (4.3.2)

65. A proposal was made to differentiate between the time/temperature processing requirements for fish with a water phase salt concentration of 3.5 - 5% and 5% and above in order to restrict possible toxin formation during hot smoking. It was pointed out that some other factors also played a role in the control of the development of C. botulinum and the Committee agreed to retain the present wording in subsection 4.4.7 but to amend subsection 4.3.2 to contain the above provision.

66. The Committee was of the opinion that if cold smoked fish were to be stored for an extended period they should be dry-salted to an aqueous water phase of 8%.

67. It was further suggested that the maximum temperature of storage of the slightly salted product be raised from 39C. to 40°C. However, no change was made.
Packaging, Storage and Distribution (4.4.5)

68. The Committee agreed to request the Committee on Fish and Fishery Products whether in view of the hygienic implications it could consider the reinstatement of a provision for date marking. The Committee was of the opinion that there should also be storage instructions on the label. It was noted that the Committee on Food Labelling had completed guidelines on date marking.

CONSIDERATION OF PROPOSED DRAFT CODE OF PRACTICE FOR SHRIMPS OR PRAWNS

69. The Committee examined the above mentioned Code (CX/FFP 77/7) on the basis of observations received from WHO; some minor amendments were made in the hygiene provisions of the Code.

70. The Committee further considered the findings of the Second Joint FAO/WHO Expert Consultation (EC/Microbiol/77/Report 2, pages 3-5 plus Annex III) with regard to microbiological criteria for frozen cooked peeled shrimps and prawns. It was noted that various types of microorganisms had been considered. The Committee concurred with the conclusions of the Expert Consultation that for the time being the inclusion of V. parahaemolyticus was not yet feasible, but that tests for Staphylococcus aureus, Salmonella and Mesophilic aerobic bacteria would be useful. The Committee agreed to include the microbiological specifications as elaborated by the Joint Consultation as an Annex to the Code. A slight amendment was made to the title to make it clear that only fully cooked, ready to eat, peeled shrimps and prawns which were frozen were covered.

71. The delegation of Canada expressed concern over the omission of faecal coliforms and E. coli from the list of microorganisms to be tested. It held the view that the omission of E. coli as an indicator organism was leaving the consumer open to risk.

72. The delegations of New Zealand and USA considered that the limit for Staphylococcus aureus proposed by the Second Consultation was not sufficiently stringent and suggested that the limit should be 100 per gramme rather than 500. It was decided for the present not to make any change in the recommendations of the Consultation. At a future date the criteria could be reviewed.

Status of the Codes for Smoked Fish and for Shrimps or Prawns

73. The Committee agreed that as far as the hygiene provisions of the Codes were concerned the documents could be advanced to Step 5. Should the Committee on Fish and Fishery Products recommend omitting Steps 6 and 7 of the Procedure this could also be agreed to.

RECONSIDERATION OF THE PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR THE PROCESSING OF FROG LEGS AT STEP 5

74. The Committee reconsidered the above mentioned Proposed Draft Code as contained in ALINORM 78/13, Appendix II, and a proposal for a revised text prepared by the delegation of the United States. It was noted that the Code was at Step 5; however, as a result of the information presented to the Second Joint FAO/WHO Expert Consultation on Microbiological Specifications for Foods and data received subsequently a revision of certain sections had appeared desirable.

75. The Committee discussed the principle of the proposed amendments and ultimately requested a small Ad Hoc Working Group to review these and present to the Committee a revision of the Code. The Ad Hoc Working Group was requested to consider in particular requirements for environmental hygiene in frog-producing areas (subsections 3.1.1 - 3) cleansing procedures and the introduction of specific temperature requirements into the Code.

76. The Ad Hoc Working Group was further requested to consider the deliberations and conclusions of the above mentioned Expert Consultation with regard to the Code. One delegation pointed out that there was no evidence of disease transmission by frog-legs to consumer countries of diseases endemic in producer countries. The Working Group reported that it had made extensive revision of the Code.

Status of the Code

77. The Committee thanked the Working Group for its efforts and agreed to return the Code to Step 3 of the Procedure for a further round of government comments. The revised Code is contained in Appendix IV to this Report.
MICROBIOLOGICAL SPECIFICATIONS FOR EGG PRODUCTS

78. The Committee had before it the microbiological end product specifications for Egg Products (ALINORM 78/13, Appendix VI) recommended by the First Joint Consultation on Microbiological Specifications for Foods (EC/Microbio1/75/Report 1).

79. At its previous session the Committee had recommended that these specifications be advanced to Step 5 of the Procedure with a request to the Commission that Steps 6 and 7 be omitted, and that reference should be made to methods developed by the ISO Subcommittee concerned with similar microbiological specifications (ISO/TC/34/SC/9).

80. The Committee noted that ISO/TC/34/SC/9 was unlikely to complete its work on methods of Salmonella detection before the next meeting of the Commission. Nonetheless, reference to the methods should be included in the Code at a later date.

81. The delegation of the United Kingdom stated that since the criteria for the establishment of microbiological specifications for foods which had now been approved by the Committee defined such specifications as advisory only, it wished to withdraw the reservations on the necessity for microbiological specifications for egg products which it had expressed at the Thirteenth Session of this Committee (ALINORM 78/13, paragraph 66).

FUTURE WORK

Need for Continued Expert Advice on Food Microbiology

82. The Committee noted that in recent years there had been increasing concern at both national and international levels with regard to the microbiological health hazards connected with foods. In addition, recommendations 78 and 82 of the United Nations Conference on the Human Environment held in Stockholm in 1972 had added impetus to the international activities relating to the microbiological contamination of foods. These recommendations had resulted in UNEP establishing a project to strengthen and expand the work of the FAO/WHO Codex Alimentarius Commission on international standards for pollutants in foods and the strengthening of FAO/WHO capabilities to assist developing countries in food control.

83. The Committee further noted that FAO, WHO and UNEP had all stressed the need for the establishment of international microbiological specifications for foods. Such specifications could only be established, however, after the significance of particular microorganisms in specific foods was fully understood and suitable microbiological methods and sampling plans had been agreed upon.

84. The Committee acknowledged the support of UNEP which had enabled the Joint FAO/WHO Expert Consultation on Microbiological Specifications for Foods to hold two meetings in 1975 and 1977 respectively. These two meetings of the Consultation had assessed the work already done by various bodies in the field of food microbiology and had made a number of recommendations to the Codex Committee on Food Hygiene in regard to microbiological specifications for a number of foods.

85. In order to define clearly the role of the Codex Committee on Food Hygiene with regard to microbiological matters, the 11th Session of the Commission in 1976 had extended the terms of reference of the Committee to make it clear that it was responsible for the endorsement of microbiological proposals of Codex Commodity Committees and, where necessary, the elaboration of microbiological criteria.

86. To date, the Committee had relied upon the Consultation for expert advice on microbiological matters. The acceptance of the recommendations of the Consultation indicated the effectiveness of its work. The Committee was therefore most disappointed to learn that funds might not be available for further meetings of the Consultation especially because of its extensive role relating to microbiological criteria in all Codex Standards and Codes of Practice. In this regard, the following points were regarded to be significant:

(i) The Second Consultation had already published a list of 13 foods which required attention as a matter of priority and six foods had been singled out for immediate attention.
(ii) The establishment of microbiological criteria for foods would undoubtedly assist in providing an important international reference point and serve to minimize disputes regarding microbiological aspects of foods. Moreover, this work could be regarded as being of universal importance in that it had relevance to both developing and developed countries.

(iii) FAO, WHO and UNEP had instituted programmes to assist developing countries with food control. A major aspect of this work related to microbiological contamination. The preparation of Codex Codes of Practice which included microbiological specifications would provide a sound basis for these programmes.

87. In view of the continuing need of the Committee for expert advice on microbiological matters, the Committee was unanimously of the view that the Commission, through its Executive Committee, should strive for the establishment of an FAO/WHO Expert Committee on Food Microbiology. Such an Expert Committee would take its place in the organization of the Joint FAO/WHO Food Standards Programme alongside the FAO/WHO Expert Committee on Food Additives (JECFA) and the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and would meet, when necessary, to consider particular subjects on which the Codex Committee on Food Hygiene required expert advice as a matter of priority.

88. The Committee received a report from Dr. de Man, Chairman of an ad hoc Working Group which had been established by the Committee to prepare proposals for future activities in food microbiology. The report of the ad hoc Working Group is contained in Appendix X to this Report.

89. As an interim solution the Committee decided to establish an Expert Group to function in the near future as its advisory scientific body. The Chairman would approach member countries for nomination to the Expert Group. The selection of members of the Expert Group would depend on the subject under study and the expertise required.

90. The Committee also noted that as UNEP had recognized the importance of the work of the Consultation in the context of achieving an improved environment, it was believed that it would support in principle the establishment of a Joint FAO/WHO Expert Committee on Food Microbiology.

Vending Machines
91. The delegation of Belgium drew the attention of the Committee to the need for a guide on the hygienic aspects related to the construction and operation of vending machines.
92. It was noted that the Code for Low-acid Canned Foods covered a limited number of food products sold through machines vending hot food.
93. The Committee agreed that vending machines could indeed pose a hazard to health. The delegation of Belgium undertook to prepare a paper on the subject for the next session of the Committee.

ECE Agreement on Special Equipment for the Transport of Perishable Foodstuff
94. The delegations of Norway and Sweden drew the attention of the Committee to the fact that the Economic Commission for Europe had prepared an "Agreement on Special Equipment for the Transport of Perishable Foodstuff" (ATF). Six countries had signed the agreement and a number of countries considered doing so. The agreement included a number of hygiene requirements including a variety of temperature requirements for various food items.
95. The delegations expressed the view that the agreement could considerably influence international trade in food. They were also of the opinion that as the ECE also belonged to the UN family and as furthermore Joint ECE/Codex Committees already existed it was desirable that hygiene provisions in ECE documents should be considered by this Committee.

The Committee agreed that the matter be brought to the attention of the Executive Committee.

ECE Standards for Egg Products
97. The Committee was informed that the Economic Commission for Europe had established a Group of Experts on Standardization of Egg Products which had held its first meeting in April 1977 to consider a standard for hen egg products. The Group of Experts had noted that this Committee had already elaborated a Code of Hygienic Practice for Egg Products and had expressed itself in favour of harmonization of efforts.
98. The Committee expressed its willingness to work jointly with the ECE Group of Experts. The delegation of the United Kingdom, author country of the Code of Hygienic Practice, agreed to represent the Committee in harmonizing the ECE Standard with the Codex Code of Practice.

Discussion of the Recommendations of the Joint FAO/WHO Expert Consultation on Microbiological Specifications for Foods

99. The Committee reviewed the general and specific recommendations of the Joint FAO/WHO Expert Consultation (EC/Microbio/77/Report 2, pages 13-20). It noted that action had already been taken on a number of recommendations.

100. Several delegations were of the opinion that the Committee should include in its future work consideration of specifications for dried foods which included a number of commodities which had caused concern for safety.

101. The Committee was informed that a background paper on vegetable protein was in preparation for the next session of the Commission. The paper would cover the types of vegetable protein at present on the market and might well help the Committee to assess the importance of developing microbiological specifications for dried foods in general. Among the examples given by the Joint FAO/WHO Expert Consultation were enzymes, gelatine, yeast, caseinate, soy bean protein and fish protein. The Committee decided to consider the matter of possible specifications at its next session in the light of any action taken by the Commission.

102. The Committee endorsed the following specific recommendations of the Consultation:

(1) That the ICMSF and other interested bodies be invited to institute a comparative and collaborative study of methods for the enumeration of *Vibrio parahaemolyticus* of enteropathogenic significance.

(2) That the Codex Committee on Food Hygiene consider the development of a Code of Practice for Ice Mixes and Edible Ices.

(3) That the Codex Committee on Food Hygiene gather information on the methods presently used by member countries and international organizations for the detection and/or enumeration of *Staphylococcus aureus* in ice mixes and edible ices.

(4) That the Codex Committee on Food Hygiene gather data from member countries on Salmonella contamination of the surface of froglegs utilizing the routine methodology developed by the Consultation (Annex VI) and that FAO/WHO assist the Codex Committee on Food Hygiene to compile and evaluate such data.

(5) That the secretariat of the Codex Committee on Processed Meat Products confine the proposed Sampling and Inspection Procedure for Microbiological Examination of Processed Meat Products to investigational purposes. In this case, the procedure should not necessarily be restricted to visual inspection of cans, but could also involve microbiological examination. Furthermore, the Consultation recommended that any development of sampling plans to be inserted in the Code of Hygienic Practice for Low-acid Canned Foods be considered by the above mentioned secretariat.

(6) That the Codex Committee on Food Hygiene develop a Code of Practice for the manufacture of dried foods and dried ingredients.

(7) That the Codex Committee on Food Hygiene limit the development of microbiological criteria for food additives to those known to be a health hazard and receiving no final treatment to control the hazard.

(8) That the Codex Committee on Food Hygiene consider the hygienic aspects of bottled waters, including the cleaning and filling of bottles. It should take into account the work of the Regional Codex Committee for Europe on mineral waters.

(9) That the Joint FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products continue to elaborate microbiological criteria for non-Fat dried milk, as proposed by the First Consultation on Microbiological Specifications for Foods, 1975.
(10) That the Joint FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products undertake to consider the elaboration of microbiological criteria for whey powder and cheese.

Acidified Low-acid Canned Foods and Products Packed in Flexible Pouches

103. During the discussions on the Code of Hygienic Practice for Low-acid Canned Foods it had been noted that the Code did not apply to certain related products.

104. Some delegations were of the opinion that hygienic requirements for acidified low-acid canned foods and products packed in flexible pouches should be elaborated. The Committee shared this point of view and agreed that the ad hoc Working Group which had revised the Code for Low-acid Canned Foods (see paras 40 and 41) be reconvened well before the 15th Session of the Committee to elaborate proposed draft codes for thermally processed low-acid foods packed in semi-rigid containers and flexible pouches and for acidified low-acid canned foods. The meeting of the ad hoc Working Group should be scheduled to allow for the elaboration of these codes and their timely distribution to member countries prior to the 15th Session. Proposals from member countries on provisions for consideration by the ad hoc Working Group in the elaboration of these codes should be submitted at an early date.

105. The Committee agreed that a representative of Norway should participate in the ad hoc Working Group which at present consisted of representatives of Canada, the Netherlands, United Kingdom and United States.

MICROBIOLOGICAL GUIDELINES FOR EDIBLE ICES

106. The Committee noted that the Joint FAO/WHO Expert Consultation on Microbiological Specifications for Foods had been asked by the Codex Committee on Edible Ices (ALINORM 78/11, paras 41-49) to comment on a draft proposal for microbiological standards for edible ices and ice mixes as contained in ALINORM 78/11, Appendix II, Annex A. The Consultation had accepted that there was a need for the establishment of microbiological criteria aimed at minimizing public health risks and promoting fair trading of edible ices and ice mixes. However, it did not endorse the microbiological standards drafted by the Codex Committee on Edible Ices. In particular, the Consultation had thought that a limit for E. coli would serve no useful purpose. In addition, it had not recommended a limit for Staphylococcus aureus as present methods might not give reliable results. The Expert Consultation further expressed the opinion that stricter microbiological guidelines were necessary in ice mixes than in those for the finished products.

107. The Committee noted that the Codex Committee on Edible Ices had adjourned sine die and had left consideration of microbiological specifications to the discretion of this Committee. The delegations of Sweden and the USA stated that they were not in full agreement with the microbiological specifications recommended by the Consultation. The Committee agreed that the Guidelines recommended by the Consultation should stand until such time as a future Consultation considered the matter further. Dissenting countries should submit their counter-proposals for consideration by that Consultation. It was further pointed out that unpasteurized yoghurt was sometimes a component of edible ices and that in such cases the microbiological guidelines could not apply.

108. The Recommendation of the Consultation is attached as Appendix IX to this Report.

DATE AND PLACE OF NEXT MEETING

109. The Committee noted that the 15th Session of the Committee would take place in Washington in the second half of 1978, at a date to be agreed between the US Government and the Codex Alimentarius Secretariat.

NOTE: Summary Status of Work is on pages 114 and 115.
LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

Chairman
Dr. Joseph C. Olson
Director, Division of Microbiology
Bureau of Foods
Food and Drug Administration
Department of Health, Education and Welfare
200 C Street, S.W.
Washington, D.C. 20204, USA

Assistant to the Chairman
Dr. Joseph W. Lepak
Assistant to the Director
Division of Microbiology
Bureau of Foods
Food and Drug Administration
Department of Health, Education and Welfare
200 C Street, S.W.
Washington, D.C. 20204, USA

AUSTRALIA
AUSTRALIE
L.J. Erwin
Principal Executive Officer
Department of Primary Industry
Canberra ACT, Australia

Dr. J.H.B. Christian
Associate Chief
Division of Food Research
Commonwealth Scientific and
Industrial Research Organization
Canberra, Australia

David J. Matthews
Attaché (Veterinary)
Embassy of Australia
1601 Massachusetts Avenue, N.W.
Washington, D.C. 20036, USA

BELGIUM
BELGIQUE
BELGICA
R.J.L. van Havere
Food Inspector
Ministry of Public and Family Health
Cité administrative de l'Etat
Quartier Vésale 4
B-1010 Bruxelles, Belgium

BRAZIL
BRESIL
BRASIL
Dr. C.R. Tavares De Almeida
Veterinary Inspector
Assistant Director
Meat Inspection Division
Ministry of Agriculture
SCS-ED. ARISTON 3 AND
70.000 Brasilia, DF, Brazil

CANADA
I.E. Erdman
Chief, Evaluation Division
Bureau of Microbial Hazards
Health Protection Branch
Health and Welfare Canada
Tunney’s Pasture
Ottawa, Ontario, K1A 0L2, Canada

Dr. Bruce E. Brown
Scientific Evaluator
Bureau of Microbial Hazards
Health Protection Branch
Health and Welfare Canada
Tunney’s Pasture
Ottawa, Ontario, K1A 0L2, Canada

R. Burke
Bureau of Field Operations
Field Operations Directorate
Health Protection Branch
Health and Welfare Canada
255 Argyle Street
Ottawa, Ontario, K1A 1B7, Canada

N. Neufeld
Inspection and Technology Branch
Fishing Services Directorate
Fisheries and Environment Canada
580 Booth Street
Ottawa, Ontario, K1A 0H3, Canada

Dr. Guy Meilleur
Associate Director,
Audit and Enforcement
Meat Inspection Division
Ministry of Agriculture
2323 Riverside Drive
Ottawa, Ontario, K1A 0Y9, Canada
APPENDIX I

CANADA (contd.)
C.P. Erridge
Assistant, Process Products Section
Fruit and Vegetable Division
Ministry of Agriculture
Sir John Carling Building
Ottawa, Ontario K1A 0C5, Canada

DENMARK
DANEMARK
DINAMARCA

Kaj Haaning
Veterinary Inspector
Institute of Microbiology and Hygiene
Bülowsvej 13
DK 1870 Copenhagen V, Denmark

Viggo Enggaard
Civileingeniør M.Sc.
The Danish Meat Products Laboratory
Howitzvej 13
DK 1870 Copenhagen F, Denmark

FINLAND
FINLANDE
FINLANDIA

Toivo J. Salmi
Head of the Division of Food Hygiene
Veterinary Department
Ministry of Agriculture and Forestry
Hallituskatu 3
00170 Helsinki 17, Finland

Erkki Petäjä
Director of Customs
Board of Customs
Box 812
00101 Helsinki 10, Finland

FRANCE
FRANCIA

Jean Rigoulet
Chef de Bureau
Veterinary Nutrition Services
5 rue Ernest Renan
92130 Issy-les-Moulineaux, France

Ms. France Soudan
Chief, Technology and Control Service
Scientific and Technical Institute of Fisheries
Route de la Jonelière
B.P. I 049, 44 037 Nantes Cedex, France

GERMANY, Fed. Rep. of (contd.)
Dr. H. Meyer
Director
Nestlé Haus
Lyoner Str. 23
D-6000 Frankfurt/M.
Niederrad
Federal Republic of Germany

Friedrich Frede
Stellvertretender Geschäftsführer des
Bundesverbandes der Diätetischen
Lebensmittelindustrie e.V.
Kelkheimerstrasse 10
D-6380 Bad Homburg v.d.H.
Federal Republic of Germany

HUNGARY
HÖRNGIE
HUNGRIA

Ferenc járma
First Secretary (Scientific)
Embassy of the Hungarian People's Republic
3910 Shoemaker Street, N.W.
Washington, D.C. 20008, USA

IRELAND
IRLANDE
IRLANDA

Dr. Thomas M. O'Toole
Food Scientist
Department of Agriculture and Fisheries
Kildare Street
Dublin 2, Republic of Ireland

JAPAN
JAPON

Katsusaburo Watanabe
Deputy Director
Environmental Health Bureau
Ministry of Health and Welfare
1-2-2, Kasumigaseki
Chiyoda-ku
Tokyo, Japan

Hiroshi Sawamura
First Secretary
Embassy of Japan
2520 Massachusetts Avenue, N.W.
Washington, D.C. 20008, USA

