codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE:

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

ALINORM 85/13A

CODEX ALIMENTARIUS COMMISSION

Sixteenth Session

Geneva, 1-12 July 1985

REPORT OF THE

TWENTIETH SESSION OF THE

CODEX COMMITTEE ON FOOD HYGIENE

Washington D.C., 1 - 5 October 1984

TABLE OF CONTENTS

	Paragraphs
INTRODUCTION	1
Opening of the Session	2
Adoption of the Agenda	3
Activities of WHO	4 - 10
Activities of ISO	11 - 14
REVIEW OF MATTERS RELEVANT TO THE COMMITTEE AS DISCUSSED BY THE EXECUTIVE COMMITTEE AND OTHER CODEX COMMITTEES	15 - 40
Approval of Amendment to International Code of Hygienic Practice for Desiccated Coconut - End-Product Specifications	15 - 16
Consideration of the Need to Revise the Codes of Hygienic Practice to Take into Account the Hazard Analysis Critical control Points (HACCP)	17 - 19
Codex Committee on Vegetable Proteins	20 - 23
Codex Committee on Processed Fruits and Vegetables	24
Joint ECE/CODEX Alimentarius Group of Experts on Standardization of Fruit Juices	25
Codex Committee on Fish and Fishery Products	26 - 27
Codex Committee on Processed Meat and Poultry Products	28 - 31
ENDORSEMENT OF HYGIENE PROVISIONS IN CODEX STANDARDS	32 - 40
Consideration of Microbiological Criteria for Pre-Cooked Frozen Shrimps and Prawns at Step 4	41 - 46
Recommended International Code of Hygienic Practice for Desiccated Coconut (CAC/RCP 4-1971)	47 - 50
Consideration of Draft Code of Practice for the Salvaging of Damaged Canned Goods at Step 4	51 - 59
Amendment of the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods	60 - 61
ELABORATION OF MICROBIOLOGICAL CRITERIA FOR: (a) Bottled Drinking Waters other than Mineral Waters	62 - 64 65 - 71 72 - 76 77 - 78
CONSIDERATION OF AMENDMENT TO CODE OF HYGIENIC PRACTICE FOR EGG PRODUCTS TO INCLUDE "MELANGE" AT STEP 4	79 - 81
AMENDMENT OF CODE OF GENERAL PRINCIPLES OF FOOD HYGIENE	82 - 112
HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP) - GENERAL CONSIDERATION FOR INCLUSION IN CODEX CODES OF HYGIENIC PRACTICE	113 - 124
CONSIDERATION OF A CODE OF HYGIENIC PRACTICE FOR SPICES	125 - 141
REPORT OF THE AD-HOC WORKING GROUP ON NATURAL MINERAL WATERS	142 - 156

	Paragraphs
CONSIDERATION OF PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRECOOKED MEALS IN MASS CATERING AT STEP 4	157 - 165
REPORT ON AN AD-HOC WORKING GROUP ON "SALVAGING OF DAMAGED CANNED GOODS" AND "LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS" - ITEMS 5-7	166 - 172
OTHER BUSINESS	173 - 181
Date and Place of Next Session	182 - 183

CODEX COMMITTEE ON FOOD HYGIENE Washington D.C., 1 - 5 October 1984

INTRODUCTION

1. The 20th Session of the Codex Committee on Food Hygiene was held in the Main Conference Room, Department of State, Washington, D.C. from 1 to 5 October 1984 by courtesy of the Government of the United States of America. The Session was attended by representatives and observers from 21 countries and 3 international organizations. The Chairman of the Session was Dr. R.B. Read, Director, Division of Microbiology, FDA. A list of participants is attached as Appendix I.

Opening of the Session

2. Dr. Read opened the Session and introduced Dr. Douglas Archer, Director of Microbiology, FDA, who made a statement on the Chronic Effects of Diarrhoeal Disease and the important role of the Committee in combatting disease by establishing criteria for food hygiene internationally. The full text of Dr. Archer's statement is attached as Appendix II.