T. Nakamura
Secretary
Japan Baby Food Processors Association
c/o O.P. Corporation
2-5 Sengawa, Chofu-shi
Tokyo, Japan

Eiji Sato
Technical Adviser
Union of the Food Additives Association
in Japan
AJINOMOTO U.S.A. Inc.
10401 Grosvenor Place, Room 306
Rockville, Maryland 20852, USA
JORDAN
JORDANIE
JORDANIA
Musa Dahdal
Food Chemist and Microbiologist
Ministry of Finance/Customs
Customs Laboratory
Aqaba, Jordan
KENYA
Julius Muturi Ngangá
Assistant Director
Veterinary Department
Ministry of Agriculture
Veterinary Laboratories
P.O. Kabete, Kenya
KOREA, Rep. of
CORÉE, Rép. du
COREA, Rep. de
Joong Il Suh
Agricultural Attaché
Embassy of Korea
2320 Massachusetts Avenue, N.W.
Washington, D.C. 20008, USA
Han Mo Kim
Fisheries Attaché
Embassy of Korea
2370 Massachusetts Avenue, N.W.
Washington, D.C. 20008, USA
MALAYSIA
MALAISIE
MALASIA
Dr. Wan Mahmud
Assistant Director of Health
Food Quality Control Unit
Ministry of Health
Young Road
Kuala Lumpur, Malaysia
NETHERLANDS
PAYS-BAS
PAISES BAJOS
Dr. K. Blichli
Public Health Officer
Ministry of Public Health and Environmental Hygiene
Dr. Reyerstraat 10
Leidschendam, Netherlands
Dr. M. van Schothorst
Head, Laboratory for Zoonoses and Food Microbiology
National Institute of Public Health
P.O. Box 1
Bilthoven, Netherlands
Dr. W. Rozenboom
Administrator
Ministry of Agriculture and Fisheries
Bezuidenhoutseweg 73
The Hague, Netherlands

NETHERLANDS (contd.)
Dr. Peter J. Anema
Section Manager, Microbiology
Unilever Research Laboratory
P.O. Box 7
Zevenaar, Netherlands
NEW ZEALAND
NOUVELLE-ZELANDE
NUEVA ZELANDIA
Rowin S. Buist
Second Secretary (Commercial)
Embassy of New Zealand
19 Observatory Circle, N.W.
Washington, D.C. 20008, USA
Dr. Neil Walker
Technical Manager
New Zealand Dairy Board in North America
P.O. Box 417
Wellington, New Zealand
NORWAY
NORVEGE
NORUEGA
Prof. Anton Skulberg
Dr. Med. Vet.
The Norwegian Food Research Institute
P.O. Box 50
1432 ÅS-NLH, Oslo, Norway
Dr. Sigmund Aasen
Director, Division of Hygiene and Epidemiology
Directorate of Health
P.O. Box 9028
Dep., Oslo 1, Norway
Atle Ørbeck Sørheim
Superintending Veterinary Officer
Veterinary Division
Ministry of Agriculture
P.O. Box 8007
Dep., Oslo 1, Norway
Olav Chr. Sundsvold
Director, Norwegian Quality Control Institute for Canned Fish Products
P.O. Box 329
4001 Stavanger, Norway
Jørg Hviding
Head of Division, Norwegian Quality Control Institute for Canned Fish Products
P.O. Box 329
4001 Stavanger, Norway
Karl H. Skramstad
Head of Division, Norwegian Quality Control Institute for Canned Fish Products
P.O. Box 329
4001 Stavanger, Norway
Jan Gjerde
Chief Engineer, Directorate of Fisheries-Central Laboratory
P.O. Box 185-186
5001 Bergen, Norway

APPENDIX I
APPENDIX I

NORWAY (contd.)
Petter Haram
Counsellor, Department of Fisheries
P.O. Box 8118
Dep. Oslo 1, Norway

Dr. Marit Kromberg
Medical Adviser, Directorate of Health
P.O. Box 8128
Dep. Oslo 1, Norway

Alf Jensen
Chief Engineer
Nordisk Aluminium A/S
P.O. Box 68
3081 Holmestrand, Norway

PANAMA
Ing. Maricela F. de Chan
Executive Director
Panamanian Commission of Industry and
Technology (Standards)
Apartado 9658
Panama 4, Panama

SENEGAL
Idy Adama Diaw
Assistant Director
Direction du Contrôle Economique
Ministère des Finances et des Affaires
BP 2050
Dakar, Senegal

SWEDEN
SUEDE
SUECIA
Sven Österling
Head of Food Handling Division
The National Food Administration
Box 622
S-751 26 Uppsala, Sweden

Sigurd Sefastsson
Head of Food Production Division
The National Food Administration
Box 622
S-751 26 Uppsala, Sweden

SWITZERLAND
SUISSE
SUIZA
Dr. H. Schwab
Head of the Section of Bacteriology
Swiss Federal Office of Public Health
Haslerstrasse 16
CH-3008 Berne, Switzerland

Dr. J.C. de Man
Nestec
Case Postale 88
CH-1814 La Tour-de-Peilz, Switzerland

THAILAND
THAILANDE
TAILANDIA
Theera Satasuk
Chief, Food Control Division
Ministry of Health
Bangkok 2, Thailand

UNITED KINGDOM
ROYAUME-UNI
REINO UNIDO
Dr. R.H.G. Charles
Senior Medical Officer
Department of Health and Social Security
Alexander Fleming House
Elephant and Castle
London, SE1 6BY, UK

D.S. Fanning
Principal, Department of Health and
Social Security
Alexander Fleming House
Elephant and Castle
London, SE1 6BY, UK

Dr. A.C. Baird-Parker
Scientific Adviser
Food Manufacturers Federation
1-2 Castle Lane, Buckingham Gate
London, SW1, UK

M.A. Hunt
Head of Science Department
Food Manufacturers Federation
1-2 Castle Lane, Buckingham Gate
London, SW1, UK

UNITED STATES OF AMERICA
ETATS-UNIS D'AMERIQUE
ESTADOS UNIDOS DE AMERICA
William V. Eisenberg
Assistant Director
Division of Microbiology
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204, USA

Gerald R. Bee
Director, Microbiology and Processing
Division
Washington Research Laboratory
National Canners Association
1133 20th Street, N.W.
Washington, D.C. 20036, USA

James Brooker
National Marine Fisheries Service
Department of Commerce
3300 Whitehaven Street, N.W.
Washington, D.C. 20007, USA

Cleve B. Denny
Director, Research Services
National Canners Association
1133 20th Street, N.W.
Washington, D.C. 20036, USA

E. Spencer Garrett
Director, National Seafood Quality &
Inspection Laboratory
National Marine Fisheries Service
P.O. Drawer 1207
Pascagoula, Mississippi 39533, USA

Daniel A. Hunt
Assistant Chief, Shellfish Sanitation Branch
Division of Food Technology
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204, USA
UNITED STATES OF AMERICA (contd.)

Nino F. Insalata
Senior Laboratory Manager
General Foods Corporation
Technical Center
250 North Street
White Plains
New York 10625, USA

Dr. Thomas R. Mulvaney
Chief, Processing Section
Division of Food Technology
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204, USA

Dr. Robert W. Weik
Acting Assistant Director for International Standards
Bureau of Foods
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204, USA

OBSERVER COUNTRY
PAYS OBSERVEUR
PAIS OBSERVADOR

SOUTH AFRICA
AFRIQUE DU SUD
SUDAFRICA

Arnold Mentz
Second Secretary (Economics)
Embassy of South Africa
3051 Massachusetts Avenue, N.W.
Washington, D.C. 20008, USA

INTERNATIONAL ORGANIZATIONS
ORGANISATIONS INTERNATIONALES
ORGANIZACIONES INTERNACIONALES
EUROPEAN ECONOMIC COMMUNITIES (EEC)

M.B. Hogben
Chief Administrator
Coordinator of Legal, Regulatory and Administrative Provisions in the Veterinary and Zootechnical Fields
Commission EEC
General Directorate Agriculture
200 Rue de la Loi
Bruxelles, Belgium

M.E. Gaerner
Chief Administrator
Commission EEC
General Directorate of Domestic Markets and Industrial Affairs
200 Rue de la Loi
Bruxelles, Belgium

Jan Ten Have
Chief Administrator
Counsel EEC
170 Rue de la Loi
Bruxelles, Belgium

APPENDIX I

INTERNATIONAL ORGANIZATION OF CONSUMERS UNIONS (IOCU)

Dr. John J. Lipari
IOCU
Consumers Union of U.S., CNC
256 Washington Street
Mount Vernon, New York 10550, USA

INTERNATIONAL SECRETARIAT FOR THE INDUSTRIES OF DIETETIC FOOD PRODUCTS (ISDI)

Friedrich Frede
Assessor
ISDI
Kelkheimer Strasse 10
6380 Bad Homburg,
Federal Republic of Germany

FAO PERSONNEL
PERSONNEL DE LA FAO
PERSONAL DE LA OMS

J.M. Hutchinson
Food Standards Officer
Joint FAO/WHO Food Standards Programme
FAO, Via delle Terme di Caracalla
00100 Rome, Italy

Willem L. de Haas
Food Standards Officer
Joint FAO/WHO Food Standards Programme
FAO, Via delle Terme di Caracalla
00100 Rome, Italy

L.G. Limpus
Fishery Industry Officer (Processing Standards)
Fishery Industries Division
FAO, Via delle Terme di Caracalla
00100 Rome, Italy

WHO PERSONNEL
PERSONNEL DE LA OMS
PERSONAL DE LA OMS

Dr. L.R.R. Reinius
Food Hygienist
Veterinary Public Health Division of Communicable Diseases
WHO
1211 Geneva 27, Switzerland
This Code of Hygienic Practice applies to peanuts, also known as ground nuts (Arachis hypogaea). It contains the minimum requirements of hygiene for farm handling, transportation, storage, in-shell operations and commercial shelling. It covers all types and forms of raw, dried peanuts in-shell and shelled.

SECTION II - DEFINITIONS

"Blows", (pops) means in-shell nuts which are unusually light-weight due to extensive damage from physiological, mould, insect, or other causes and which can be removed mechanically, for example, by an air-separation process.

"Curing" means drying of in-shell peanuts to a safe moisture level whether by natural or mechanical means, or a combination of both.

"Farmer's stock peanuts" means in-shell peanuts as they come from the field, after separation from the vines by hand and/or mechanical means.

"Safe moisture level" means a moisture level of in-shell and shelled peanuts that will prevent growth of microorganisms normal to the nut harvesting, processing and storage environment. The maximum safe moisture level for peanuts is established by its water activity (aw). Water activity is defined as the quotient of the water vapour pressure of the substance (peanut - in-shell or shelled) divided by the vapour pressure of pure water at the same temperature. An aw exceeding 0.70 at 25°C (77°F) is unsafe.

SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREAS

A. Environmental Hygiene in Areas from which Raw Materials are derived

(1) Hygienic disposal of human, animal and plant wastes. Adequate precautions should be taken to ensure that human and animal wastes are disposed of in such a manner as not to constitute a public health or hygiene hazard, and extreme care should be taken to protect the products from contamination with these wastes. Vine and peanut waste should not be permitted to accumulate in such a manner as to promote mould growth or to attract rodents or insects.

(2) and (3) - As in the General Principles of Food Hygiene.

B. Hygienic Harvesting and Production

(1) Curing. After being dug pods should be exposed for maximum rate of drying. This may be accomplished by turning the vines to leave the pods uppermost where they are away from the ground and exposed to sun and wind. Curing, whether by natural or mechanical means or a combination of both, should be completed as rapidly as possible to a safe moisture level, so as to prevent growth of microorganisms, particularly moulds that produce aflatoxins. When using mechanical drying, excessive heat should be avoided since this impairs the general quality of the nuts, e.g. splitting of kernels after shelling. Close checks of moisture content or water activity of lots of farmers' stock peanuts should be maintained.

(2) Equipment and product containers. As in the General Principles of Food Hygiene.

(3) Sanitary techniques. Harvesting and production operations, methods and procedures should be clean and sanitary. Drying equipment should be so constructed as to be easily cleaned and maintained and should contain no pockets in which debris may become lodged.
APPENDIX II

(4) **Removal of obviously unfit materials.** Damaged or imperfect peanuts and lots that contain any obvious contamination with human or animal wastes, insect infestation, decomposition, broken shells, embedded dirt, blows, 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 peanuts should be disposed of in such a place and in such a manner as to avoid contamination of sound nuts, water supplies, or other crops.

(5) **Protection of peanuts from contamination.** Suitable precautions should be taken to protect the nuts from contamination by domestic animals, rodents, birds, insects, mites and other arthropods, or other biological agents, or with chemical or other objectionable substances during handling and storage. The nuts should be moved to suitable storage, or to the processing area for immediate processing, as soon as possible after harvesting or drying. Where nuts are likely to become infested with insects, mites (and other arthropods) during or after harvesting, suitable treatment such as fumigation or application of a pesticide spray should be carried out as a preventive measure. Nuts held for processing should be stored in covered containers, buildings, or under covering. Fumigation or spray methods and chemicals used should be approved by the official agency having jurisdiction. High humidities which are conducive to proliferation of mould and elaboration of mycotoxins should be avoided in storage areas in order to maintain peanuts at a safe moisture level. Recommended storage conditions are specified in Section IV D.(1)(b).

C. **Transportation**

(1) **Facilities.** Conveyances for transporting the harvested crop from the place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit thorough cleaning and should be so cleaned and maintained as not to constitute a source of contamination to the product. In addition, bulk transport such as ship or rail car should be well ventilated with dry air to remove moisture resulting from respiration of the peanuts and to prevent moisture condensation as the vehicle moves from warm to cool regions or from day to night.

(2) **Handling procedures.** All handling procedures should be such as will prevent the product from becoming contaminated. Extreme care should be taken in transporting peanuts with an unsafe moisture level to prevent spoilage or deterioration. Special equipment - such as refrigerated transport - should be used if the nature of the product or distances involved indicate the need.

D. **Shelling Plant**

(1) **Purchasing of farmers' stock.** Most of the damage may have already been done to the peanuts during growing, harvesting, curing, handling, and storage. A buyer for a shelling plant, whether located at the plant or at an outlying commission buying point, should monitor the quality of peanut lots offered to him, and with the cooperative extension service assist suppliers in eliminating improper practices. Buyers should encourage suppliers of farmers' stock peanuts to follow good production practices as described herein.

(2) **Receiving and inspection.** Farmers' stock peanuts received at the shelling plant should be inspected on arrival. It is advisable to know the origin and history of each lot of peanuts. The transport vehicle should be examined for cleanliness, insect infestation, dampness or unusual odours. If the vehicle is not an enclosed van-type, it should have available a covering such as a tarpaulin to keep out the rain or other forms of water. The general appearance of the peanuts should be observed during the process of unloading. If the peanuts are wet to the touch, insect infested, insect damaged, or contain an unusual amount of dirt, debris or other foreign material, they should not be co-mingled with known good peanuts in a bulk warehouse. The vehicle should be set aside until a decision is made for its disposition. If possible, remove a sample from each lot, separate the "loose shelled" kernels and shell the remainder for peanut grade observation before an acceptance decision is made. Examine all "loose shelled", damaged and under-sized kernels for possible presence of mould. If no external mould is seen, split the kernels to disclose possible hidden mould growth. A magnifying lens or microscope should be used to determine whether any mould observed resembles Aspergillus flavus. Excessive mould or presence of mould resembling A. flavus warrants a chemical test for aflatoxin or rejection of the lot.
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If the peanuts are to be stored in a bulk warehouse or storage bin, the warehouse or bin should be thoroughly cleaned of all debris and extraneous material and fumigated or otherwise treated with a pesticide before use. Peanuts should not be stored in a warehouse containing any openings which may permit entrance of rodents or birds or which may have leaks in the roof or walls that can allow the rain to enter. The warehouse should be checked frequently for leaks or infestation, both before and after filling. To prevent condensation drippage, warehouses should be ventilated as, for example, by screening around tops or eaves.

(3) Unloading equipment and area. Unloading equipment such as an unloading hopper, conveyor belt, bucket elevator, and dirt removing equipment should be so designed as to prevent accumulation of debris. Only areas which can be easily inspected and cleaned should be used for processing peanuts. A programme of periodic cleaning, together with preventive pest control measures, should be carried out. Peanuts should be handled so as to avoid cracking or tearing of hulls which may permit damage to the kernels.

(4) Precleaning. The maximum possible amount of dust and dirt should be removed from the farmers' stock peanuts before they enter the shelling plant. Sand screens and aspirators will take out much of the dust and dirt and improve the overall sanitation of the shelling plant. The maximum possible amount of foreign material, loose shell, loose kernels, and blows should be removed. Foreign material not removed by the cleaner can cause mechanical problems by clogging the sheller, as well as by requiring more picking and sorting of the shelled peanuts. Removal of loose kernels and blows before shelling will improve the quality of the peanuts as well as the sheller and plant performance.

(5) Shelling and sizing. All foreign material should be removed from the shelled peanuts (using stoners, magnets, sorters, etc.). The shelled peanuts should be continuously inspected to determine whether the plant equipment is performing properly and the peanuts are free of foreign material, damage, and contamination. Any equipment adjustments indicated by the inspection should be made promptly.

Once the shelled peanuts are size graded, additional stoning should be done in order to remove small light stones, dirt balls and other foreign material which could not be removed in the farm stock sorters. Special care should be taken to avoid overloading size grading equipment.

(6) Sorting. Sorting is the final step for removing debris and defective kernels. It can be done by hand picking or photo-electric sorting machines or a combination of both. Sorting belts should be well lighted, loaded no more than one layer deep, and operated at a speed and with the number of sorters to assure removal of foreign material and defective kernels. Photo-electric sorting machines should be adjusted as often as practical against standards selected to assure removal of foreign material and defective kernels. Adjustment should be checked frequently and regularly. One contaminated kernel may contain sufficient aflatoxin to endanger as many as 10,000 co-mingled kernels. Foreign material and defective kernels (mouldy, discoloured, rancid, decayed, shrivelled, insect or otherwise damaged) should be bagged separately and tagged as unsuitable for human or animal consumption. Bags of defective peanuts should be removed as soon as practicable from the processing room.

(7) Cleaning of special areas

(a) Boots or wells of elevators accumulate peanuts and peanut material. Accumulated material should be removed and the boots (wells) cleaned and sprayed and/or fumigated regularly to prevent insect and rodent infestation. Fumigation or spray methods and chemicals used should be approved by the official agency having jurisdiction.

(b) Canvas conveyor belts will accumulate product between belt and conveyor pan. Pulleys can accumulate crushed material. Undersides of moulding on conveyors can accumulate particles of peanuts. These areas should be cleaned and sprayed and/or fumigated on a regular basis to prevent insect and rodent infestation.

(c) Storage and surge hoppers should be cleaned and sprayed between runs.

(d) Every piece of machinery whether open or enclosed should be cleaned of lodged material on a regular schedule.

(e) The area immediately surrounding the plant should be kept clean of all debris that might attract insects, rodents or birds, and subjected to an adequate pest control programme.
Dry clean-up procedures should be utilized to avoid wet spots in which microorganisms can propagate and contaminate contacted peanut kernels. Even though water may not be used directly on equipment, spray and elevated humidity from continuous use can increase moisture in organic matter trapped in crevices in equipment, such as conveyors, to the point where microorganisms can proliferate.

SECTION IV - PLANT FACILITIES AND OPERATING REQUIREMENTS

A. Plant Construction and Layout

(1) Location, size and sanitary design. As in the General Principles of Food Hygiene.

(2) Sanitary facilities and controls. (a), (b), (d), (e), (f), (g) and (h) as in the General Principles of Food Hygiene.

B. Equipment and Utensils

(1), (2) and (3) as in the General Principles of Food Hygiene.

C. Hygienic Operating Requirements

(1), (2), (3), (4), (5) and (6) as in the General Principles of Food Hygiene (with the deletion of the introductory paragraph).

D. Operating Practices and Production Requirements

(1) Raw material handling

(a) Acceptance criteria. Peanuts should not be accepted by the plant if known to contain decomposed, toxic, or extraneous substances which will not be reduced to acceptable levels by normal plant procedures, sorting or preparation. Particular care should be taken to avoid contaminating in-shell peanuts or nut meats with animal or human faecal material; nuts suspected of being contaminated should be rejected for human consumption. Special precautions must be taken to reject nuts showing signs of insect damage or mould growth because of the danger of their containing mycotoxins such as aflatoxins. Aflatoxin test results should be known before allowing lots of raw peanuts to be processed. A lot of raw peanuts with an unacceptable level of aflatoxins, which cannot be reduced to permitted levels by the available sorting equipment, should not be accepted.

(b) Storage. Raw materials stored on the plant premises should be maintained under conditions that will protect against contamination and infestation and minimize deterioration. Peanuts not scheduled for immediate use should be stored under conditions that prevent infestation and mould growth. See Section D,(6)(b). The warehouse should be of sound construction, in good repair and built and equipped so that it will provide suitable storage and adequate protection for peanuts. All breaks or openings in the walls, floors, or roof shall have been repaired. Any breaks or openings around doors, windows and eaves shall have been repaired or screened. The use of screens should be restricted to areas of the building protected from moisture entry. The building should have sufficient ventilation to prevent accumulation of moisture in areas where it can condense and wet the peanuts. Provision should be made in existing storages or at the design stage in new storages for gas tightness to permit in situ fumigation of peanuts.

Areas with new concrete floors or walls should not be used for storage until it is absolutely certain that the new concrete is well-cured and free of excess water. For the first year it is safest to use an approved plastic cover spread over the entire new concrete floor as a moisture barrier prior to use for peanuts. However, other means of protecting the peanuts against moisture from "sweating" of concrete can be used, such as stacking of containers on pallets. The plastic can be removed when the warehouse is emptied. This system will protect against moulding of the peanuts due to sweating of new concrete.

Products which affect the storage life, quality or flavour of peanuts should not be stored in the same room or compartment with peanuts. For example, such items as fertilizer, gasoline or lubricating oils should not be stored with peanuts, and some fruits or vegetables contribute objectionable odours or flavours.
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(2) Inspection and sorting. Prior to introduction into the processing line, or at a convenient point within it, raw materials should be inspected, sorted or culled as required to remove unfit materials. See Section III, D, (2) and (6).

Experience has shown that aflatoxin is most frequently associated with mouldy, discoloured, shrivelled, insect damaged or otherwise damaged peanuts. Mould contaminated peanuts may exhibit some of the following characteristics:

1. Darker skin colouring before and/or after roasting.
2. Darker flesh (after blanching) before and/or after roasting.
3. Resistance to splitting and/or blanching.

To remove effectively mould-contaminated nuts, sorting should be performed before and after blanching and roasting. Where splitting is part of the processing operation, nuts that resist splitting should be removed. The effectiveness of sorting techniques should be checked by regular aflatoxin analyses of the sorted peanut stream or of the finished product, or both. This should be done frequently enough to give assurance that the product is completely acceptable.

Rejected peanuts from the sorting procedure (pickouts) should be destroyed or segregated from edible products. If they are to be used for crushing, they should be separately bagged and tagged as unsuitable for direct human or animal consumption in their present state.

(3) and (4) as (4) and (5) in the General Principles of Food Hygiene.

(5) Preservation of product. In-shell nuts or nut meats should be dried to a moisture level low enough so that the product can be held under normal storage conditions without development of mould or significant deterioration by oxidative or enzymatic changes. Finished roasted products may be (a) treated with antioxidants at levels approved by the Codex Committee on Food Additives as referenced in the Commodity Standard; and (b) heat processed and/or packed in gas tight containers under nitrogen or vacuum, to protect quality and retard possible mould growth.

(6) Storage and transport of product. Peanuts should be stored and transported under such conditions as will maintain the integrity of the container and the product within it. Carriers should be clean, dry, weatherproof, free from infestation and sealed to prevent water, rodents or insects from reaching the peanuts. Peanuts should be loaded and unloaded in a manner that protects from damage or water. Refrigerated vehicles are recommended for transport when climatic conditions indicate such a need. Extreme care should be taken to prevent condensation when unloading peanuts from cold storage or from a refrigerated vehicle. In warm, humid weather, the peanuts should be allowed to reach ambient temperature before exposure to external conditions. This tempering may require 1-3 days. Peanuts that have been spilled are vulnerable to contamination and should not be used for edible products.

(a) All products should be stored in clean, dry buildings, protected from insects, mites and other arthropods, rodents, birds, or other vermin, chemical or microbiological contaminants, debris and dust.

(b) Optimum storage conditions:

(i) Optimum storage conditions are 0-6°C (32-42°F) with a relative humidity between 55% to 65%. A dry environment should be maintained to protect quality and prevent mould growth. No peanuts should be stored closer than 0.5 metres (1 ½ feet) from any outside wall. An active programme should be maintained to detect and control hazards from damp pallets, damp floors and walls, overhead moisture, condensation, wet unloading and loading out conditions – all conducive to moisture pick-up and mould. Growth of toxicogenic moulds may be prevented by packing nut products that have been dried to a "safe moisture level" or by storing at a temperature sufficiently low to reduce both water activity and mould viability to a point that mould growth is prevented. Exposed nut products in storage may be maintained at or dried to a "safe moisture level" by control of the relative humidity of the circulating air. Those who use refrigerated storage should be aware that the water activity of nut meats increases with increased temperature; this fact should be taken into account when changing storage temperatures.
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(ii) Where peanuts are stored under conditions in which they may become infested by insects and/or mites or other arthropods, they should be inspected regularly and if necessary fumigated by appropriate methods. Peanuts should be stored in such a manner that they can be fumigated in situ or alternatively they can be removed for fumigation in special facilities (e.g. fumigation chambers, steel barges). In the latter situation, the storage area should be separately cleaned, disinfected and disinfested. Cold storage can be used, either to prevent infestation in localities where insects are likely to be present in ordinary storage or to prevent insects already present from damaging the peanuts.

E. Sanitary Control Procedures
   As in the General Principles of Food Hygiene.

F. Laboratory Control Procedures
   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 nut products processed and of the pest control procedures. The amount and type of such control will vary with the different nut products as well as the needs of management. Such control should provide for rejection of all nuts that are unfit for human consumption and monitoring of the quality of the finished products. Analytical procedures used should follow recognized or standard methods so that the results may be readily interpreted.

SECTION V - END-PRODUCT SPECIFICATIONS

Standard methods should be used for sampling, analysis and other determinations to meet the following specifications:

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

B. When tested by appropriate methods of sampling and examination, the products:
   (a) should be free from pathogenic microorganisms; and
   (b) should not contain any substances originating from microorganisms, particularly mycotoxins, such as aflatoxins, formed by moulds, in amounts which may represent a hazard to health.

C. The products should comply with the provisions for food additives and contaminants laid down in Codex Commodity Standards and with maximum levels for pesticide residues recommended by the Codex Alimentarius Commission.
PROPOSED DRAFT CODE OF HYGIENIC PRACTICE
FOR MOLLUSCAN SHELLFISH
(Advanced to Step 5)

To be read in conjunction with the Recommended General Principles of Food Hygiene and the Guide to Shellfish Hygiene, WHO Offset Publication No. 31. Side-lined portions indicate material which is particular to this Code of Hygienic Practice and therefore does not appear in the General Principles of Food Hygiene (CAC/RCP 1-1969)

SECTION I - SCOPE

This Code applies to those bivalve molluscan shellfish such as oysters (Ostreidae), clams (Veneridae, Mactridae, Cooperellidae and Arcidae), mussels (Mytilidae), and cockles (Cardiidae), which are filter feeders, may be eaten raw or partially cooked and are normally consumed whole including the viscera. The Code is concerned with sanitary requirements for those species of shellfish intended for human consumption whether in the raw condition or destined for further processing.

SECTION II - DEFINITIONS

For the purpose of this Code:
1. Accepted means accepted by the official agency having jurisdiction.
2. Clean sea water means estuarine or marine waters which are free of pollution and toxic marine algae in amounts which will adversely affect the quality and/or safety of shellfish.
3. Conditioning (dégorgement) means placing non-contaminated shellfish harvested from acceptable areas in tanks or floats to remove sand, mud or slime and to improve product acceptability.
4. Disinfected (sanitized) means to have reduced, without adversely affecting the food, by means of hygienically satisfactory chemical agents and/or physical methods, the number of microorganisms to a level that will not lead to harmful contamination of food.
5. Growing Areas means all estuarine and marine areas used for the commercial production or the sports harvesting of shellfish either by natural growth or by aquaculture.
6. Heat Shucking means the process of subjecting shellfish in the shell to any form of heat treatment, such as steam, hot water, or dry heat for a short period of time prior to shucking, to facilitate rapid removal of meat from the shell. Such treatment should not be considered as any part of a cooking process.
7. Pollution means agricultural, domestic, industrial and naturally occurring contaminants adversely affecting sea water quality. Thermal changes in sea water quality may also be considered as pollution.
8. Process Shellfish means shellfish which have been subjected to heat treatment and/or preservation by salt, acid, smoking, pickling, jellying or canning.
9. Purification (depuration) means the process of holding live, initially polluted shellstock for a period of time under approved, controlled conditions in natural or artificial sea water, which may be treated or untreated, in tanks, floats or rafts, thereby rendering the shellfish suitable for human consumption without further treatment.
10. Relaying means the removal of shellfish from a polluted growing area to an acceptable growing or holding area under the supervision of the agency having jurisdiction.
11. Shellfish means only those bivalve molluscs such as oysters, clams, mussels and cockles which are filter feeders, may be eaten raw or partially cooked and are normally consumed whole including the viscera.
12. Shellstock means live shellfish in the shell after harvesting.
13. Shucked Shellfish means fresh or fresh frozen shellfish, which have not been subjected to any form of processing other than removal of the meat from the shell, sorting, washing, packing and/or freezing before shipment to market.
SECTION III - RAW MATERIAL REQUIREMENTS

A. Environmental Sanitation in Growing Areas

1. Sanitary disposal of human and animal wastes. In moderately sewage polluted zones shellfish may be grown and harvested for subsequent purification according to the standards of the official agency having jurisdiction. Adequate precautions should be taken to ensure that shellfish growing areas are free from pollution capable of causing pollution of the shellfish and extreme care should be taken to protect the shellfish from contamination by any wastes. A clean area surrounding the shellfish growing areas should be established and the dumping of all wastes of agricultural, domestic or industrial origin, including wastes from private residences or boats, should be prohibited. Precautions of this kind should be particularly strict when protecting from such sources of contamination, shellfish which are not intended for purification or heat processing.

2. Determination of Pollution Types and Sources. Surveys of the shoreline should be conducted to determine sources of both domestic and industrial pollution. Sources may include municipal sewage outfalls, industrial outfalls, mine wastes, geophysical contaminants, domestic animal holding pens, nuclear power plants, refineries or other sources. The need to reschedule sanitary surveys will be determined by changes in populations shifts caused by commercial development of the shoreline or other factors affecting local population stability.

3. Classification of the Growing Area. When pollution sources have been identified and evaluated, sampling stations for water, shellfish and/or bottom muds should be established and studies conducted to determine the effects of the pollutants on water and shellfish quality. The data should be evaluated by the official agency having jurisdiction and growing areas classified or designated according to official standards and criteria. When interpreting growing area data, the official agency having jurisdiction should take into account variations which may affect the level of pollution during the most unfavourable hydrographic and climatic conditions as influenced by rainfall, tides, winds, methods of sewage treatment, population variations and other local factors, since shellfish respond rapidly to an increase in the number of bacteria or viruses in their environment by accumulating these agents. The agency should also consider that shellfish have the ability to accumulate toxic chemicals in their tissue in concentrations greater than the levels found in the surrounding water. FAO, WHO, or other international or national food standards may be used as a guide to acceptable levels.

4. Growing Area Control. Designated growing areas should be routinely monitored for changes in water quality, and sub-standard areas patrolled to prevent harvesting for purposes other than that established by the official agency. Tests for suitable indicator bacteria such as faecal coliforms or Escherichia coli should be used to determine the degree of faecal contamination.

5. Areas known to be affected by blooms of toxic dinoflagellates should be monitored at appropriate seasons for the presence of marine biotoxins such as paralytic shellfish poison. The official agency having jurisdiction should close immediately and effectively patrol affected areas when acceptable levels are exceeded in edible portions of shellfish meats.

6. Reclassification of Growing Areas. When pollution conditions are modified as indicated by routine monitoring programmes or resurveys and water quality either improves or no longer meets designated water quality criteria, the official agency having jurisdiction should reclassify the area accordingly.

7. Animal, Plant, Pest and Disease Control. Where environmental control measures are undertaken, treatment with chemical, biological or physical agents should be done only in accordance with the recommendations of the appropriate official agency, by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of toxic residues being retained by the shellfish.
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B. **Hygienic Harvesting and Food Protection**

(1) **Handling techniques**

(a) Shellstock to be stored in sea water tanks, floats or rafts should be harvested from and stored in an area acceptable to the official agency having jurisdiction.

(b) Shellstock should be freed from excessive mud and weed soon after being harvested by washing it with clean sea water or approved fresh water under suitable pressure. Wash water should not be allowed to flow over shellfish already cleaned. The water should not be re-circulated.

(c) Shellstock held on boats should not come into contact with accumulated wash-down water, bilge water or shell fluid.

(d) On removal from water, shellstock should not be subjected to extremes of heat or cold, nor should it be damaged as a result of excessive abrasion. This is particularly important for those shellstock which are to be subjected to purification. Whenever possible, storage at temperatures above 10°C (50°F) or below 2°C (35°F) and direct contact with ice or other cold surfaces should be avoided.

(e) Shellstock should be protected from excessive abrasion to prevent damage.

(f) If shellstock is to be re-immersed after harvest, the sea water quality should comply with the standards of the official agency having jurisdiction.

(g) Sea water or fresh water if used for washing shellstock, equipment, decks, holds and containers should comply with standards of the official agency having jurisdiction.

(2) **Equipment and product containers**

(a) Equipment and product containers should not constitute a hazard to health. Containers which are re-used should be of such material and construction as will facilitate thorough cleaning, and should be so cleaned and maintained as not to constitute a source of contamination to the product.

(b) Dredges and other harvesting equipment, decks, holds and containers which come into contact with shellstock should be capable of being well drained and easily cleaned.

(c) Dredges and other harvesting equipment, decks, holds and containers which are contaminated from use in a polluted area should be cleaned and if applicable disinfected (sanitized) as recommended by the official agency having jurisdiction before being used for shellfish from an unpolluted area.

(d) Holds for washed shellstock should be well ventilated. Containers (i.e. baskets, barrels and boxes) made of properly treated wood, plastic or metal should be in sound condition and not constitute a source of contamination. Wood if used should be so treated as to be rendered impermeable.

(e) Holds in which shellstock is held or containers should be so constructed that the shellstock is held above the floor level and drained so that the shellstock is not in contact with wash-down or bilge water, or shell fluid.

(3) **Removal of obviously unfit materials**

(a) Shellfish which are dead, dying, permanently gaping with broken shells or tainted should not be passed for human consumption.

(b) Shellfish which do not conform to acceptable sanitary standards and shellfish which are found in areas where the water quality does not conform to these standards should be segregated and condemned as unfit for human consumption unless they can be subjected to a process which renders them fit for human consumption to the satisfaction of the official agency.

(4) **Protection of product from contamination**

(a) Suitable precautions should be taken to protect shellstock and those parts of the harvesting boat, harvesting equipment, containers and other equipment likely to come into contact with shellstock from being contaminated by polluted water, droppings from sea birds, footwear which has been in contact with faecal matter or by other polluted material.
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(b) No animals should be permitted to live on any harvesting boats or to enter any part of any establishment where shellstock is prepared, handled, packed or stored.

(c) Fuel, lubricating oils, chemicals used for the control of pests and other noxious chemicals should not be stored near shellstock or containers and equipment likely to come into contact with shellstock.

(d) Wash-down pumps should draw water only from non-contaminated sea water and should not be connected directly or indirectly to the bilge or the toilet facilities.

(e) Effective measures should be taken to protect against the entrance of rodents and other vermin into harvesting boats.

C. Transportation

(1) Conveyances. Conveyances for transporting the harvested shellstock from the growing area, place of harvest or storage should be adequate for the purpose intended and should be of such material and construction as will permit proper drainage and thorough cleaning. They should be so cleaned and maintained as not to constitute a source of contamination to the shellstock.

(2) Handling Procedures

(a) General

(i) During handling and transportation, shellstock should be held under hygienic conditions and should not come into contact with substances which may render the meats unfit for human consumption. Shell washings should be drained from the shellstock containers.

(ii) During handling and transportation, shellstock should not be subjected to extremes of heat or cold or sudden excessive variations in temperature. Special equipment, such as insulated containers and refrigeration equipment, should be used if prevailing temperatures and the time involved so require. For shipping, over extended periods of time, shellstock should be cooled to temperatures below 10°C (50°F); at no time should the temperature fall below 2°C (35°F). Shellstock should not be exposed to full sun or surfaces heated by the sun or come into direct contact with ice and other freezing surfaces, nor should it be held in closed containers with solid carbon dioxide.

(b) Shellstock for relaying, storage in water and purification

(i) At all times shellstock should be handled and transported carefully to avoid damage to the shells and under conditions which will prevent death of the shellfish. Containers should not be dropped or subjected to excessive weights where there is a danger of damage occurring to the shells in the course of normal handling. The use of shallow rigid boxes, trays or baskets will minimize damage. The handling of shellstock in large bulk containers should be avoided.

(ii) The interval between harvesting and immersion in water for relaying, storage or purification should be kept as short as possible.

(c) Shellstock for processing (excluding relaying, storage in water and purification)

The interval between final harvesting and processing should be kept as short as possible.

SECTION IV - PLANT FACILITIES AND OTHER OPERATING REQUIREMENTS

A. Plant Construction and Layout

(1) Location, size and sanitary design. The building and surrounding area should be such as can be kept reasonably free of objectionable odours, smoke, dust, or other contamination; of sufficient size for the purpose intended without crowding of equipment or personnel; of sound construction and kept in good repair, of such construction as to protect against the entrance and harbouring of insects or birds or vermin; and so
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designed as to permit easy and adequate cleaning. The plant and particularly clean storage tanks and purification tanks should be located above the level of normally expected extremes of tide and storm and against expected run-off.

(2) Hygiene facilities and controls

(a) Separation of processes. Areas where raw materials are received or stored should be so separated from areas in which final product preparation or packaging is conducted as to preclude contamination of the finished product. The shucking area should be physically separated from other processing areas. Areas and compartments used for storage, manufacture or handling of edible products should be separate and distinct from those used for inedible materials. The food handling area should be completely separated from any part of the premises used as living quarters.

(b) Water supply. Where necessary plants should have an ample supply of cold water available and an adequate supply of hot water. The water supply should be of potable quality. Standards of potability shall not be less than those contained in the latest edition of "International Standards for Drinking Water", World Health Organization.

(c) Ice. Ice should be made from water of potable quality and should be manufactured, handled, stored and used so as to protect it from contamination.

(d) Auxiliary water supply. Where non-potable water is used for such purposes as fire control - it must be carried in completely separate lines, identified preferably by colour and with no cross-connection or back-siphonage with the lines carrying potable water.

(e) Plumbing and waste disposal. All plumbing and waste disposal lines (including sewer systems) must be large enough to carry peak loads. All lines must be watertight and have adequate traps and vents and installed with grills or screens particularly for protection against rodents. Disposal of waste should be effected in such a manner as not to permit contamination of potable water supplies, clean sea water, purification tanks or approaches to the plant.

(f) Lighting and ventilation. Premises should be well lit and ventilated. Special attention should be given to the venting of areas and equipment producing excessive heat, steam, noxious fumes or vapours, or contaminating aerosols. Good ventilation is important to prevent both condensation (which may drip into the product) and mould growth in overhead structures - which growth may fall into the food. Light bulbs and fixtures suspended over food in any step of preparation should be of the safety type or otherwise protected to prevent food contamination in the case of breakage. Where practicable lighting fixtures should be set flush to the ceiling.

(g) Toilet-rooms and facilities. Adequate and convenient toilets should be provided and toilet areas should be equipped with self-closing doors. Toilet rooms should be well lit and ventilated and should not open directly into a food handling area. They should be kept in a sanitary condition at all times. There should be associated hand-washing facilities within the toilet area and notices should be posted requiring personnel to wash their hands after using the toilet.

(h) Hand-washing facilities. Adequate and convenient facilities for employees to wash and dry their hands should be provided wherever the process demands. They should be in full view of the processing floor. Single-use towels are recommended, where practicable, but otherwise the method of drying should be accepted by the official agency having jurisdiction.

(i) Establishments used only for receiving, packing, and shipping shellstock may not need all of the requirements listed in (a) through (h); however, such establishments should meet the requirements of the official agency having jurisdiction.

B. Equipment and Utensils

(1) Materials. All food contact surfaces should be smooth; free from pits, crevices and loose scale; non-toxic; unaffected by food products; capable of withstanding repeated exposure to normal cleaning; and non-absorbent.
(2) **Sanitary design, construction and installation.** Equipment and utensils should be so designed and constructed as will prevent hygienic hazards and permit easy and thorough cleaning. Stationary equipment should be installed in such a manner as will permit easy and thorough cleaning.

(3) **Equipment and utensils.** Equipment and utensils used for inedible or contaminating materials should be so identified and should not be used for handling edible products. Equipment in contact with sea water including tanks, pumps, and circulating systems should be constructed of non-corrodible and non-toxic materials.

C. **Hygienic Operating Requirements**

(1) **Sanitary maintenance of plant, facilities and premises.** The building, equipment, utensils and all other physical facilities of the plant should be kept in good repair and should be kept clean and maintained in an orderly, sanitary condition. Waste materials should be frequently removed from the working area during plant operation and adequate waste receptacles should be provided. Detergents and disinfectants employed should be appropriate to the purpose and should be so used as to present no hazard to public health.

(b) Tables, bowls, mincers, scales and other equipment used in the process of extracting and preparing the meats from shellfish should be scrub-washed or cleaned by an efficient mechanical process with hot water containing a suitable cleaning agent, rinsed with potable hot water and disinfected (sanitized) with a suitable disinfectant. Acceptable detergents and disinfectants should be employed and so used as to present no hazard to public health.

(2) **Vermin control.** Effective measures should be taken to protect against the entrance into the premises and the harbourage on the premises of insects, rodents, birds or other vermin.

(3) **Exclusion of domestic animals.** Dogs, cats and other domestic animals should be excluded from areas where food is processed or stored.

(4) **Personnel health.** Plant management should advise personnel that any person afflicted with infected wounds, sores, or any illness, notably diarrhoea, should immediately report to management. Management should take care to ensure that no person, while known to be affected with a disease capable of being transmitted through food, or known to be a carrier of such disease microorganisms, or while afflicted with infected wounds, sores, or any illness, is permitted to work in any area of a food plant in a capacity in which there is a likelihood of such person contaminating food or food-contact surfaces with pathogenic organisms.

(5) **Toxic substances.** All rodenticides, fumigants, insecticides or other toxic substances should be stored in separate locked rooms or cabinets and handled only by properly trained personnel. They should be used only by or under the direct supervision of personnel with a thorough understanding of the hazards involved, including the possibility of contamination of the product.

(6) **Personnel hygiene and food handling practices**

(a) All persons working in a food plant should maintain a high degree of personal cleanliness while on duty. Clothing, including suitable headdress, should be appropriate to the duties being performed and should be kept clean.