Adoption of the Agenda

3. The Committee adopted the agenda with some changes in the sequence of the items to be discussed.

Information on Activities within WHO of Interest to the Committee

- The representative of WHO reviewed the activities of his organization relating to the work of the Committee. He informed the Committee of the different programmes of WHO (Veterinary Public Health, Food Safety Programme, Diarrhoeal Diseases Programme, Nutrition, International Programme on Chemical Safety) involved in food hygiene activities. WHO had convened at the beginning of 1984 a consultation on Veterinary Public Health Aspects of Prevention and Control of Campylobacter infections. The consultation reviewed the problem of campylobacteriosis in different countries and new data on the ecology of C. jejuni; considered the role of animals and foods of animal origin in the epidemiology of this disease, selected the most suitable methods for the isolation of this organism from animals, foods and the environment, and considered the most important and practical veterinary public health measures for the prevention and control of this foodborne disease in humans. The report of this consultation (VPH/CDD/FOS/84.1) is still available in the Organization.
- 5. WHO Guidelines on Small Slaughterhouses and Meat Hygiene for Developing Countries (VPH/83.56) have been finalized and issued in Geneva. They contain valuable information on the hygienic slaughtering of animals and are well illustrated (15 figures, 12 photographs and 8 detailed plans of the construction of small slaughterhouses).
- 6. The draft Monograph on Histamine Poisoning which was introduced at the previous meeting of the Food Hygiene Committee, was considered by the Codex Committee on Fish and Fishery Products (7-11 May 1984, Bergen). Some comments received from fish specialists will be incorporated into the document which is planned for issue this year.

- 7. The document on Paralytic Shellfish Poisoning (WHO Offset Publication No. 70, Geneva, 1984) was published and may be obtained from WHO Headquarters or from official WHO booksellers in the member countries. It contains up-to-date information on the public health significance of paralytic shellfish poisoning, chemical and physical properties of the toxins, surveillance, prevention and control of such intoxication and recommendations on international programmes, coordination and cooperation in this field.
- 8. The Organization also published the following documents: "Role of Food Safety to Health and Development" (WHO Technical Report Series No. 705, 1984); "International Source List of Audiovisual Materials" (for food safety); "WHO Guidelines for Drinking Water Quality" (Vol. I, 1984); "Guidelines for the Study of Dietary Intakes of Chemical Contaminants" (1983); "Mass Catering" (WHO Regional Publication, EURO Series N15, 1983).
- 9. In November this year, a FAO/WHO Expert Consultation on Veterinary Drug Residues in Food will be convened. These residues were tentatively defined as "any substance applied or administered orally or parenterally to any food-producing animals, meat or milk-producing animals, poultry, fish, or bees, whether for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour". The agenda of the expert consultation will include consideration of the current use of veterinary drugs, their health aspects, safety evaluation, regulatory schemes for the control of residues, methods of analysis and detection and the international approach to the safety evaluation and control.
- 10. In the near future the Organization will issue: Volumes II and III, "WHO Guidelines for Drinking Water Quality"; "WHO Training Guidelines for Safe Food Handling in Hotels, Restaurants and Similar Establishments"; "Professional Profile for Food Inspectors"; "Disinfection in Animal Husbandry for Prevention and Control of Zoonotic Diseases"; "Safe and Hygienic Disposal of Dead Animals".

ACTIVITIES OF ISO

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

Food Microbiology TC34/SC9

- 12. The 10th Session of Sub-Committee 9 of Technical Committee 34 "Agricultural Food Products" had taken place in Helsinki, from 11 to 13 April 1984, at the same time as the meeting on microbiology of the International Dairy Federation (IDF).
- 13. The following topics were discussed:

ISO/DIS 7218 General Guidance for Microbiological Analysis

The following points were raised:

It seemed interesting to introduce a paragraph on the isolation and purification of colonies and to give more details in the MPN section.

The stipulated 2 mm minimum thickness of petri dish agar medium was thought to be insufficient.

The draft would be considerably amended and presented as a final draft before the end of the year.

DP 7954 General Guidance for the Enumeration of Yeasts and Moulds

The detailed comments on the project had been studied and agreement reached on the follow-ing points:

The request of several countries to add tween 80 to the culture medium was not accepted since tests had not given significant results.

A note was added giving oxytetracycline as an alternative to chloramphenicol.

Reference incubation for enumeration is 5 days at 25°C with examination and enumeration at 3 and 4 days as a precaution against invasion before completion of the incubation period.

Expression of Results

The formula recommended in recent IDF documents was adopted with a certain number of modifications which will be given in the general document DIS 7218.

DP 7932 General Guidance for Enumeration of Bacillus Cereus-Colony Count Technique

It was decided to prepare a note giving instructions for handling egg yolks aseptically since filtration of egg yolk emulsion presented difficulties in many countries.

More precise details were added to the description of <u>Bacillus cereus</u> with regard to colony colour, fermentation reactions and the precautions to be taken in the presence of mannitol fermenters.

It was also decided to provide for an alternative (alpha-naphthol) to detect nitrites since the reagents for 5-2 ANSA solution are not easily obtained commercially.