(b) Hands should be washed as often as necessary to conform to hygienic operating practices.

(c) Spitting, eating, chewing and the use of tobacco should be prohibited in food handling areas.

(d) All necessary precautions should be taken to prevent the contamination of the food product or ingredients with any foreign substance.

(e) Minor cuts and abrasions on the hands should be appropriately treated and covered with a suitable waterproof dressing. Adequate first-aid facilities should be provided to meet these contingencies so that there is no contamination of the food. Personnel wearing dressing on wounds should not be permitted to work in direct contact with the product or food product surfaces.
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(f) Gloves used in food handling should be maintained in a sound, clean and sanitary condition; gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

D. Operating Practices and Production Requirements

(1) Acceptance criteria. Shellstock should not be accepted if they are contaminated with microorganisms or substances not removed by normal plant procedure.

(2) Relaying and purification (depuration) of shellstock in tanks, floats, and rafts

(a) Shellstock subjected to the purification process should not contain metallic ions, pesticides, industrial wastes or marine biotoxins in such quantities that it presents a health hazard to the consumer. A low rate of removal of these substances makes depuration impracticable.

(b) The process and the equipment used for purification should be acceptable to the official agency having jurisdiction.

(c) Sea water for the tanks, or sea water where floats or rafts are used in purification should be clean and of a salinity acceptable to the official agency having jurisdiction. Where clean sea water is not available, a method of sanitizing the water which should be approved by the official agency having jurisdiction should be employed. Water used in purification tanks should be changed continuously or at suitable intervals.

(d) Shellfish should not be weak or dead when submitted to the purification process. Surfaces of shells should be free from mud and soft commensal organisms.

(e) Shellstock should be laid out at a density which will permit them to open and undergo natural purification. There should be no toxic substances in the water at levels that will prevent the shellfish from functioning properly.

(f) The oxygen content of the water should be maintained at an adequate level by aeration, or by intermittent or continuous replacement.

(g) During the process of purification, the water temperatures should not be allowed to fall below the minimum at which shellfish remain physiologically active; high water temperature which adversely affects the pumping rate and the purification process should be avoided; tanks should be protected from the direct rays of the sun when necessary.

(h) Equipment in contact with water, i.e. tanks, pumps, pipes or piping, and other equipment should be constructed of non-porous, non-toxic materials. Copper, zinc, lead and their alloys should preferably not be used in tanks, pumps or piping systems used in purification (depuration) processing.

(i) To avoid recontamination of shellstock undergoing purification, unpurified shellstock should not be placed in the same tank as shellstock which are already undergoing purification.

(j) Shellstock undergoing purification should remain immersed in approved, clean, sea water until it satisfies the sanitary requirements of the official agency having jurisdiction.

(k) On removal from the purification system, shellstock should be washed with running fresh water or sea water meeting the standards of the official agency having jurisdiction, and handled in the same manner as living shellstock taken directly from a non-polluted area. Dead, dying, permanently gaping, with broken shells or otherwise unwholesome shellfish should be removed.

(l) Tanks should be drained, cleaned and disinfected at suitable intervals as determined by the official agency having jurisdiction.

(3) Relaying

When biologically feasible (some species such as the soft shell clam (Mya arenaria) can not be relayed) shellstock may be relayed from polluted growing areas to areas approved for harvesting. Relaying operations should be strictly supervised by the official agency having jurisdiction to prevent contaminated shellstock from being diverted directly to the
consumer market. Holding time in the accepted area prior to harvest will be determined by the official agency according to species involved and local geographic or hydrographic conditions.

(4) Storage of shellstock in sea water
(a) The process of storing shellstock in sea water tanks, basins, floats or rafts can be used if it is acceptable to the official agency having jurisdiction and a record of the origin of each lot of shellstock should be maintained.
(b) Sea water in the tanks, floats or rafts should be of a sanitary quality acceptable to the official agency having jurisdiction and should be of an adequate salinity to permit the shellfish to function normally. Optimum salinity will vary with species.
(c) During storage shellstock should be laid out at a density and under such conditions that will permit them to open and function normally.
(d) The oxygen content in sea water tanks should be maintained at an adequate level at all times.
(e) The temperature of the water in storage tanks should not be allowed to rise to such levels as to cause weakness of the shellstock. If ambient temperatures are excessively high, tanks should be placed in a well-ventilated building or away from the direct rays of the sun.
(f) Shellfish should be stored in sea water only for such time as they remain sound and active.

(5) Washing, grading and packing of shellstock
(a) When strength of shell permits, the outsides of the shells should be washed free of mud, and all soft adhering organisms should be removed. Hard adhering organisms should also be removed when possible, care being taken not to chip lips of shells by vigorous washing.
(b) Bivalved shellfish having one cupped shell should, when packed in wooden or other rigid containers, be placed with the concave shell downwards and the flat surface at top to prevent dehydration from loss of shell liquor.
(c) Shellfish to be eaten raw on the shell should be landed and packed for onward transmission as quickly as possible, so permitting them to reach the consumer in a sound, live condition.
(d) Shellfish which are dead, dying, permanently gaping, with broken shells, or otherwise unwholesome should not be passed for human consumption.
(e) Containers used for packing shellstock should be free from any materials which may contaminate the product. They should be cleaned and disinfected as recommended by the official agency having jurisdiction.

(6) Washing, heat-shucking, and packing of shellstock
(a) Shellstock intended for heat-shucking should be sound and practically free from adhering organisms; the outside of the shell should be thoroughly washed free from mud before processing.
(b) After heat-shucking, the removal of the shells and the washing of the meats should be carried out under hygienic conditions. Washing should be conducted under conditions which avoid soaking of the meats, minimizing water uptake. Consequently, washing or flowing time should not exceed the maximum time needed to cleanse adequately the shellfish meats. Unnecessary addition of water to the finished product reduces flavour and quality and should be avoided. Immediately after heat-shucking the meats should be cooled rapidly to prevent spoilage. The water used for this purpose should be of potable quality, flowing continuously or frequently changed to maintain the meats at the lowest possible temperature.
(c) To prevent subsequent spoilage, washed meats should be refrigerated, preserved in salt, pickled, or immediately canned. Meats intended for human consumption soon after heat-shucking should be held under cool conditions suitable for the period between processing and consumption; meats not intended for early consumption should be stored at a temperature not exceeding 30°C (37°F).
APPENDIX III

E. Laboratory Control Procedures

(1) Laboratory facilities and technical personnel should be readily available to the official agency having jurisdiction for the sanitary control of the industry and should be capable of providing adequate laboratory support to the control agency.

(2) The official agency having jurisdiction should take water and shellfish samples from the growing area, relaying areas and purification plants and samples of shellstock and processed shellfish from purification plants and processing plants whenever necessary. Tests should be performed to assure that water and shellfish samples conform to the standards of the official agency having jurisdiction.

(3) Tests of the waters from growing areas should, where necessary, include bacteriological, biological, physical, and chemical tests for evidence of faecal and chemical pollutants. Tests should be carried out with such frequency as to provide adequate control.

(4) Tests of shellfish should include microbiological tests for faecal pollution and, where applicable, for spoilage. Biological tests should be made for biotoxins and faecal parasites and chemical and physical tests for other pollutants.

(5) Laboratory procedures should be developed and standardized and microbiological and other criteria promulgated to ensure that shellfish are free from pathogenic organisms and do not contain toxins or toxic chemicals at levels that constitute a hazard to health.

F. Lot Identification

(1) Shellstock
Each container (bag, basket or box) should be labelled according to shipper or processor, depuration plant, harvest area and date of harvest before shipment to market. Complete records of harvest area and date of harvest and length of time of relaying or purification of each lot should be maintained by the establishment for a period designated by the official agency having jurisdiction.

(2) Shucked Shellfish
Each container should be embossed or otherwise permanently marked in code or in clear prior to shipment to market so that information regarding harvest area, date of harvest and shipper can be established if necessary.

SECTION V - END PRODUCT SPECIFICATIONS

Appropriate methods should be used for sampling and examination to determine the compliance with the following specifications:

A. The products should be, to the extent possible in good manufacturing practice, free from objectionable matter.

B. The products should be free from microorganisms in amounts harmful to man and should not contain any substances originating from microorganisms in amounts which may represent a hazard to health.

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

D. The products should comply with any requirements set forth by the Codex Alimentarius Commission on pesticide residues and food additives as contained in permitted lists of Codex commodity standards, or should comply with the requirements on pesticide residues and food additives of the country in which the fish will be sold.
ANNEX TO THE MOLLUSCAN SHELLFISH CODE

CURRENT LABORATORY PROCEDURES AND STANDARDS

INTRODUCTION

During the development of the Draft Code of Hygienic Practice for Molluscan Shellfish, a variety of microbiological standards and methods were discussed. Recognizing that (a) successful shellfish control programmes have been in operation in a number of member states for many years using a wide range of bacteriological standards and methods, and (b) that it was virtually impossible to reach agreement at this time on any specific set of standards and methods, the Committee concluded that a listing of bacteriological standards and methods currently in force in several developed countries would serve a useful purpose. Such a list could be useful to developing countries establishing shellfish sanitation control programmes and provide information on bacteriological standards and methods of prospective import markets. Accordingly, the following list of bacteriological standards and methods are proposed as an annex to this Appendix.

A. DENMARK

Ten oysters sampled at random are examined individually:

1. Average of total plate count at 20°C for 5 days should not exceed 100,000/g.

2. E. coli Type I must not be present in any of the 10 samples. The inoculation dose must be a minimum of 1/5 of a gramme. Plating and identification take place in violet red-bile agar incubated 48 hours at 45°C. Verification by IMVIC tests is recommended.

3. Salmonella must not be present in any of the 10 samples. The inoculation dose must be a minimum of 1/5 of a gramme. Enrichment for 24 and 48 hours followed by streaking on brilliant green agar or any other specific substrate.

The figures are tentative limits and apply to live oysters only.

B. FRANCE

1. Bacteriological Control at the Production Sites

Bacteriological quality of shellfish is determined by the MPN of E. coli found in the flesh and fluid from a sample of 5-10 shellfish according to individual size.

2. Bacteriological Control at the Sales Points

Control depends essentially on determination of E. coli and detection of Salmonella.

Preparation of Test Samples

Five to 10 samples are drawn at random from each lot of shellfish. After washing, brushing and surface rinsing with alcohol, then drying, the meats are separated from the shells aseptically. The flesh and fluid of the mollusc are transferred to a sterile flask where they are finely and uniformly macerated. In the case of shellfish with little liquid, maceration is accomplished after mixing with equal parts of sterile peptone water diluent.

E. coli determination

Presumptive test is conducted in brilliant green lactose bile broth distributed in fermentation tubes. The inocula represent 1.0 ml, 0.5 ml, 0.2 ml, and 0.1 ml of the macerated mollusc. Incubation is conducted at 30°C for 24-48 hours. Identification of E. coli is made according to Mackenzie, Taylor and Gilbert for each primary culture fermenting lactose with production of gas.
APPENDIX III

Proposed Bacteriological Standards of Quality

- Oysters and molluscs ordinarily eaten raw: less than 1 E. coli per ml.
- Mussels and molluscs ordinarily eaten cooked: number of E. coli does not exceed 2 per ml.

Note: In order to determine the most probable number of E. coli, it is advisable not to limit inoculation to a single level.

Detection of Salmonella

Twenty-five ml of macerated mollusc are transferred to a flask containing 100 ml peptone water (40 g/litre). After incubation for 6 hours at 37°C for pre-enrichment, two aliquots of 25 ml are transferred to two flasks containing 225 ml of an enrichment mixture for Salmonella (Selenite or Tetrathionate); one is incubated at 43°C, the other at 37°C for 24-48 hours.

Isolation of Salmonellae is conducted according to the classical method.

- Proposed standard of safety: absence of Salmonella in 25 ml of sample (flesh plus fluid).

Note: It is planned to investigate the presence of Streptococci D.

C. ITALY

Microbiological Control

Representative samples of growing area water or shellfish are collected at different points in the growing area. If the sample cannot be examined within 6 hours from time of sampling, it is quick frozen and held at -20°C until examined. Unfrozen samples should be stored at 4°C until examined. Shellfish meats and shell liquor are combined for the examination. The total volume of the molluscs, consisting of 10 molluscs should be specified. The total volume of sample of shellfish is diluted to 200 ml using a sterile physiological solution.

Laboratory Procedure

The sample is homogenized in a mechanical mixer for 3 to 5 minutes at 10,000 RPM and filtered through sterile gauze. A 3 tube 3 dilution MPN procedure is used. Samples are inoculated into lactose broth and incubated at 37°C for 48 hours.

All gas positive tubes are transferred to brilliant green lactose bile broth and tryptone broth. All subcultures are incubated at 44°C for 48 hours. The E. coli results are based upon gas positive tubes of BGLB and a positive test for indole production. Results are reported as E. coli MPN per 100 ml of sample.

Bacteriological Standards

Approved Water.

An E. coli MPN of 2/100 ml shall not be exceeded in 90% of samples taken during one year. An E. coli MPN of 6/100 ml shall not be exceeded by more than 10% of samples taken during one year.

Shellfish from Acceptable Areas

An E. coli MPN of 160/100 ml of sample shall not be exceeded in 90% of samples during one year. An E. coli MPN of 500/100 ml sample shall not be exceeded in 10% of samples taken during one year.

Market Standard

E. coli MPN shall not exceed 600/100 g of sample.

Chemical Requirements

Edible marine invertebrates must not contain substances of any nature or origin making them dangerous to public health or substances which may produce abnormal organoleptic characteristics, in greater quantity than that permitted for drinking water.
D. **NETHERLANDS**

The control method of analysis and recommendations used in the Netherlands is identical to the controls, methods and recommendations used in the United Kingdom.

E. **UNITED KINGDOM**

**Control** - An order made under the Public Health (Shellfish) Regulations may prohibit removal for sale for human consumption of all or certain species of shellfish or may permit removal pending treatment in an acceptable manner, i.e. relaying in pure water, heat sterilization, purification in an acceptable installation.

**Methods of Analysis**

**Shellfish growing water** - Methods in current use for the examination of waters are the MacConkey Broth, 15 tube, three dilution MPN test (Department of Health 1957) and the membrane filtration technique using teepol lactose broth (Department of Health 1969). Counts of faecal **coli** in waters are made under various hydrographic conditions and seasons and the information obtained is used, in conjunction with observations on shellfish to make assessments about the degree of faecal contamination. There are no standards used to assess the sanitary quality of shellfish growing waters.

**Shellfish** - Samples of 10 shellfish are taken at random and examined individually or pooled together. Dilutions equal to twice the volume of shellfish tissue are made with 0.1 percent peptone water and 1 ml aliquots of the resulting extract inoculated into roll tubes of the MacConkey Agar No.3 (Reynolds and Wood, J. Appl. Bact. 19(1)(1956). Results are expressed as mean number of **E. coli** per ml of tissue based on the count of 10 replicate tubes.

The recommendations of Sherwood and Scott Thompson (1953), made after comparing the 44°C roll tube method with the Fishmongers' Company test, have been generally accepted by examining authorities.

<table>
<thead>
<tr>
<th><strong>E. coli/ml tissue</strong></th>
<th><strong>Action taken</strong></th>
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<tbody>
<tr>
<td>0-2</td>
<td>Sale permitted</td>
</tr>
<tr>
<td>3-4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Temporary prohibition</td>
</tr>
<tr>
<td>6-15</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Sale prohibited</td>
</tr>
</tbody>
</table>

At the present time, standards in current use are more stringent and shellfish from a particular source consistently containing more than 2 **E. coli/ml** are regarded with suspicion pending further samples or investigation.

F. **UNITED STATES**

Laboratory procedures used by the official agencies responsible for the sanitary control of shellfish in the United States are based upon the procedures outlined in Recommended Procedures for the Examination of Sea Water and Shellfish, 4th Edition, American Public Health Association, 1970. Current standards are as follows:

**Growing area bacteriological standard**

The coliform median MPN of the water does not exceed 70 per 100 ml, and not more than 10 percent of the samples ordinarily exceed an MPN at 230 per 100 ml for a 5-tube decimal dilution test (or 330 per 100 ml, where the 3-tube decimal dilution test is used) in those portions of the area most probably exposed to faecal contamination during the most unfavourable hydrographic and pollution conditions.

**Wholesale Market Standard**

Satisfactory. Faecal coliform density of not more than 230 MPN per 100g and **35°C** plate count of not more than 500,000 per gramme will be acceptable without question. This standard applies only to shellfish "certified" under the auspices of the National Shellfish Sanitation Program.

Conditional. Faecal coliform density of more than 230 MPN per 100 grammes and/or **35°C** plate count of more than 500,000 per gramme will constitute a conditional sample and may be subject to rejection by the States shellfish regulatory authority.

**Growing Area Standard for Paralytic Shellfish Poison**

If the paralytic shellfish poison content reaches 80 microgrammes/100 grammes of edible portions of raw shellfish meat, the area shall be closed to taking of the species of shellfish in which the poison has been found.
DRAFT CODE OF HYGIENIC PRACTICE FOR PROCESSING OF FROGLEGS
(Returned to Step 3)

The hygiene requirements of this Code are partially based on the revised Recommended International Code of Practice - General Principles of Food Hygiene (ALINORM 78/13A, Appendix V) and the Recommended International Code of Practice for Fresh Fish (CAC/RCP 9-1976). Where inserted in this Code the subsections are indicated in the right hand margin (GP - General Principles; FF - Fresh Fish).

SECTION I - SCOPE
This code of hygienic practice applies to froglegs derived from edible frogs. It contains the minimum requirements of hygiene in the production, processing, handling, packing, storage, transportation and distribution of froglegs to ensure a healthful and wholesome supply of this product.

SECTION II - DEFINITIONS
2. For the purposes of this Code the following expressions have the meaning stated:

2.1 "Chilling" means the process of cooling to a temperature approaching that of melting ice.

2.2 "Contamination" means the addition of any objectionable matter, directly or indirectly, to the product or the presence of any such matter in the product. GP Contamination includes infestation by pests.

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

2.4 "Establishment" means any building(s) or area(s) in which food is handled after harvesting and the surroundings under the control of the same management.

2.5 "Fresh Froglegs" means the skinless hind legs of freshly killed frogs.

SECTION III - HYGIENE REQUIREMENTS IN PRODUCING/HARVESTING AREA
3.1 Environmental Hygiene in Areas from which Froglegs are Obtained

3.1.1 Protection from contamination by wastes. Frogs should be protected in so far as practicable from contamination with human, animal, domestic, industrial and agricultural wastes and adequate precautions should be taken to ensure that these wastes are not used or disposed of in a manner which may constitute a health hazard through the food.

3.1.2 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 retained in the food. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

3.1.3 Harvest areas. The environment where frogs are caught or collected should be protected in so far as practicable against contamination which may constitute a health hazard to the consumer through the product.

3.2 Harvesting and Production

3.2.1 Techniques
3.2.1.1 Methods and procedures associated with harvesting and production should be hygienic and such as not to constitute a potential health hazard or result in GP contamination of the product.
3.2.1.2 To prevent deterioration in the quality of frog legs, it is essential that steps should be taken to prevent the live frogs from:

(i) injury or bruising of the flesh during catching, for example, from use of unsuitable equipment;
(ii) contamination with dirt or any other extraneous matter;
(iii) exposure to unfavourable temperatures;
(iv) rough handling, such as improper stacking of containers.

3.2.1.3 Harvesting should be carried out under conditions of minimal stress, such as proper fill to avoid overloading containers.

3.2.2 Equipment and product containers. Equipment and containers used for harvesting 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 maintained clean and, where necessary, disinfected.

3.2.3 Removal of obviously unfit materials. Unfit frogs, for example those less active, that are injured or have blood clots or parasites in the flesh, should be segregated during collection to the fullest extent practicable prior to delivery to the processing plant. Similarly, on arrival, unfit frogs should be removed as soon as possible and segregated for disposal in an appropriate manner. Arrangements for removal and segregation should be approved by the official agency having jurisdiction.

3.2.4 Protection against contamination and damage. Suitable precautions should be taken to protect the frogs from being contaminated by animals, insects, vermin, birds, chemicals or microbiological contaminants or other objectionable substances during handling and storage.

3.3 Storage at the place of production/harvesting. Frogs that are stored alive should be kept alive in a sanitary environment until they are processed. Frogs that die, become weak or appear abnormal in any way should be immediately removed from the live store and discarded.

3.4 Transportation

3.4.1 Conveyances for transporting the harvested frogs 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 maintained clean and where necessary disinfected.

3.4.2 All handling procedure should be such as will prevent raw materials from being contaminated. Care should be taken to keep the frogs alive, to protect against contamination and to minimize damage and stress. Special equipment - such as refrigeration equipment - should be used if the distances involved so indicate. If ice is used in contact with the product it should be of the quality required in paragraph 4.4.1.2.

3.5 Cutting Stations. In butchering and cutting carried out at collection points or cutting centres away from the main processing plant, facilities and operating practices should comply with all applicable requirements contained in sections 4, 5, 6 and 7, particularly 7.4.1 involving slaughter, cutting and de-skinning.

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

4.3 Buildings and Facilities

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

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 harvouring of pests and the entry of environmental contaminants such as smoke, dust, etc.

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

4.3.5.2 Any plant producing food not intended for human consumption should be entirely separate from a plant which is processing froglegs for human consumption. Processing of by-products not intended for human consumption should be conducted in separate buildings or in areas which are physically separated to prevent any possible contamination of froglegs.

4.3.6 Buildings and facilities should be designed to secure hygienic operations by means of a regulated flow in the process from the arrival of the raw material at the premises to the finished product without overcrowding of equipment and personnel, 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.
- 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 stables should be completely separated from and should not open directly on to food handling areas.

4.3.10 Where appropriate, establishments should have facilities for control of access.

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 Adequate facilities should be available to maintain froglegs in a chilled condition, as required.

4.3.13 Refrigeration and freezing equipment should be properly designed and constructed to accomplish rapid freezing and should be of adequate capacity.

4.3.14 Freezer and cold storage facilities should be adequate for the intended production and should be fitted with automatic temperature controlling and recording devices.

4.4 Sanitary Facilities

4.4.1 Water supply

4.4.1.1 An ample supply of potable water 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 and pollution. The standards of potability should not be less than those contained in the latest edition of "International Standards of Drinking Water" (WHO). GP

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

4.4.1.3 Steam used in direct contact with food or food contact surfaces should not contain any substances which may be hazardous to health or may contaminate the food. GP

4.4.1.4 Non-potable water 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. It should not be possible to connect lines carrying non-potable water to any equipment or cleaning/disinfection apparatus used in the handling of food. The facilities for non-potable water should be approved by the official agency having jurisdiction. GP

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. GP

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 handled. 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 disinfectant, and with suitable hygienic means of hand drying, should be provided adjacent to toilets. 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. GP

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 suitable hand cleaning preparations 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. The facilities should be furnished with waste pipes leading to drains. GP

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

4.4.6 Lighting. Adequate natural or artificial lighting which does not alter colours should be provided throughout the establishment. The intensity should not be less than: GP

- 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.
APPENDIX IV

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 and disposal of waste and inedible material. Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material by pests and to avoid contamination of food.

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-absorbing, is resistant to corrosion and is capable of withstanding repeated cleaning and disinfection. Surfaces should be smooth and free from pits and crevices. The use of wood and other materials which cannot be adequately cleaned and disinfected should be avoided except when their use would clearly not be a source of contamination.

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. The use of different materials in such a way that contact corrosion can occur should be avoided.

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 and be fitted with close-fitting lids. Such containers, used on the processing line, should be located below the level at which the froglegs are processed and in such a way that there is no splashback on the processing line.

4.5.3 Equipment identification. Equipment and utensils used for inedible materials should be so identified and should not be used for edible products.

SECTION V - ESTABLISHMENT: HYGIENIC REQUIREMENTS

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

5.2 Cleaning and Disinfection

5.2.1 Cleaning and disinfection should meet the requirements of this code. For further information on cleaning and disinfection procedures see Code of Practice, General Principles of Food Hygiene, Annex I.

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 conform to public health requirements. 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 commencing work.

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 be a permanent member of the staff of the establishment and whose duties ought to be divorced from 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 should also be cleaned and disinfected.

5.6 Exclusion of Domestic Animals. Dogs, cats and other domestic animals 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 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 processing areas.

SECTION VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene Training. Managers of establishments should arrange for adequate and continuing training of every food handler in hygienic handling of food and in personal hygiene so that they understand the precautions necessary to prevent contamination of food. Instruction should include relevant parts of this Code.
6.2 Medical Examination. Persons who come in contact with food in the course of their work should have a medical examination prior to their employment if the official agency having jurisdiction, acting on medical advice, considers that this is necessary, either because of epidemiological considerations, the nature of the food prepared in a particular establishment or the medical history of the prospective food handler. Medical examination of a food handler should be carried out at other times when clinically or epidemiologically indicated.

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

6.4 Injuries. Any person who has a cut or wound should not continue to handle food or food contact surfaces until the injury is completely protected by a 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 soap or other detergent under running warm, potable water while on duty. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 Personal Cleanliness. Every person engaged in a food handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor.

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. Gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

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

6.10 Supervision. Responsibility for ensuring compliance by all personnel with all requirements of paragraphs 5.9.1 - 5.9.10 inclusive should be specifically allocated to competent supervisory personnel.

SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

7.1.1 Unfit frogs should not be accepted.

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

7.1.3 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.
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7.1.4 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.

7.1.5 Frogs should be held under conditions of minimum stress.

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 material or semi-processed products.

7.2.3 Each employee should be assigned his definite place and duty on the processing line to prevent intermingling or movement of employees from more contaminated to less contaminated areas.

7.2.4 Ice should be supplied along the processing line only by the employees assigned for this purpose, using clean containers and being fully aware of the danger of cross contamination. Any left-over ice should be discarded.

7.2.5 Any containers and utensils used for ice, water, chlorine, salt solutions, or other food contact material or containing froglegs should be kept off the floor. Small, elevated, readily cleanable platforms or stands may be utilized.

7.2.6 All equipment and utensils used in the processing of froglegs should be assigned exclusively for this purpose. Processing of froglegs should be carried out as a separate operation divorced entirely from other food processing operations such as for shrimp, shellfish, or other fish.

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

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

7.3.4 When in-plant chlorination of water is used the residual content of free chlorine should be maintained at no more than the minimum effective level for the use intended. Chlorination systems should not be relied upon to solve all hygienic problems. The indiscriminate use of chlorine cannot compensate for unhygienic conditions in a processing plant.
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7.4 Processing
7.4.1 Operating Practices - General Considerations
7.4.1.1 Only good quality frogs should be accepted for processing.
7.4.1.2 Sampling and inspection procedures for evaluation of frogs and/or froglegs received for processing should not result in undue delay in entry of frog stock to the processing line.
7.4.1.3 Volume of frogs and/or froglegs received for processing should be regulated and scheduled to prevent large accumulations which may result in excess holding time prior to processing.
7.4.1.4 Frogs and froglegs should be handled and processed and packaged with care, a minimum of delay, and under conditions which will prevent the possibility of contamination, deterioration or the development of pathogenic and spoilage microorganisms.
7.4.1.5 Froglegs should at all times be processed rapidly and kept chilled during processing.
7.4.1.6 Any food additives used for dipping or spraying the froglegs should meet the requirements of the official agency having jurisdiction.

7.4.2 Preparatory Operations
7.4.2.1 Washing or other preparation. Frogs should be washed as needed to remove any contamination. Water used for washing and rinsing should be of potable quality. Water used for such purpose should not be recirculated unless suitably treated to maintain in a condition as will not constitute a public health hazard.
7.4.2.2 Frogs obtained from polluted habitats may be subjected to washing in running clean water for at least 24 hours. For this purpose, a clean holding tank, with an outlet at the bottom or an overflow pipe, may be employed.
7.4.2.3 Live frogs, before being placed into any holding tank, should be washed (hosed down or immersed in rapidly changing water) to remove soil, faeces and slime. Only potable water should be used for this purpose.

7.4.3 Slaughter and Butchering
7.4.3.1 Slaughter should be carried out with minimal stress to the animal. For example, after cleaning the live frogs may be put into a 10% solution of common salt containing an adequate quantity (see Code of Practice, General Principles of Food Hygiene, Annex I) of chlorine, for 15 minutes. By treatment in brine solution the live frogs become paralyzed (anaesthetized) so they are relieved from pain during the cutting.
7.4.3.2 The hind legs should be cut at the abdomen close to the waist and in such a manner that the intestines are left intact. Any remaining viscera should be removed as hygienically as possible.

7.4.4 Bleeding
7.4.4.1 Immediately after cutting, the legs should be washed thoroughly under running chlorinated water (see Code of Practice, General Principles of Food Hygiene, Annex I) to remove blood, remnants of viscera, slime, faeces and other extraneous materials. Immersion in chilled brine is recommended for proper bleeding and prevention of clotting of blood inside. The legs may be skinned either before or after bleeding in brine. Immediately after washing, the legs are immersed for a period of 2 minutes in chilled water (chilled by addition of crushed ice) containing an adequate quantity (see Code of Practice, General Principles of Food Hygiene, Annex I) of chlorine.
7.4.5 Holding and transporting for further processing

7.4.5.1 If the froglegs are not processed immediately after bleeding it is preferable to leave the skin on.

7.4.5.2 Froglegs intended for further processing should be chilled immediately and held in this condition until the next processing stage.

7.4.5.3 Froglegs should be transported from cutting stations to freezing and packing plants as quickly as possible under chilled conditions.

7.4.5.4 Where froglegs cannot be processed on arrival, or when the final product cannot be frozen soon after butchering, adequate facilities are required to keep the froglegs cool. Chill rooms should not be used to cool the froglegs but only to maintain them chilled after they have been cooled by ice or other means. It is poor practice, therefore, to load the chill room with large quantities of fresh froglegs that were not pre-chilled effectively to the temperature of melting ice.

7.4.6 Acceptance Criteria. Only good quality froglegs should be accepted by a freezing and packing plant. Froglegs should be inspected to ensure cutting was properly carried out.

7.4.7 Skinning and Trimming

7.4.7.1 Removal of skin and clipping of feet should be carried out on clean surfaces and with a minimum of delay. After this operation the legs should be carefully washed in an adequate amount of running water and bled immediately by placing them into a container of ice and chlorinated water (see Code of Practice, General Principles of Food Hygiene, Annex I) for a period of not less than 20 minutes.

7.4.7.2 After bleeding, the legs should be trimmed by removing bits of membrane, hanging pieces of flesh and a remaining portion of the cloaca in a hygienic manner. During this dressing operation, the dressed materials should be carefully examined for parasites, bruises, blood spots and other defects. This operation should be followed by washing the legs thoroughly in an adequate amount of running water and then immersing them again in a container of ice and chlorinated water (see Code of Practice, General Principles of Food Hygiene, Annex I) for 15 minutes. The legs should then be taken out and washed in four or five changes of chilled, chlorinated water (see Annex I as above).

7.4.8 Grading. The material should be given a final wash in clean water and graded in the different sizes demanded by the market. Size grading should preferably be done before freezing.

7.5 Packaging

7.5.1 All packaging material should be stored in a clean and sanitary manner. The material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product objectionable substances beyond the limits acceptable to the official agency having jurisdiction. The packaging material should be sound and should provide appropriate protection from contamination.

7.5.2 Product containers should not have been used for any purpose which may lead to contamination of the product. Where practicable containers should be inspected immediately before use to ensure that they are in a satisfactory condition and, where necessary, cleaned and/or disinfected; when washed they should be well drained before filling. Only packaging material required for immediate use should be kept in the packing or filling area.

7.5.3 Packing should be done under conditions that preclude the introduction of contamination into the product.

7.5.4 During packaging, extreme care should be taken not to contaminate the product. The legs should either be wrapped hygienically, individually in polyethylene film or preferably inserted into small polyethylene bags. The wrapping material or the bags should be dipped into clean water containing an adequate quantity of chlorine. There is no necessity to dip the rubber bands in chlorine solution.
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7.5.5 Product coding. Products sold or otherwise distributed from a manufacturing, processing, packing, or repacking establishment should be coded to enable identification of lots and, when necessary, segregation of specific food lots which may have become contaminated or otherwise unfit for their intended use. Records adequate to identify the processing history of each lot, should be retained for a period that exceeds the shelf life of the product, except that unless a specific need exists, they need not be retained more than two years.

7.6 Freezing. The legs should be frozen in the minimum possible time. Bruised, squeezed or broken legs should not be used for freezing. After freezing, the material should be transferred into cold storage, the temperature of which should not be higher than -18°C.

7.7 Storage and Transport of the end product

7.7.1 The end product should be stored and transported under such conditions as will preclude the contamination with and/or proliferation of microorganisms and protect against deterioration of the product or damage to the container. During storage, periodic inspection of the end product should take place to ensure that only food which is fit for human consumption is despatched and that end product specifications should be complied with when they exist. The product should be despatched in the sequence of the lot numbers.

7.7.2 Doors should not be left open for extended periods and should be closed immediately after use.

7.7.3 No chilling room and cold storage should be loaded beyond its designed capacity.

7.7.4 Where recording thermometers are not used, temperature should be read at regular intervals and the readings recorded in a log book.

7.7.5 Frozen froglegs should be stored at a uniformly low temperature if a considerable quality loss is to be avoided. Freezer stores should be able to operate at -18°C. Thermometers, or other temperature recording devices, should be capable of being read easily within a two-degree accuracy. More detailed requirements for the construction and operation of a freezer store are given in the "Code of Practice for Frozen Fish".

7.8 Laboratory Control Procedures. In addition to any control by the official agency having jurisdiction, it is desirable that each plant in its own interest should have access to laboratory control of the sanitary quality of the product processed. Such control should reject all products that are unfit for human consumption. Analytical procedures used should follow recognized or standard methods in order that the results may be readily interpreted. As necessary, representative samples of the production should be taken to assess the safety and wholesomeness of the product.

SECTION V - END PRODUCT SPECIFICATIONS

Appropriate methods should be used for sampling and examination to determine the compliance with the following specifications:

A. Froglegs should, to the extent possible in good manufacturing practice, be free from objectionable matter and parasites.

B. Froglegs should be free from microorganisms in amounts harmful to man, free from parasites harmful to man and should not contain any substances originating from microorganisms in amounts which may represent a hazard to health.

C. Froglegs should be free from chemical pollutants in amounts which may represent a hazard to health.

D. Froglegs should comply with any requirements set forth by the Codex Alimentarius Commission on pesticide residues and food additives as contained in permitted lists of Codex commodity standards, or should comply with the requirements on pesticide residues and food additives of the country in which the froglegs will be sold.
REVISED PROPOSED DRAFT CODE OF PRACTICE

GENERAL PRINCIPLES OF FOOD HYGIENE
(Advanced to Step 5)

SECTION I - SCOPE

1.1 This Code recommends general hygiene practices for use in the handling (including production, preparation, processing, packaging, storage, transport, distribution and sale) of food for human consumption in order to ensure a safe, sound and wholesome product.

1.2 It is further intended to provide a basis for establishing codes of hygienic practice for individual commodities or groups of commodities which have specific requirements relating to food hygiene.

SECTION II - DEFINITIONS

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

2.1 **Adequate** - sufficient to accomplish the intended purpose of this code.

2.2 **Cleaning** - the removal of food residues, soil, dirt, grease or other objectionable matter.

2.3 **Contamination** - the addition of any objectionable matter, directly or indirectly, to the product or the presence of any such matter in the product. Contamination includes infestation by pests.

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

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

2.6 **Food Handling** - any operation in the production, preparation, processing, packaging, storage, transport, distribution and sale of food.

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

2.8 **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.

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

SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA

3.1 **Environmental Hygiene in 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 naturally occurring substances would lead to an unacceptable level in the food.

3.1.2 **Protection from contamination by wastes**

3.1.2.1 Raw food materials should be protected from contamination with human, animal, domestic, industrial and agricultural wastes to an extent likely to be a hazard to health and adequate precautions should be taken to ensure that these wastes are not used or 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**

Water used for irrigation of food growing or producing areas should not constitute a health hazard to the consumer through the food.
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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 retained 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.

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

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

3.3 Storage at the Place of Production/Harvesting
Raw materials should be stored under conditions which provide protection against contamination and minimize damage and deterioration.

3.4 Transportation

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

3.4.2 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 paragraph 4.4.1.2.

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

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 secure 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.
- 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 stables should be completely separated from and should not open directly on to food handling areas.

4.3.10 Where appropriate, establishments should have facilities for control of access.

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.

4.4 Sanitary Facilities

4.4.1 Water supply

4.4.1.1 An ample supply of potable water 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 and pollution. The standards of potability should not be less than those contained in the latest edition of "International Standards of Drinking Water" (WHO).

4.4.1.2 Ice should be made from potable water and should be manufactured, handled and stored so as to protect it from contamination.
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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 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. It should not be possible to connect lines carrying non-potable water to any equipment or cleaning/disinfection apparatus used in the handling of food. The facilities for non-potable water should be approved by the official agency having jurisdiction.

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 hand drying, should be provided adjacent to toilets. 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. 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. The facilities should be furnished with 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 warm and cold water in sufficient quantities.

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

- 540 lux (50 foot candles) at all inspection points ≥750 lux
- 220 lux (20 foot candles) in work rooms ≥300 lux
- 110 lux (10 foot candles) in other areas ≥150 lux

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 and disposal of waste and inedible material
Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material by pests and to avoid contamination of food, potable water, equipment, buildings or roadways.
4.5 Equipment and Utensils

4.5.1 Materials

All equipment and utensils used in food handling areas and which may contact food should be made of material which does not transmit toxic substances, odour or taste, is non-absorbent, is resistant to corrosion and is capable of withstanding repeated cleaning and disinfection. Surfaces should be smooth and free from pits and crevices. The use of wood and other materials which cannot be adequately cleaned and disinfected should be avoided except when their use would clearly not be a source of contamination.

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. The use of different materials in such a way that contact corrosion can occur should be avoided.

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 and be fitted with close-fitting lids.

4.5.2.3 All refrigeration units should be equipped with thermometers.

4.5.3 Equipment identification

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

SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS

5.1 Maintenance

The buildings, equipment, utensils and all other physical facilities of the establishment, including drains, should be maintained in 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 Annex I.

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 conform to public health requirements. 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 commencing work.

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 be a permanent member of the staff of the establishment and whose duties ought to be divorced from 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.
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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**
Dogs, cats and other domestic animals 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 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 processing areas.

**SECTION VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS**

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

6.2 **Medical Examination**
Persons who come in contact with food in the course of their work should have a medical examination prior to their employment if the official agency having jurisdiction, acting on medical advice, considers that this is necessary, either because of epidemiological considerations, the nature of the food prepared in a particular establishment or the medical history of the prospective food handler. Medical examination of a food handler should be carried out at other times when clinically or epidemiologically indicated.
6.3 Communicable Diseases
The management should take care to ensure that no person, while known or suspected to be suffering from, or to be a carrier of a disease likely to be transmitted through food or while afflicted with infected wounds, skin infections, sores or with diarrhoea, is permitted to work in any food handling area in any capacity in which there is any likelihood of such a person directly or indirectly contaminating food with pathogenic microorganisms. Any person so affected should immediately report to the management that he is ill.

6.4 Injuries
Any person who has a cut or wound should not continue to handle food or food contact surfaces until the injury is completely protected by a 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 soap or other detergent under running warm, potable water while on duty. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 Personal Cleanliness
Every person engaged in a food handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor.

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. Gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

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 5.9, 6.3, 6.4 and 6.7.

6.10 Supervision
Responsibility for ensuring compliance by all personnel with all requirements of paragraphs 5.9.1 - 5.9.10 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 material or ingredient should be accepted by the establishment if known to contain parasites, microorganisms or toxic, decomposed or extraneous substances which will not be reduced to acceptable levels by normal plant procedures of sorting and/or preparation or 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.
APPENDIX V

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.

7.2 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 material or semi-processed products.

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 Processing

7.4.1 Processing should be supervised by technically competent personnel.

7.4.2 All steps in the production process, including packaging, should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination, deterioration, or the development of pathogenic and spoilage micro-organisms.

7.4.3 Rough treatment of containers should be avoided to prevent the possibility of contamination of the processed product.

7.4.4 Methods of preservation and necessary controls should be such as to protect against contamination or development of a public health hazard and against deterioration within the limits of good commercial practice.

7.5 Packaging

7.5.1 All packaging material should be stored in a clean and sanitary manner. The material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product objectionable substances beyond the limits acceptable to the official agency having jurisdiction. The packaging material should be sound and should provide appropriate protection from contamination.

7.5.2 Product containers should not have been used for any purpose which may lead to contamination of the product. Where practicable containers should be inspected immediately before use to ensure that they are in a satisfactory condition and where necessary cleaned and/or disinfected; when washed they should be well drained before filling. Only packaging material required for immediate use should be kept in the packing or filling area.

7.5.3 Packing should be done under conditions that preclude the introduction of contamination into the product.
7.5.4 **Product coding**

Products sold or otherwise distributed from a manufacturing, processing, packing, or repacking establishment should be coded to enable identification of lots and, when necessary, segregation of specific food lots which may have become contaminated or otherwise unfit for their intended use. Records, adequate to identify the processing history of each lot, should be retained for a period that exceeds the shelf life of the product, except that unless a specific need exists they need not be retained more than two years.

7.6 **Storage and Transport of the End Product**

The end product should be stored and transported under such conditions as will preclude the contamination with and/or proliferation of microorganisms and protect against deterioration of the product or damage to the container. During storage, periodic inspection of the end product should take place to ensure that only food which is fit for human consumption is despatched and that end product specifications should be complied with when they exist. The product should be despatched in the sequence of the lot numbers.

7.7 **Sampling and Laboratory Control Procedures**

7.7.1 It is desirable that each establishment should have access to laboratory control of the products processed. 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.

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

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

**SECTION VIII - END PRODUCT SPECIFICATIONS**

8. Specifications such as microbiological, chemical or physical may be required depending on the nature of the food. Such specifications should include sampling procedures, analytical methodology and limits for acceptance.

**ANNEX I**

**CLEANING AND DISINFECTION PROCEDURES**

(To be prepared)
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Appendix VI

Draft Code of Hygienic Practice for Low-Acid Canned Foods

Section 1 - Scope

This code of practice is concerned with the canning and heat processing of low-acid foods packed in rigid hermetically sealed containers except those foods which have only been precooked or pasteurized and therefore require refrigeration. This document excludes semi-rigid and flexible containers made of plastic or metal either singly or in combination.

Section 2 - Definitions

For the purposes of this code:

2.1 Aseptic processing and packaging means the filling of a commercially sterile product into sterilized containers followed by hermetic sealing with a sterilized closure in an atmosphere free from microorganisms.

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

2.3 Canned means product packed in rigid containers which have been hermetically sealed and sufficiently heated to achieve commercial sterility.

2.4 Cleaning means the removal of food residues, soil, dirt, grease or other objectionable matters.

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

2.6 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.

2.7 Commercial sterility of food means the condition achieved by application of heat which renders such food free from viable microorganisms, including those of known public health significance, capable of growing in the food at temperatures under which the food is likely to be held during storage and distribution.

2.8 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 viable microorganisms, including those of known public health significance, capable of growing in the food at temperatures under which the food is likely to be held during storage and distribution.

2.9 Cooling means the procedure necessary to cool the contents of a container from the sterilization temperature to approximately 40°C (104°F).

2.10 Disinfection means the application of hygienically satisfactory chemical and/or physical agents or processes to cleaned surfaces with the intention of eliminating microorganisms thereby preventing infection of food products.

2.11 Flame Sterilizer means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, over gas flames to achieve commercial sterility of foods. A holding period in a heated section may follow the initial heating period.

2.12 Heating Curve means a graphical representation of the rate of temperature change in the food during a heat process; this is usually plotted as time against temperature on semi-log graph paper.

2.12.1 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.

2.12.2 Simple heating curve means a heating curve which approximates to a straight line.

2.13 Headspace means the volume in a container not occupied by the product.

2.14 Heat process means the heat treatment of product and is defined in terms of time and temperature.

2.15 Hermetically sealed container means a container which is designed and intended to protect the contents against the entry of microorganisms during and after heat processing.
2.16 **Holding time** - see sterilization time.

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

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

2.19 **Leaker** means a container which has lost its hermetic seal.

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.


2.22 **Retort** means a pressure vessel designed for heat processing food, packed in hermetically sealed containers, by an appropriate heating medium and where necessary with superimposed pressure.

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

2.24 **Sterilization temperature** means the temperature maintained throughout the heat process as specified in the scheduled process.

2.25 **Sterilization time** means the time between the moment sterilization temperature is achieved and the moment cooling is started.

2.26 **Venting** means flushing the air out of retorts by steam prior to a scheduled process.

2.27 **Water Activity** \((a_w)\) is a measure of free moisture in a product and is the quotient of the water vapour pressure of the substance divided by the vapour pressure of pure water at the same temperature.

## SECTION 3 - RAW MATERIAL REQUIREMENTS

This entire section is as in Section III of the General Principles of Food Hygiene.

## SECTION 4 - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 As in 4.1 in the General Principles of Food Hygiene.

4.2 As in 4.2 in the General Principles of Food Hygiene.

4.3 As in 4.3 in the General Principles of Food Hygiene.

4.4 As in 4.4 in the General Principles of Food Hygiene.

4.5 As in 4.5 in the General Principles of Food Hygiene except 4.5.2.1 and additional 4.5.2.4.

4.5.2.1 As in General Principles of Food Hygiene with addition: 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.

4.5.2.4 **Retorts and Product Sterilizers**

*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.

## SECTION 5 - ESTABLISHMENTS: HYGIENE REQUIREMENTS

All this section as in Section V of the General Principles of Food Hygiene.

## SECTION 6 - HYGIENE AND HEALTH OF PERSONNEL

All this section as in Section VI of the General Principles of Food Hygiene.
7. SECTION 7 – ESTABLISHMENTS: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw material requirements and preparation.

7.1.1 As in 7.1.1 General Principles of Food Hygiene.

7.1.2 As in 7.1.2 General Principles of Food Hygiene.

7.1.3 As in 7.1.3 General Principles of Food Hygiene.

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 canning, should be performed as rapidly as possible and under conditions which will prevent contamination and deterioration, and will minimize the growth of microorganisms in the food.

7.2 As in 7.2 of the General Principles of Food Hygiene.

7.3 As in 7.3 of the General Principles of Food Hygiene.

7.4 Packaging.

7.4.1 As in 7.5.1 of the General Principles of Food Hygiene, with an addition:

The product containers should be sufficiently durable to withstand the mechanical and thermal stresses encountered during processing and to resist physical damage during normal distribution.

7.4.2 Inspection of empty product containers

Containers and covers should be inspected carefully for cleanliness immediately before use and if any are found not to be clean the whole lot should be washed or effectively cleaned in some other way before they are used. Containers intended for use on aseptic filling lines should not be washed 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 and so might otherwise go undetected. In washing glass containers, care must be taken to avoid breakage through rough handling or thermal shock.

It is advisable to have all containers turned upside down just before filling to make certain that they do not contain any foreign material before they are used. If containers are delivered to filling machines or packing tables by conveyor, it is usually possible to have them inverted mechanically during their travel.

Care should be taken to minimize the use of faulty containers and closures by the use of appropriate sampling and inspection schemes. These include cans that have been dented or pierced, or with defective side or bottom seams or with scratches or flaws in the plating or enamel (lacquer) and covers with defective sealing compound or gaskets. If these are filled, material will be wasted and there is always a danger of damaged containers tampering a filling or sealing machine and necessitating a shut-down. Slight faulty containers may cause trouble by becoming leakers during or after heat processing and storage.

The canner should ensure that the container and closure specifications, which may at some times incorporate a key or some other easy opening feature, 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 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 on to the production line and result in the packing of food in the same container with very objectionable or possibly 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. Alternatively they may be shielded or located so they will not become contaminated or obstruct clean-up operations.
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7.4.5 Filling of product containers

The filling of containers, either mechanically or by hand, should be controlled so that the filling and headspace requirements as specified in the scheduled process are met. It is important to achieve a constancy of filling not only for economic reasons, but also for reasons that heat penetration and headspace may be adversely affected by fill variation. In rotationally processed containers the headspace should be accurately controlled and sufficient to ensure consistent and adequate agitation of the contents. The exhausting of containers for the removal of air should be controlled so as to meet the conditions for which the process was designed.

7.4.6 Closing Operations

Seams and other closures should be tight and secure and meet requirements of the can manufacturer as well as those of the agency having jurisdiction. Particular attention should be given to the operation and maintenance of closing equipment. Sealing machines should be modified or adjusted for each type of container used. In all cases the manufacturer's instructions concerning the operation, maintenance and adjustment should be followed meticulously.

Regular observations should be made during production runs for gross closure defects. Any such defects should be recorded and corrective action should be taken and recorded. 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 closing machine, after adjustment of closing machines or after starting up of machines following a prolonged shut-down.

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

7.4.7 Inspection of Closures

7.4.7.1 Inspection of glass container closures

Many different designs of closures exist for glass jars so that it is impossible to give definitive recommendations for such closures. For this reason, the recommendations of the manufacturer should be carefully followed. Appropriate detailed inspections and tests should be conducted by competent personnel at intervals of sufficient frequency to ensure consistently reliable hermetic sealing. Records of such tests and corrective actions should be maintained.

7.4.7.2 Inspection of can seams

In addition to regular observations for gross closure defects and visual inspections, teardown 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. When abnormalities are found, the corrective actions taken should be recorded.

Either of the two following systems may be used to inspect can seams:

Micrometer measurement: Measure and record the following dimensions at, for example, three points approximately 120° apart around the double seam excluding the juncture with the side seam (see diagram). As well as measuring the seam thickness, the double seam should be stripped down and observed for wrinkling, chuck
impression (indicating tightness) and for other visual characteristics. The overlap (O) can be calculated by the following formula: 

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

Schematic Diagram of "Double Seam"

Seamscope projection: overlap, body and coverhook lengths are directly visible in a cross-section of the seam by the viewer. The other double seam dimensions should be measured by a micrometer. (Wrinkling and other visual defects should 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.

7.4.8 Handling of Containers after Closure: After closing, containers should be handled in a manner that protects seams and closures from damage which may cause defects in the closures, and subsequent contamination.

7.4.9 Coding: Each container from a code lot should be marked with an identifying code which is permanent and visible to the naked eye. Where the container does not permit the code to be embossed or inked, the label can be legibly perforated or otherwise marked, provided that the label is securely affixed to the product container. The code should identify the establishment where packed, the product contained therein, the day packed and preferably the period of the day during which the product was filled into the container. The filling period code should be changed with sufficient frequency to enable identification and isolation of the code lots during their 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.

Case and tray coding may aid in the identification of code lots.

7.4.10 Washing: Where necessary, before sterilization of containers, water or detergent sprays at adequate temperature should be used to remove product which is adhering to the outside of the container after filling and closing. After sterilization not only may it be much more difficult to clean the container but washing after sterilization increases the risk of leakers unless carefully controlled, and is therefore not advised.
APPENDIX VI

7.5 Heat Processing

7.5.1 General Considerations

The heat process required to make low-acid canned foods commercially sterile depends on the microbial load, storage temperature, the presence of various preservatives and composition of the product. It is absolutely necessary to establish the required heat process with accepted scientific methods.

Low-acid foods with pH values above 4.6 may be able to support the growth of many kinds of microorganisms including the heat resistant spore-forming pathogens such as Clostridium botulinum. It should be emphasized that the heat 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. Scheduled processes for low-acid canned foods must be established only by competent persons having expert knowledge of thermal processing and having adequate facilities for making such determinations.

7.5.2 Establishing scheduled processes

The procedure to establish the required heat treatment for a product can be divided into two steps.

First, the required heat process to achieve commercial sterility should be established on the basis of factors such as:

- Microbial flora including Clostridium botulinum and spoilage microorganisms
- Container size
- pH of the product
- Product composition or formulation
- Levels and types of preservatives
- Water activity
- Likely storage temperature of the product

The second step is to determine the scheduled process taking into account the sterilizing facilities available and the desired product quality.

In the second step, 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.

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

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

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. It is essential to confirm this by further heat-penetration studies.

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

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:

- Product code or recipe identification;
- Container size (dimensions);
- Ingoing weight of product(s) including liquor where appropriate;
- Minimum initial temperature;
- Type and characteristics of heat processing system;
- Sterilization temperature;
- Sterilization time;
- Cooling method.

For aseptically processed packs a similar list should be made to include also equipment and container sterilization requirements.
The product code should, clearly, correspond to a complete and accurate product specification containing 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 specification 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 over the range of shear rates and temperatures likely to be met during heat processing. 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.

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.

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.

7.5.3 Heat processing room operations

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. 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. 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.

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.

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.

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 wrist-watches, etc. Where two or more clocks are used in a heat processing room they should be synchronized.

7.5.3.1 Critical factors and the application of the scheduled process

In addition to the minimum product initial temperature, sterilization time and sterilization 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:

- Maximum fill-in or drained weight.
- Minimum headspace of product containers.
- Product consistency as determined by objective measurement on product taken before processing.
- Product style which results in layering or stratification of the product in containers requiring specific orientation of containers in the retort.
- Percent solids.
- Minimum net weight.
- Minimum closing vacuum (in vacuum packed products).
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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 should be equipped with at least one indicating thermometer.

The mercury-in-glass thermometer is generally recognized as the master temperature indicating reference 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 in steam or water as appropriate in the operational aspect against a known accurate standard thermometer 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 replace, if found, thermometers with divided mercury columns or other defects.

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.

7.6.1.2 Temperature recording devices

Each retort should be equipped with at least one temperature 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.

Each chart should have a working scale of not more than 12°C per cm (55°F per inch) within a range of 10°C (20°F) of the sterilizing temperature. The recording accuracy should be equal to or better than ± 0.5°C (1°F) at the sterilizing temperature. The recorder should agree within 0.5°C (1°F) of 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 time. The chart timing device should also be accurate.

7.6.1.3 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 66% 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 inch) in diameter. The instrument may be connected to the retort by means of a gauge cock and syphon.

7.6.1.4 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.

7.6.1.5 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.

7.6.2 Pressure processing in Steam

7.6.2.1 Batch (still) retort

7.6.2.1.1 Indicating thermometers and temperature recording devices (see 7.6.1.1 and 7.6.1.2)
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 processing period. Thermometers should be installed where they can be accurately and easily read.

7.6.2.1.2 Pressure Gauges (see 7.6.1.3)
7.6.2.1.3 Steam Controllers (see 7.6.1.4)
7.6.2.1.4 Pressure Relief Valve (see 7.6.1.5)

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
Crate supports employed in vertical still retorts should not substantially affect venting or steam distribution.

7.6.2.1.7 Steam Spreaders
Perforated steam spreaders, if used, should be checked regularly to ensure that they are not blocked or otherwise inoperative.

Horizontal still retorts should be equipped with steam spreaders that extend along the bottom for the length of the retort.

In vertical still retorts the steam spreaders, if used, should be in the form of a cross or coil with the perforations along the top or sides of the pipe.

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 1½ to 2 times the cross-sectional area of the smallest part of the steam inlet line.

7.6.2.1.8 Bleeders
Bleeders should be of suitable size, e.g. 3 mm (1/8 inch) and location and should be wide 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.

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 designed, installed and operated in such a way that air is removed from the retort before timing of the heat 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. The vent should be located in that portion of the retort opposite the steam inlet. Where a retort manifold connects several pipes from a single still retort, it should be controlled by a suitable valve. The retort 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. Retorts using air for pressure during 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.
7.6.2.11 Critical Factors (see 7.5.3.1)

7.6.2.2 Batch Agitating retorts

7.6.2.2.1 Indicating thermometers and Temperature recording devices (see 7.6.2.1.1).

7.6.2.2.2 Pressure gauges (see 7.6.2.1.2).

7.6.2.2.3 Steam Controller (see 7.6.2.1.3).

7.6.2.2.4 Pressure Relief Valve (see 7.6.2.1.4).

7.6.2.2.5 Steam Inlet (see 7.6.2.1.5).

7.6.2.2.6 Steam Spreaders (see 7.6.2.1.7).

7.6.2.2.7 Bleeders (see 7.6.2.1.8).

7.6.2.2.8 Venting and Condensate Removal (see 7.6.2.1.8 and 7.6.2.1.10).

7.6.2.2.9 Retort Speed Timing

The rotational speed of the retort should be specified in the scheduled process. The speed should be adjusted and recorded when the retort is started at any time a speed change is made and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process. Additionally, a recording tachometer may be used to provide a continuous record of the speed. The speed should be checked against a stop watch at least once per shift. A means of preventing unauthorized speed changes on retorts should be provided.

7.6.2.2.10 Critical Factors (see 7.5.3.1)

7.6.2.3 Continuous Agitating Retorts

7.6.2.3.1 Indicating Thermometers and Temperature recording devices (see 7.6.2.1.1).

7.6.2.3.2 Pressure gauges (see 7.6.2.1.2).

7.6.2.3.3 Steam Controllers (see 7.6.2.1.3)

7.6.2.3.4 Pressure Relief Valve (see 7.6.2.1.4)

7.6.2.3.5 Steam Inlet (see 7.6.2.1.5)

7.6.2.3.6 Steam Spreaders (see 7.6.2.1.7)

7.6.2.3.7 Bleeders

Bleeders should be of suitable size and location and should be wide open during the entire process, including the coming-up time. All bleeders should be arranged in such a way that the operator can observe that they are functioning properly.

7.6.2.3.8 Venting and condensate removal

Vents should be located in that portion of the retort opposite the steam inlet. Air should be removed before processing is started. At the time 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 bleeder in the bottom of the shell serves as an indicator of continuous condensate removal. The retort operator should observe and periodically record how this bleeder is functioning.

7.6.2.3.9 Retort Speed Timing

The rotational speed of the reel should be specified in the scheduled process. The speed should be adjusted and recorded when the retort is started, at any time a speed change is made and at intervals of sufficient frequency to ensure that the retort speed is maintained as specified in the scheduled process.

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 a shift. A means of preventing unauthorized speed changes on retorts should be provided.

7.6.2.4 Hydrostatic retorts

7.6.2.4.1 Indicating Thermometers (see 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 or water levels in the hydrostatic water legs, at least one indicating thermometer should be located in each hydrostatic water leg so that it can be accurately and easily read.
7.6.2.4.2 Temperature recording device (see 7.6.1.2)
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 7.6.2.1.3)
7.6.2.4.4 Steam Controllers (see 7.6.2.1.4)
7.6.2.4.5 Steam Inlet (see 7.6.2.1.5)
7.6.2.4.6 Bleeders (see 7.6.2.1.8)
Bleeders of adequate size 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 Retort Speed
The speed of the container conveyor chain 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 ensure that the retort speed
is maintained as specified. An automatic device should be used to stop the chain and
provide warning when the temperature drops below that specified in the scheduled process.
A means of preventing unauthorized speed changes should be provided.

7.6.3 Pressure processing in water
7.6.3.1 Batch (Still) retorts
7.6.3.1.1 Indicating thermometer as in 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 thermo-
meter bulbs should extend directly into the water for a minimum of at least 5 cm (2 inches).

7.6.3.1.2 Temperature recording device as in 7.6.1.2
The recording thermometer probe should be located adjacent to the bulb of the indicating
thermometer except in the case of a vertical retort equipped with a combination recorder-
controller. In vertical retorts it is important that the temperature recorder-controller
probe should be located at the bottom of the retort below the lowest crate rest in such
a position that the steam does not strike it directly. In a horizontal retort the
temperature recorder-controller probe should be located between the water surface and
a horizontal plane passing through the centre of the retort. This prevents direct steam
impingement upon the controller bulb.

7.6.3.1.3 Pressure gauge as in 7.6.1.3.
7.6.3.1.4 Pressure relief valve as in 7.6.1.5.
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.

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 as in 7.6.1.4.
7.6.3.1.8 Steam Inlet as in 7.6.2.1.5.
7.6.3.1.9 Steam spreaders (distributors)
The distribution of steam in the bottom of the retort should be accomplished in a manner
adequate to provide uniform heat distribution throughout the retort. In vertical retorts,
uniform steam distribution can be achieved by any of several methods. In horizontal
retorts, the steam distributor should run the length of the bottom of the retort with
perforations distributed uniformly along the upper part of the pipe.
7.6.3.10 **Crate supports**

A bottom crate support should be employed in vertical still retorts. 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.

7.6.3.11 **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.

7.6.3.12 **Drain valve**

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

7.6.3.13 **Water level indicator**

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 cms (6 inches) over the top layer of product containers in the retort.

7.6.3.14 **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.

7.6.3.15 **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.

7.6.3.16 **Retort headspace**

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

7.6.3.17 **Water circulation**

All water circulation systems, whether by pump 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.

7.6.3.18 **Critical factors in the application of the scheduled process as in 7.5.3.1.**

7.6.3.2 **Batch agitating retorts**

7.6.3.2.1 **Indicating thermometer** as in 7.6.1.1.

7.6.3.2.2 **Temperature recording device**

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

7.6.3.2.3 **Pressure gauges** as in 7.6.1.3.

7.6.3.2.4 **Pressure relief valve** as in 7.6.1.5.

7.6.3.2.5 **Pressure control valve** as in 7.6.3.1.5.

7.6.3.2.6 **Pressure recorder** as in 7.6.3.1.5.

7.6.3.2.7 **Steam controller** as in 7.6.1.4.

7.6.3.2.8 **Steam Inlet** as in 7.6.2.1.5.

7.6.3.2.9 **Steam spreader** as in 7.6.3.1.9.

7.6.3.2.10 **Drain valve** as in 7.6.3.1.12.

7.6.3.2.11 **Water level indicator** as in 7.6.3.1.13.

7.6.3.2.12 **Air supply and controls** as in 7.6.3.1.14.

7.6.3.2.13 **Cooling water entry** as in 7.6.3.1.15.

7.6.3.2.14 **Water circulation** as in 7.6.3.1.17.

7.6.3.2.15 **Retort speed timing** as in 7.6.2.2.9.
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7.6.3.2.16 Critical factors in the application of the scheduled process as in 7.5.3.1.

7.6.4 Pressure processing in steam/air mixtures

Both the temperature distribution and the rates of heat transfer are critically important in the operation of steam/air retorts.

There should be a means of circulating the steam/air mixtures to prevent formation of low temperature pockets. The circulating system used should provide acceptable heat distribution as established by adequate tests. The operation of the processing system should be the same as that required by the scheduled process. A recording pressure controller should control the air inlet and the steam/air mixture outlet.

Some items of equipment may be common to those already described in this code and those standards given may be relevant.

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.

7.6.5 Aseptic processing and packaging systems

7.6.5.1 Product sterilization equipment and operation

7.6.5.1.1 Temperature indicating device

Each product sterilizer should be equipped with at least one temperature indicating device. The device can either be a mercury-in-glass thermometer that has divisions that are easily readable to 0.50°C (1°F) and whose temperature range is not more than 4°C per cm (1°F per inch) of graduated scale or an equivalent temperature indicating device such as thermocouple-recorder. The temperature indicating device should be capable of being read with an accuracy of 0.50°C (1°F) within the range of 5°C (10°F) of the product sterilization operating range. The device should be installed in the product at the holding section outlet. The temperature indicating device should be tested for accuracy against a known accurate temperature standard upon installation and at least once a year thereafter or more frequently as may be necessary to ensure its accuracy. The device should be installed so that it can be accurately and easily read. A thermometer that has a divided mercury column and any device that deviates more than 0.50°C (1°F) from the standard should be repaired or replaced. The temperature indicating device should be the reference instrument for indicating the processing temperature.

7.6.5.1.2 Temperature recording device

There should be an accurate temperature recording device on each product sterilizer. The temperature sensor should be located in the sterilized product at the holding section outlet. The recording device should be adjusted to agree with a known accurate temperature standard. A means of preventing unauthorized changes in adjustment should be provided. The recording device should not deviate more than 0.50°C (1°F) from the temperature standard; it should be installed so that it can be accurately and easily read. The recording chart graduations should not exceed 1°C (2°F) within a range of 5°C (10°F) of the desired product sterilization temperature. The chart should have a working scale of not more than 12°C per cm (55°F per inch) within a range of 10°C (20°F) of the product sterilization temperature.

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. It should be capable of ensuring that the desired product sterilization temperature is maintained. The chart graduations should not exceed 1°C (2°F) within a range of 5°C (10°F) of the desired product sterilization temperature.

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 .14 kg per sq cm per cm (2 lbs per square inch per inch) on a working scale of not more than 1.4 kgs per sq cm per 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 determines the sterilization holding time, should be checked at sufficient frequency to ensure that it is specified in the scheduled process.

7.6.5.1.7 Product-holding tube
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 per metre (0.25 inches 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 Start-up
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 sterilizing holding tube
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 per square cm (1 lb per square inch) greater than the pressure of unsterilized product. Product flow should be directed either to waste or recirculated until the cause of the improper pressure relationship has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

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

7.6.5.2.2 Timing method(s)
A method(s) should be used either to give the retention time of containers and closures if applicable, as specified in the scheduled process, or to control the sterilization cycle at the rate as specified in the scheduled process. A means of preventing unauthorized speed changes should be provided.

7.6.5.2.3 Start-up
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 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 controls used for the manufacture, processing and/or packing of such foods are operated or administered in a manner adequate to achieve commercial sterility.

7.6.8 Cooling

Only with relatively small metal cans is it possible to cool the cans with water under atmospheric pressure. For large metal cans and all other types of containers it is necessary to apply an extra pressure to compensate for the internal pressure inside the can at the beginning of cooling, otherwise the containers may deform or leak. This extra pressure may be achieved by introducing water or compressed air into the retort under pressure. Glass containers are very sensitive to thermal shocks so that at the beginning of cooling, water with a temperature slightly lower than the contents should be first introduced into the retort.

Although the containers normally may be considered as hermetically sealed, a small number of containers may leak during the cooling period mainly due to mechanical stresses. The vacuum inside the container will promote the penetration of minute amounts of cooling water into the container. This is the reason that cooling water should be of suitable microbiological quality, and should preferably be chlorinated and maintained at a measurable residual chlorine or be otherwise suitably treated. Records should be kept of tests showing either that cooling water treatment was maintained or that the microbiological quality was suitable.

If cooling water is chlorinated in the plant, there should be a sufficient contact time to reduce the microbial content of the water to a level which will prevent contamination of the can contents during cooling; a 20 minute minimum contact time at suitable pH and temperature is normally considered adequate. Checks should be made on the water after its use for cooling to ensure the presence of free residual chlorine. Where water is recirculated any insoluble organic matter should be separated. To avoid the growth of thermophilic microorganisms, it is necessary to cool containers rapidly through the range of 60°C - 40°C (140°F to 105°F). In practice, water cooling is used to reduce the average temperature of the container contents to 40°C (105°F). Further cooling is done in air to evaporate the adhering water-film. This aids in preventing corrosion and microbiological contamination and allows containers to be labelled when they are dry.

7.7 Post-process contamination

All heat processed canned products should be handled with care and not manually handled while the seals are still wet. Manual handling of wet containers presents a risk of infection by food poisoning microorganisms.

Moisture on the processed and cooled can may transfer microorganisms, left on the surface of the container by handling, into the container. Cooling and drying procedures should be conducted in a manner to protect against such contamination. Mechanical shocks may cause the container momentarily to leak and the vacuum in the container may allow infected liquid in the seal area to be sucked into the container. Conveyors and other equipment for handling the containers should therefore be kept clean, disinfected and dry. Where certain areas of conveyors or other equipment which are in contact with processed containers are consistently wet and cannot be maintained in a dry condition, the rapid growth of bacteria on such wet surfaces may be prevented by manual or mechanical spraying with an appropriate disinfectant on a continuous or semi-continuous basis during production. Cylindrical cans should preferably not be rolled on their double seams or subjected to mechanical shock.

7.8 Evaluation of deviations in heat processing

Whenever any process is less than the scheduled process for any low-acid food or container system as disclosed by in-process monitoring records, by processor check or otherwise, the processor of such low-acid food should either fully reprocess to commercial sterility that portion of the production involved, keeping full records of the reprocessing conditions, or segregate and retain that portion of the production involved for further 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 potential hazard to public health. If this evaluation of the processing records demonstrates that the product has not been given a safe thermal process the product segregated and retained should either be fully reprocessed to render it commercially sterile or be destroyed under adequate and proper supervision. A record should be made of the evaluation procedures used, the results obtained and the actions taken on the product involved.
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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 sections 7.5.1 and 7.5.2.

8.

SECTION 8 - QUALITY ASSURANCE

It is important that heat processes be properly established, correctly applied, sufficiently supervised and documented to provide positive assurance that the requirements of the scheduled process have been met.

An end product analysis by itself is not sufficient, because of statistical considerations, to detect beyond a gross defect level the adequacy of the heat process.

8.1 Processing and production records

Permanent 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 any particular lot had received adequate heat processing. These records should be made by the retort or processing system operator or other designated person, on a form which should include: product name and style, the code lot number, the retort or processing system and recorder chart identification, the container size, 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, or other critical factors specified in the scheduled process should also be recorded. When deviations occur in the application of the scheduled process refer to 7.8. In addition the following records should be maintained:

8.1.1 Processing in steam

8.1.1.1 Batch still retorts

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

8.1.1.2 Batch agitating retorts

As for still retorts (8.1.1.1) with additions of: in-going product consistency, functioning of condensate bleeder as well as retort speed. Where specified in the scheduled process it is important to also record container headspace and critical factors such as product consistency, maximum drained weight, minimum net weight and percent solids (7.5.3.1).

8.1.1.3 Continuous agitating retorts as for 8.1.1.2.

8.1.1.4 Hydrostatic retorts

The temperature in the steam chamber at the top and just above the steam-water interface, speed of the container conveyor chain, 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, other critical factors such as the headspace or 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 (8.1.2.1) with the addition of retort 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 (7.5.3.1).

8.1.2.3 Water hydrostatic retorts

Sterilization water temperature(s); sterilization chamber pressure; container conveyor chain speed; temperatures in the water legs as specified in the scheduled process; maintenance of water circulation.

8.1.3 Processing in steam/air mixtures

8.1.3.1 Batch still retorts
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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

8.1.4.1 Product sterilization

Product temperature in the final heater outlet; product temperature in the holding section outlet; differential pressure if a product-to-product regenerator is used; product flow rate.

8.1.4.2 Product container sterilization, filling and closing operations

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

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 and other data as necessary, so they can be correlated with the written record of lots processed. Each entry on 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 the product received the scheduled process. The records, including the recorder thermometer chart(s), should be signed or initialled by the person conducting the review.

8.2.2 Container closure records

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

8.2.3 Water quality records

Records should be kept of tests showing either that effective treatment was maintained or that the microbiological quality was suitable.

8.2.4 Retention of records

The records specified in 8.1 should be retained for not less than three years.

9. SECTION 9 - STORAGE AND TRANSPORT OF FINISHED PRODUCT

The materials used for labelling and casing or shrink wrapping canned products should not be conducive to corrosion of the container. Warm containers should not be stacked so as to form incubatory conditions for the growth of thermophilic organisms. If tinplate is kept moist, particularly for a long time in the presence of mineral salts or substances which are even very weakly alkaline or acidic, it is likely to corrode. 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 should be thoroughly dry. If they are made of wood it should be well seasoned. They should be 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. Canned products should be stored so that they will be kept dry to protect the containers from corrosion. The mechanical properties of outer cartons etc. are adversely affected by moisture and the protection of the containers against transport damage may become insufficient.

The storage temperature should be such as to prevent deterioration 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.
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SECTION 10 - LABORATORY CONTROL PROCEDURES
As in the General Principles of Food Hygiene (7.8).

SECTION 11 - 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 not contain (a) any harmful microorganisms or any other microorganisms capable of development in the food under normal storage conditions, or (b) any substances originating from microorganisms in amounts which may represent a hazard to health.

11.3 Low-acid canned foods should have received a heat processing treatment sufficient to provide commercial sterility.

11.4 The products should not contain any chemical pollutants in amounts which may represent a hazard to health.

11.5 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.
CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN

(UP TO THREE YEARS)
(Advanced to Step 5)

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CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN  
(UP TO THREE YEARS)

Sideline positions indicate material which is particular to this Code of Hygienic Practice and therefore does not appear in the "General Principles of Food Hygiene".

SECTION I - SCOPE

1.1 This Code of Hygienic Practice applies to all prepackaged foods produced, represented, or purported to be for the special use of infants and/or children.

It contains the minimum hygienic requirements for the handling (including production, preparation, processing, packaging, storage, transport, distribution and sale) of such food to ensure a safe, sound and wholesome product.
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#### SECTION II - DEFINITIONS

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

<table>
<thead>
<tr>
<th>Term</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate</td>
<td>Sufficient to accomplish the intended purpose of this code.</td>
</tr>
<tr>
<td>Children</td>
<td>Persons from the age of more than 12 months up to the age of three years.</td>
</tr>
<tr>
<td>Cleaning</td>
<td>The removal of food residues, soil, dirt, grease or other objectionable matter.</td>
</tr>
<tr>
<td>Contamination</td>
<td>The addition of any objectionable matter, directly or indirectly, to the product or the presence of any such matter in the product. Contamination includes infestation by pests.</td>
</tr>
<tr>
<td>Disinfection</td>
<td>The reduction without adversely affecting the food by means of hygienically satisfactory chemical agents and/or physical methods of the number of microorganisms to a level that will not lead to harmful contamination of food.</td>
</tr>
<tr>
<td>Edible Product</td>
<td>Product fit for human consumption.</td>
</tr>
<tr>
<td>Establishment</td>
<td>Any building(s) or area(s) in which food is handled after harvesting and the surroundings under the control of the same management.</td>
</tr>
<tr>
<td>Food Handling</td>
<td>Any operation in the production, preparation, processing, packaging, storage, transport, distribution, and sale of food.</td>
</tr>
<tr>
<td>Food Hygiene</td>
<td>All measures necessary to ensure the safety, wholesomeness, and soundness of food at all stages from its growth, production or manufacture until its final consumption.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<td>-------------------------------</td>
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</tr>
<tr>
<td>Hermetically sealed container</td>
<td>A container which is designed and intended to protect the contents against the entry of microorganisms during and after heat processing.</td>
</tr>
<tr>
<td>Infant</td>
<td>A person not more than 12 months of age.</td>
</tr>
<tr>
<td>Low acid food</td>
<td>Any food, other than alcoholic beverages, where any component has a pH value greater than 4.6 after heat processing.</td>
</tr>
<tr>
<td>Packaging Material</td>
<td>Any containers such as cans, bottles, cartons, boxes, cases, and sacks, or wrapping and covering material such as foil, film, metal, paper, waxpaper, and cloth.</td>
</tr>
<tr>
<td>Perishable food</td>
<td>To be elaborated, if necessary.</td>
</tr>
<tr>
<td>Pests</td>
<td>Any animals capable of directly or indirectly contaminating food.</td>
</tr>
<tr>
<td>Protective Clothing</td>
<td>Special garments intended to prevent the contamination of food and used as outer wear by persons in an establishment and includes head coverings and footwear.</td>
</tr>
<tr>
<td>Unfit for human consumption</td>
<td>An article that would normally be edible but is inedible because of disease, decomposition or any other reason.</td>
</tr>
</tbody>
</table>
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SECTION III - HYGIENIC REQUIREMENTS IN PRODUCTION/HARVESTING AREAS

3.1 Environmental Hygiene in areas from which raw materials are derived

3.1.1 Unsuitable growing or harvesting areas
Food should not be grown or harvested when the presence of naturally occurring substances would lead to an unacceptable level in the food.

3.1.2 Protection from contamination by wastes

3.1.2.1 Raw food materials should be protected from contamination with human, animal, domestic, industrial and agricultural wastes to an extent likely to be a hazard to health and adequate precautions should be taken to ensure that these wastes are not used or disposed of in a manner which may constitute a public 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
Water used for irrigation of food growing or producing areas should not 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 retained 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.

3.2.3 Removal of obviously unfit materials

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

3.2.4 Protection against contamination and damage

Suitable precautions should be taken to protect the raw products 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 on the place of production/harvesting

Raw materials should be stored under conditions that will protect against contamination and minimize damage and deterioration.

3.4. Transportation

3.4.1 Conveyances

Conveyances for transporting the harvested crop or raw product 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.

3.4.2 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 paragraph 4.4.1.2
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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 Yards
Roadways and yards serving the establishment and which are within its boundaries or in its immediate vicinity should have a hard paved surface suitable for wheeled traffic. There should be adequate drainage, and provision should be made to allow for cleaning.

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

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

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

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

4.3.5 Design: cross contamination
Buildings and facilities should be designed to provide separation between those operations which may cause cross-contamination, by partition, location or other effective means. Separate rooms or areas should be provided for unpacking, washing or peeling of raw materials, as the case may be.
4.3.6 Design: operation flow

Buildings and facilities should be designed to secure hygienic operations by means of a regulated flow in the process from the arrival of the raw material at the premises to the finished product, and should provide for appropriate temperature conditions for the process and the product. Where appropriate, separate rooms or areas suitably equipped for the required purpose, should be provided for cooking or sterilization of food.

Where cooling is required, the establishments should provide sufficient capacity in cooling and freezer space to handle maximum product flow.

4.3.7 In food handling areas:

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

- Ceilings should be so 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 Overhead structures
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 etc.
Living quarters, toilets and stables should be completely separated from and not open directly on to food handling areas.

4.3.10 Access control
If the establishment is not in its own building or buildings, the layout and control of access should be to prevent unauthorized persons from entering the establishment.

4.3.11 Materials
The use of material which cannot adequately be cleaned and disinfected such as wood, should be avoided, unless their 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 potable water 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 and pollution. The standard or potability should not be less than those contained in the latest edition of "International Standards of Drinking Water" (WHO). An adequate supply of hot potable water not less than +92 °C should be available at all times during the working hours.
4.4.1.2 Ice should be made from potable water 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 should be carried in completely separate lines, identified preferably by colour and with no cross-connection with or backsiphonage into the system carrying potable water. It should not be possible to connect lines carrying non-potable water to any equipment or cleaning-disinfection apparatus used in the handling of food. The constructions for non-potable water should be accepted by the official agency having jurisdiction.

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. These areas should be well lit, ventilated and, where appropriate, heated and should not open directly into food handling areas. Hand washing facilities with warm or hot and cold water and with suitable hand-cleaning preparations with suitable hygienic means of hand drying should be provided near toilets. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility. Taps should be of a non-hand operable type. Notices should be posted directing personnel to wash their hands after using the toilet.
4.4.4 Hand washing facilities in processing areas

For the use of personnel during operations adequate and conveniently located facilities for hand washing and drying should be provided wherever the process demands, especially in all areas where unpacked edible material is handled, and, where appropriate, facilities for hand disinfection. The facilities should be full view of the production area. Warm or hot and cold water and suitable hand-cleaning preparations 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 should be of a non-hand operable type. The facilities should be furnished with waste pipes leading to drains.

4.4.5 Disinfection facilities

In all processing areas wherever the process demands, adequate facilities for cleaning and disinfection of working implements and equipment should be provided. These facilities should be of such nature as to permit proper cleaning and disinfection. They should be constructed of corrosion-resistant materials and should be easy to clean. Facilities for cleaning and disinfection of implements should be fitted with suitable means of supplying hot and cold water in sufficient quantity. The temperature of the hot water should be not less than +82°C at all times while food is being handled in that part of the establishment.

4.4.6 Lighting

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

- 540 lux (50 foot candles) at all inspection points or points requiring otherwise close examination
- 750 lux
- 220 lux (20 foot candles) in work rooms
- 300 lux
- 110 lux (10 foot candles) in other areas
- 150 lux
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 another protecting enclosure of non-corrodable material. Screens should be easily removable for cleaning.

In areas where dry powdered materials are handled, special provisions such as suction hoods or room partitions should be used to prevent the spreading of dust.

4.4.8 Facilities for storage and disposal of waste and inedible material

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

4.5 Equipment and Utensils

4.5.1 Materials

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

4.5.2.2 Containers for inedible material and waste should be leak proof, constructed of metal or other suitable impervious material which is easy to clean, and be fitted with close-fitting lids.

4.5.2.3 All refrigeration units should be equipped with a thermometer.

4.5.3 Equipment identification

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

4.5.4 Tanks and vessels

All surfaces which may come in contact with food should be visible for inspection and readily accessible for manual cleaning. Bottoms of fixed vessels may be of the cone type or may be flat and inclined at an angle of 3-5° for easy drainage. In either case, a drain cock should be provided at the lowest point.

Mixing, blending and homogenizing equipment should be of a type which does not allow food to come into direct contact with seals and bearings which are often a serious source of contamination.
4.5.5 Piping

The piping system should be designed so as to permit free drainage and prevent the occurrence of blind sections in pipes, joints, valves and gauges.

Pipe runs should be kept as short as possible; right-angled joints should be avoided and pipes should slope to a drainage point with a recommended fall of at least 1 in 120.

Cocks, valves and gauges should be accessible and easily dismantled for inspection and cleaning.

4.5.6 Pumps

Pumps should be so designed as to be readily dismantled for cleaning.

Shaft seals should be of the mechanical type and accessible for inspection, and maintenance.

Bearings should be located outside the food zone and be of sealed or self-lubricating type.
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SECTION V - ESTABLISHMENT: HYGIENIC REQUIREMENTS

5.1 Maintenance

The buildings, equipment, utensils and all other physical facilities of the establishment, including drains, should be maintained in good repair and in an orderly condition.

As far as practicable, rooms should be kept free from steam, vapour and surplus water.

5.2 Cleaning and disinfection

5.2.1 Cleaning and disinfection should meet the requirements of this code. For further information on these procedures see Annex I of the Code of Practice "General Principles of Food Hygiene".

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

They should also be cleaned and disinfected at the conclusion of the work shift.

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 conform to public health requirements.

Any residues of these agents should be removed by thorough rinsing with potable water from any area or equipment that comes into contact with the food 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 be a permanent member of the staff of the establishment and whose duties ought to be divorced from 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. Completion of each task in the cleaning and disinfection schedule should be signed and dated in an appropriate record.

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

Dogs, cats and other domestic animals should be excluded from establishments.
APPENDIX VII

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 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 processing areas.
SECTION VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene training

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

6.2 Medical examination

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

6.3 Communicable 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 waterproof covering which is firmly secured, and which is conspicuous in colour. Adequate first-aid facilities should be provided for this purpose.
APPENDIX VII

6.5 Washing of hands
Every person engaged in a food handling area should wash his hands frequently and thoroughly with soap or other detergents under running warm, potable water while on duty. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 Personal cleanliness
Every person engaged in a food handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of, and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor.

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. Gloves should be made of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

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 paras 5.9, 6.3, 6.4, 6.7.

6.10 Supervision
Responsibility for ensuring compliance by all personnel with all requirements of paragraphs 5.9.1 - 5.9.10 inclusive should be specifically allocated to competent supervisory personnel.
SECTION VII - HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw material requirements in the establishment

Raw materials used for the production of food for infants and children should, where applicable, comply with their appropriate Codes of Hygienic Practice. If no appropriate Code of Hygienic Practice exists, the "General Principles of Food Hygiene" should apply.

7.1.1 Acceptance

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

Raw materials used for the production of food for infants and children should not contain pesticide residues or other objectionable substances in a concentration in the final product believed to constitute a health hazard for infants and children.

Raw materials destined for the production of food for infants and children should be of high hygienic condition.

Food of animal origin should only be derived from healthy stock.

7.1.2 Inspection and sorting

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 Storage of raw materials and ingredients

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.
APPENDIX VII

If perishable food has to be stored for any time longer than 30 minutes, the temperature of any part of this food should not exceed +7°C.

7.2 Prevention of cross-contamination

7.2.1 General remarks
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 Personal behaviour
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 or raw materials or semi-processed products which have come into direct contact with or have been soiled by raw material or semi-processed products.

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

7.2.4 Equipments
All equipments 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 General requirements
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
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 to food. However non-potable water may, with special acceptance of the official agency, be used in certain food handling areas, when this does not constitute a hazard to health.
7.3.3 Re-circulated water

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

7.4 Processing

7.4.1 Processing should be supervised by technically competent personnel.

7.4.2 All steps in the production process, including packaging, should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination, deterioration, or the development of pathogenic and spoilage micro-organisms.

7.4.3 Rough treatment of containers should be avoided to prevent the possibility of contamination of the processed product.

7.4.4 Methods of preservation should be such as to protect against contamination or development of a public health hazard and against deterioration within the limits of good commercial practice.

7.5 Packaging

All food for infants and children should be packed in containers which protect the food from contamination and deterioration.

7.5.1 Packaging material

All packaging materials 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
APPENDIX VII

should be sound and should provide appropriate protection from contamination.

7.5.2 Inspection

Product containers should not have been used for any purpose which may lead to contamination of the product. Containers should be inspected immediately before use to ensure that they are in a satisfactory condition and where necessary cleaned and/or disinfected; no water, other than potable water, should be used for washing empty containers. When washed they should be well drained before filling. Only packaging material required for immediate use should be kept in the packing or filling area.

7.5.3 Precluding contamination

Packing should be done under conditions that preclude the introduction of contamination into the product.

7.5.4 Product coding

Products sold or otherwise distributed from a manufacturing processing, packing, or repacking establishment should be coded to enable identification of lots and when necessary, segregation of specific food lots which may have become contaminated or otherwise unfit for their intended use. Records, adequate to identify the processing history of each lot, should be retained for a period that exceeds the life of the product, except that unless a specific need exists, they need not be retained more than two years.

7.6. Storage and transport of the end product

The end product should be stored and transported under such conditions as will preclude the contamination with and/or proliferation of micro-organisms and protect against deterioration of the product or damage to the container. During storage, periodic inspection of the end product should take place to ensure that only food which is fit for human consumption is despatched and that end product specifications should be complied with. The product should be despatched in the sequence of the lot numbers.

7.6.1 Thermally processed low acid canned food should be produced according to the Code of Hygienic Practice for Low Acid Canned Foods.
7.6.2 Checking for defects
Each lot should be checked after filling. Containers showing defects which may affect product quality, should be rejected.

7.6.3 Vacuum checking
In case of thermally processed vacuum packed containers, the vacuum of all containers should be checked after processing. Vacuum packed containers sealed with quick-twist, screw-on or snap-on lids, which have an annular space between the inner edge of the lid's rim and the container itself, should have such space eliminated by lid or container design or be made inaccessible by sealing.

7.7 Sampling and Laboratory Control Procedures
7.7.1 Each establishment should have access to laboratory control of the products processed. Such control should reject all food that is unfit for human consumption or that does not comply with the end product specifications.

7.7.2 Sampling
Representative samples of the end product should be taken to assess the safety and quality.

SECTION VIII - END PRODUCT SPECIFICATIONS

8.1 General
The food for infants and/or children should be free from foreign and other objectionable matter to the extent possible in good manufacturing practice, as well as free from toxic substances in a concentration believed to constitute a health hazard for infants and children.

8.2 Pesticide residues and food additives
The food for infants and/or children should comply with the requirements for pesticide residues and food additives laid down by the Codex Alimentarius Commission.

8.3 Microbiological specifications
The food should comply with the microbiological specifications laid down in Annex I. For the microbiological analysis, the methods contained in Annex II should be used.
### MICROBIOLOGICAL SPECIFICATIONS FOR FOODS FOR INFANTS AND CHILDREN (UP TO THREE YEARS)

<table>
<thead>
<tr>
<th>Product</th>
<th>Test Case</th>
<th>Class Plan</th>
<th>Limit per g m</th>
<th>Limit per g M</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>a) dried biscuit type product</strong>&lt;sup&gt;1&lt;/sup&gt;</td>
<td>none</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>1. plain</td>
<td>coliform</td>
<td>5</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>2. coated</td>
<td>Salmonella&lt;sup&gt;3&lt;/sup&gt;</td>
<td>11</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td><strong>b) dried &amp; instant products</strong>&lt;sup&gt;4,5&lt;/sup&gt;</td>
<td>Mesophilic aerobic bacteria&lt;sup&gt;6&lt;/sup&gt;</td>
<td>6</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>coliform</td>
<td>6</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Salmonella</td>
<td>12</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td><strong>c) dried products requiring heating before consumption</strong>&lt;sup&gt;5,8&lt;/sup&gt;</td>
<td>Mesophilic aerobic Bacteria</td>
<td>4</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>coliform</td>
<td>4</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Salmonella</td>
<td>10</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td><strong>d) thermally processed products packaged in hermetically sealed containers</strong>&lt;sup&gt;9&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>These products:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) shall be free of microorganisms capable of growth in the product under normal nonrefrigerated conditions of storage and distribution; and</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>c) products with a pH above 4.6 shall have received a processing treatment which renders the products free of viable forms of microorganisms having public health significance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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<sup>1</sup> dry shelf-stable products

<sup>2</sup> <3 means no positive tube in the standard-3-tube MPN method

<sup>3</sup> applies only to products containing one or more salmonella sensitive ingredients, e.g. chocolate coatings

<sup>4</sup> products intended for consumption after addition of liquid; includes dried infant formulas, instant infant cereals, etc.; microbial limits apply to dry product

<sup>5</sup> Supplementary foods, when end products are included. Examples are sweetening agents, starches, texturizers and similar products, singly or in combination

<sup>6</sup> not applicable to products which are produced by a microbial fermentation process

<sup>7</sup> products, intended for consumption after addition of liquid and which are specified to be heated at least to the boiling point before consumption; microbial limits apply to dry product

<sup>8</sup> includes aseptically canned products and liquid infant formulas.
APPENDIX VII

ANNEX II

METHODS FOR MICROBIOLOGICAL ANALYSIS FOR FOODS FOR INFANTS AND CHILDREN
(UP TO THREE YEARS)

Mesophilic aerobic bacteria

Draft International Standard ISO/DIS 4833
Refer to ICMSF (1974) chapter 7, page 83-91 for collection and preparation of samples for analysis; in all instances 25 g shall constitute a sample unit (analytical unit); incubation of agar plates shall be at 30°C.

Coliform count

Draft International Standard ISO/DIS 4831
Collection and preparation of samples, sample unit and incubation as in viable colony count above.

Salmonellae

According to the "Report of the 13th Session of the Codex Alimentarius Committee on Food Hygiene, Rome, 10 - 13 May, 1976, Appendix VI, para 9".
Collection and preparation of samples, sample unit and incubation as in viable colony count above.

Labour and cost of testing may be reduced by testing pooled sample units (analytical units). Studies have shown that salmonellae may be detected with equal accuracy, and that there is no significant difference in sensitivity when testing a large sample versus multiple subsamples. Therefore, the Working Group recommended that 25 g sample units may be composited to a quantity not to exceed 400 g. Analysis may then proceed as for a 25 g unit with appropriate change in equipment, media volume, etc.

American Health Association, 1015 18th St., N.W.
Washington D.C. 20036
GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF MICROBIOLOGICAL CRITERIA FOR FOODS

1. DEFINITION OF MICROBIOLOGICAL CRITERIA FOR FOODS

A microbiological criterion, as defined for Codex purposes, consists of:

1.1 a statement of the microorganisms of concern and/or their toxins. For this purpose, microorganisms comprise bacteria, viruses, yeasts, moulds and parasites;

1.2 the analytical methods for their detection and quantification;

1.3 a plan defining the number of field samples to be withdrawn and the size of the sample unit;

1.4 the microbiological limits considered appropriate to the food; and

1.5 the proportion of sample units that should conform to these limits.

2. APPLICATION OF A MICROBIOLOGICAL CRITERION

Microbiological criteria, as defined for Codex purposes, fall into three categories.

2.1 A microbiological standard is attached to a Codex Alimentarius standard, which is mandatory. It is intended for use in case of disputes. It shall not be introduced de novo but shall be derived from specifications which have accompanied Codes of Practice through the Codex Procedure and which have been extensively applied to the food.

2.2 A microbiological specification is attached to a Code of Practice, which is of an advisory nature, and is intended to increase assurance that the provisions of hygienic significance in the Code have been adhered to.

2.3 A microbiological guideline is to be used where no standard or Code of Practice for the particular food exists. A guideline should be established only when a microbiological criterion is urgently required for a food moving in international trade.
3. PURPOSES OF MICROBIOLOGICAL CRITERIA FOR FOODS

The purposes of microbiological criteria for foods are to protect the health of the consumer by providing safe, sound and wholesome products and to meet the requirements of fair practices in trade.

To fulfil these purposes, consideration should be taken of

- the microbiology of the raw material;
- the effect of processing on the microbiology of the food;
- the likelihood and consequences of microbial contamination and/or growth during subsequent handling and storage;
- the consumer at risk; and
- the costs associated with the application of the criteria.

4. GENERAL CONSIDERATIONS CONCERNING PRINCIPLES FOR ESTABLISHING AND APPLYING CRITERIA

The basis of control of microbiologically sensitive foods should be through the application of Codes of Practice and a microbiological criterion should be established and applied only where there is a definite need for it. The criterion should be technically attainable by good manufacturing practice in every instance so that it does not encourage the use of objectionable treatments in an attempt to reduce microorganisms to the acceptable level.

Special attention should be given to the development of criteria for rapidly perishable foods, where consumption may precede completion of current testing procedure.

The extent of testing shall be as defined in the criterion, and shall not be exceeded.

When establishing a microbiological criterion for a food, consideration should be given, on the one hand, to the hazard (taking into account the nature of the food, the processing, the subsequent handling practice and the consumer at risk) that may be associated with the food and, on the other hand, to the costs associated with the application of the criterion.
APPENDIX VIII

To make the best use of limited resources in money and manpower, it is essential that only specifically appropriate tests be applied for those foods and at those points in the processing and distribution of food that offer maximum benefit in terms of providing the consumer with a safe, sound and wholesome food.

5. INTERPRETATION OF RESULTS

It should be recognized that when a product fails to meet a criterion, the responsible person or authority has several options as to the action to take in response to the finding. Guidance with respect to certain options has been provided by ICMSF (1974) as follows:

"A food unsuitable for one purpose may still be suitable for another; for example, if 'rejected' for humans it might still be suitable for animals. Or a rejected food might even, if sorted to remove objectionable material, or if re-processed, be so improved as to pass the test and become acceptable for the original purpose. Normally, therefore, a rejected lot will simply be withheld while the responsible authority decides what to do with it: to return it to the producer, order re-processing, forbid its use for human consumption, or order its destruction, according to circumstances."

An official authority might in certain cases even decide to permit food having failed to meet a standard to enter normal commercial channels, if it is certain that thereby the consumer cannot be harmed. The risk that unacceptable food reaches the consumer must be kept to a minimum, but food must not be unnecessarily destroyed or declared unfit for human consumption.

6. COMPONENTS OF A MICROBIOLOGICAL CRITERION

6.1 Microorganisms of importance in a particular food

The microorganisms stated in a criterion should be widely accepted as...
relevant as pathogens, as indicator organisms or as spoilage organisms to the particular food and technology. Organisms whose significance or usefulness in a criterion would be contentious should be avoided.

The mere finding, with a presence-absence test of certain organisms which have caused food-borne illness (e.g. Staphylococcus aureus, Clostridium perfringens and Vibrio parahaemolyticus) does not necessarily indicate a hazard.

When choosing a test for an indicator organism, there should be a clear understanding as to whether the demonstration of this organism is used to indicate an unsatisfactory manufacturing practice or whether it is used to indicate the possible presence of a pathogen. In the latter case, such a test, however, should only be used when the pathogen cannot be detected directly.

6.2 Microbiological methods

For use in a criterion, official methods elaborated by international organizations occupying themselves with food or a group of foods should be preferred. Preference should be given to methods the reliability of which (accuracy, reproducibility, inter- and intra-laboratory variation) has been statistically established in comparative or collaborative studies in several laboratories. Where available, reference should be made to such studies. While reference methods to be used in standards should be the most sensitive and reproducible for that purpose, methods to be used in specifications and guidelines might often sacrifice to some degree sensitivity and reproducibility in the interest of speed and simplicity. They should, however, have been proved to give a sufficiently reliable estimate of the information needed.

When choosing a microbiological method as a reference method, consideration should be given to universal availability of media, equipment, etc.

Methods which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

Reference methods should serve as a basis of comparison where other methods are being selected for use in routine inspection or other control purposes.
APPENDIX VIII

6.3 Microbiological limits

Limits should be based on microbiological data appropriate to the food and the kind of criterion in question. Limits for standards and specifications should be based on data gathered at various stages of production and distribution, while limits for guidelines could be based on data obtained in monitoring programmes of the product offered for sale. They should take into consideration the risk associated with the presence of the organism and the number of organisms likely to affect the acceptability of the food, where these are known. Numerical limits should also take account of the distribution of microorganisms in the food and the inherent variability of the analytical procedure.

If a criterion requires absence of a particular microorganism, size of sample shall be indicated. It should be borne in mind that no feasible sampling plan can ensure complete absence of a particular organism. For the purpose of meeting a standard, absence is demonstrated when the criterion is met with.

Microbiological limits can be related only to the point of sampling and not to the presumed number of microorganisms at an earlier or a later stage.

6.4 Sampling plans

A sampling plan is the particular choice of sampling procedure and the decision criteria.

Sampling plans should be administratively and economically feasible and indicate the decision criteria used to determine lot acceptability.

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The criteria employed in describing 3-class plans are defined as follows:

n = The number of sample units which must be examined from a lot of food to satisfy the requirements of a particular sampling plan.

m = A microbiological criterion which, in a 2-class plan, separates good quality from defective quality; or, in a 3-class plan, separates good quality from marginally acceptable quality. In general m represents an acceptable level and values above it are marginally acceptable or unacceptable in the terms of the sampling plan.

M = A microbiological criterion which, in a 3-class plan, separates marginally acceptable quality from defective quality. Values above M are unacceptable in the terms of the sampling plan. In a 2-class plan M is not applicable.

c = The maximum allowable number of defective sample units. When more than this number are found, the lot is rejected by the sampling plan.
In particular, sampling plans should accommodate for heterogeneity of distribution of microorganisms. The 2- or 3-class plans, as proposed by the ICMSF (1974) may find useful applications.

Examples of sampling plans and microbiological limits are:

Salmonellae: Salmonella organisms should not be recovered from any of 10 sample units examined when the test is carried out according to the method described \((n = 10, c = 0, m = 0)\).

Mesophilic aerobic bacteria: Mesophilic aerobic bacteria should not be recovered from any of 5 sample units examined when the test is carried out according to the method described in a number exceeding \(10^6\) per g, nor in a number exceeding \(5 \times 10^4\) per g from 3 or more of the 5 sample units examined \((n = 5, c = 2, m = 5 \times 10^4, M = 10^6)\).

7. SAMPLING METHODS AND HANDLING OF SAMPLES

The time between field sampling and analysis should be as short as possible and the conditions (e.g. temperature), during transport to the laboratory, appropriate to the food, so that the results reflect - within the limitations given by the sampling plan - the microbiological condition of the lot presented for inspection.

8. REPORTING

The test report shall give the information needed for complete identification of the sample, the results, and the test method.

9. PROVISION FOR RECONSIDERATION AT REGULAR INTERVALS

Criteria should be reviewed and if necessary revised at three year intervals after their acceptance.
MICROBIOLOGICAL GUIDELINES FOR ICE MIXES AND EDIBLE ICES

Methods

For the purpose of these guidelines the procedures outlined in the Microbiological Specifications for Egg Products can be used for obtaining the appropriate number of field samples from a lot together with sampling methods and reference methods for detecting salmonellae and for enumeration of mesophilic aerobic bacteria and coliform bacteria.

MICROBIOLOGICAL GUIDELINES FOR ICE MIXES

Sampling plans and microbiological limits

Mesophilic aerobic bacteria: Mesophilic aerobic bacteria should not be recovered from any of the 5 sample units examined, when the test is carried out according to the method described, in a number exceeding $10^5$ per g, nor in a number exceeding $2.5 \times 10^4$ per g from 3 or more of the 5 sample units examined ($n = 5, c = 2, m = 2.5 \times 10^4, M = 10^5$).

Coliform bacteria: Coliform bacteria should not be recovered in a number exceeding 100 per g from any of the 5 sample units examined nor in a number exceeding 10 per g from 3 or more of the 5 sample units examined when the test is carried out according to the method described ($n = 5, c = 2, m = 10, M = 10^2$).

Salmonellae: Salmonella organisms should not be recovered from any of the 10 sample units examined when the test is carried out according to the method described ($n = 10, c = 0, m = 0$).

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2 Concentrated and dried ice mixes should be tested after the addition of the prescribed amount of water to give a product which conforms to the definition under section 3.2.1 of ALINORM 78/11.
MICROBIOLOGICAL GUIDELINES FOR EDIBLE ICES

Sampling plans and microbiological limits

Mesophilic aerobic bacteria: Mesophilic aerobic bacteria should not be recovered from any of the 5 sample units examined, when the test is carried out according to the method described, in a number exceeding $2.5 \times 10^5$ per g, nor in a number exceeding $5 \times 10^4$ per g from 3 or more of the 5 sample units examined ($n = 5$, $c = 2$, $m = 5 \times 10^4$, $M = 2.5 \times 10^5$).

Coliform bacteria: Coliform bacteria should not be recovered from any of the 5 sample units examined when the test is carried out according to the method described, in a number exceeding $10^3$ per g nor in a number exceeding 100 per g from 3 or more of the 5 sample units examined ($n = 5$, $c = 2$, $m = 10^2$, $M = 10^3$).

Salmonellae: Salmonella organisms should not be recovered from any of the 10 sample units examined when the test is carried out according to the method described ($n = 10$, $c = 0$, $m = 0$).
PROPOSALS FOR FUTURE ACTIVITIES IN FOOD MICROBIOLOGY —
REPORT OF THE AD HOC WORKING GROUP

I. INTRODUCTION

The Codex Committee on Food Hygiene had noted with appreciation the support of the United Nations Environment Programme which had enabled it to have expert advice on microbiological health hazards connected with foods through the discussions and recommendations of two Joint FAO/WHO Expert Consultations on Microbiological Specifications for Foods. The Consultations, held in 1975 and 1977 respectively, had reviewed the work already done by various international bodies in the field of microbiology and had made a number of recommendations to the Committee on Food Hygiene concerning Microbiological Specifications for Foods.

In particular the 2nd Session of the Expert Consultation had pointed out that while international specifications were necessary for a number of foods moving in international trade, such specifications could only be established when the significance of particular organisms in specific foods was fully understood and suitable microbiological methods and sampling plans had been agreed upon. To assist the Committee in this, the Consultation had set out guiding principles for the establishment and application of microbiological specifications for foods and had drawn up a list of 13 foods which in its view required attention as a matter of priority.

The Committee attached great importance to the advice given by the two Consultations and was most disappointed to learn that funds might not be available for further meetings of the Consultation. It was of the opinion that to provide continuity in the work already undertaken and to assure that the Committee had the best advice possible on microbiological matters, the Commission should strive for the establishment of an FAO/WHO Expert Committee on Food Microbiology. Such a committee would meet when necessary to consider particular subjects on which the Codex Committee on Food Hygiene required expert advice as a matter of priority.

The Committee during the session established an ad hoc Working Party to consider what measures were necessary to ensure that it received continuous advice on microbiological matters.

II. MEMBERSHIP OF THE WORKING PARTY

The membership of the Working Party was:

Dr. J.C. de Man (Chairman) Switzerland
Dr. J.H.B. Christian Australia
Mr. I.E. Erdman Canada
Dr. K. Gerigk Federal Republic of Germany
Dr. M. van Schothorst Netherlands
Dr. A.C. Baird Parker UK
Mr. E. Spencer Garrett USA
Mr. N. Insalata USA
Dr. L. Reinius WHO

III. PROPOSALS FOR FUTURE ACTIVITIES IN FOOD MICROBIOLOGY

The Working Party took note of the "Australian Comments on the Future of the Joint FAO/WHO Expert Consultation on Microbiological Specifications for Foods" and wholeheartedly endorsed the proposal to establish a joint FAO/WHO Expert Committee that will provide on a continuous basis advice in microbiological matters needed by the Codex Committee on Food Hygiene.

This expert committee would serve the following functions:

1. Identify the areas of potential microbiological concern
2. Determine priorities
3. Collect and evaluate available microbiological data
4. Review microbiological sampling plans, limits and methodologies, taking into account developments in microbiology and food technology and newly generated data.
This committee would therefore carry out some of the tasks given to the two Joint FAO/WHO Consultations, which have been widely recognized as very useful. Inasmuch as the proposed Committee will probably not be established in the next few years, a way must be found to carry out the work needed to fulfil the terms of reference of the Codex Committee on Food Hygiene.

As an interim solution the Working Party therefore recommended that a working group be established to function in the near future as an advisory scientific body to the Codex Committee on Food Hygiene.

This microbiological working group, which would meet on an ad hoc basis, would comprise a small number of knowledgeable food microbiologists with demonstrated experience and expertise in the specific subjects to be dealt with. The members of the working group would be appointed by the Chairman of the Codex Committee on Food Hygiene.

The first assignment for the microbiological working group would be to determine the utility, in terms of public health relevance, of the establishment of microbiological criteria for raw foods in general. More specifically, the group would address itself to the need of microbiological criteria for chilled and frozen raw poultry. This latter subject was recognized by the 2nd Joint FAO/WHO Expert Consultation to merit immediate attention. Economically, this choice was justified because of the great importance of chilled and frozen raw poultry in international trade.

The technical rationale for the choice of chilled and frozen raw poultry was based on the following:

1. Epidemiological data identifying raw poultry as a major cause of food-borne salmonellosis in man.
2. The recognized difficulty in breaking the epidemiological chain leading to human salmonellosis.
3. Data identifying that the great majority of documented food-borne disease was a result of consumer misuse of susceptible and/or contaminated foods. Poultry was a raw food commodity which traditionally had its widest usage in the home and through food service establishments.
4. Assessment of raw poultry as a source of microbial contamination could result in:
   - Reassessment of the probability of success of pathogen eradication programmes
   - Realization that it was necessary to accept a limited level of salmonella contamination in raw poultry
   - The necessity for periodic review of microbiological specifications
   - Further review of the use of indicator organisms as a measure of good manufacturing practices
   - Optimal use of the microbiological data as they became available to governments in their assessment of the incidence of salmonella in raw poultry.
## SUMMARY STATUS OF WORK
(prepared by the Secretariat)

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* To be distributed in due course
* Recommended omission of Steps 6 and 7
* Elaborated independently by the Codex Committee on Meat Hygiene
* Elaborated independently by the Codex Committee on Processed Meat Products
* Elaborated in collaboration with the Codex Committee on Fish and Fishery Products
### Table: Status of Documents on Hygienic Practice

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1/ Recommended omission of Steps 6 and 7
4/ The Codex Committee on Fish and Fishery Products also recommends omission of Steps 6 and 7. The Codes will not be attached to ALINORM 78/18A, but will be issued separately.
2/ To be included in the Code of Hygienic Practice for Egg Products (following adoption at Step 8).