DP 8523 General Guidance for the Detection of Enterobacteriaceae

The usefulness of the method with resuscitation was confirmed as essential for enumeration of small numbers (MPN technique) and should now be included in the above document. Delegates were asked to try out the method so that their comments could be studied at the next SC9 meeting.

Preparation of a Sample for Microbiological Analysis

It was thought difficult to establish a document on sample preparation because of the great variety of products to be covered.

However, it seemed useful to include some general information on microbiological examination in the general document DIS 7218 including prevention of spoilage, keeping temperatures and sample-opening procedures.

Detection of Vibrio Parahaemolyticus

Tests carried out by France and interlaboratory tests by ICMSF were discussed. The latter demonstrated difficulties in the method because of the considerable number of unexpected results which made it difficult to draw conclusions. Comparison of the media used by France; (Salt/peptone water and GSTB-Glucose salt tryptone broth) and by ICMSF, (GSTB and salt/polymyxin broth) did not show any great differences and France would propose a first draft of a method for trial in the near future.

Influence of Temperature on the Enumeration of C. perfringens

Results of an interlaboratory study in France were reported but no amendments were made to the international standard "General Guidance for the Enumeration of Clostridium perfringens

(DIS 7937)". Countries were nevertheless asked to make comparative tests at 46° C and 37° C so that more results would be available should temperature modification be reviewed in a future version of the Standard.

Microbiological Examination of Canned Products

Codex work on this point was noted and the results awaited.

Revision of ISO Standards 4831 - 4832 - 4833

It was decided to revise the above standards (for details see Appendix III of the Report). Revision of ISO 6579 relating to Salmonella was already in progress.

Future Work

It was decided to begin work on procedures to be followed when conducting interlaboratory microbiological trials. A first draft would be prepared by The Netherlands.

Interest in methods for Campylobacter and Yersinia was reiterated.

The next meeting of SC9 would take place in October 1985 in a country to be nominated.

ISO/TC 147/SC4 Water Microbiology

14. Progress in the above Committee which met in Stockholm in June 1982 was given in the report of the last session of the Committee (see ALINORM 85/13, para. 17) at which time France had relinquished the Secretariat of SC4. At the last meeting in The Hague (October 1983) no member body was prepared to assume the Secretariat and the TC 147 Secretariat agreed to carry on with the task for a limited period of time. The Working Group SC4 was therefore able to meet during the session.

Progress of work:

General guidance for microbiological analysis (SC4/WG 1)

A proposal for a DP (DP 8199) has been examined by the working group. A revised version should be circulated in 1984.

Coliforms (SC4/WG 2)

The proposals for enumeration of presumptive coliforms and presumptive thermotolerant coliforms by enrichment in liquid medium and by membrane filtration (completed by a method for the detection of presumptive $E.\ Coli.$) have been studied by the working group. They should be circulated as ISO/DP in 1984.

Pseudomonas aeruginosa (SC4/WG 3)

The comments on DP 8360/1 (Enrichment in Liquid Medium) and DP 8360/2 (Membrane Filtration) have been discussed by the working group. Revised documents should be sent to the ISO Secretariat for registration as DIS.

Faecal streptococci (SC4/WF 4)

ISO/DIS 7899 (parts 1 and 2) has been submitted to the ISO member bodies for voting. The voting was terminated on 8 March 1984.

Spores of sulfite reducing anaerobics (SC4/WG 5)

DP 6461 (parts 1 and 2) were circulated to the members of SC4 in 1983. The revised document has been given to the Central Secretariat of ISO for registration as DIS.

Salmonella (SC4/WG 7)

DP 6340 has been submitted for voting in 1984.

Quality of membrane filters used for water microbiology (SC4/WG 9)

ISO/DIS 7704 were circulated to the TC 147 (voting terminated on 15 March 1984. The publication of an international standard is expected for the next months.

A list of the existing ISO documents in the field of Food Products Microbiology is given in Appendix III.

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

Approval of Amendment to International Code of Hygienic Practice for Desiccated Coconut - End-Product Specifications

- 15. The Committee noted that the Executive Committee at its 31st Session (ALINORM 85/3) had considered the Committee's proposal to amend the end-product specifications of the above Code (CAC/RCP 4/5 1971) to include limits for Salmonella (see ALINORM 85/3, paras 111-115) and to advance the amendment to Step 3 of the Procedure.
- 16. The Executive Committee had approved the measures taken by the Committee with regard to the above amendment.

CONSIDERATION OF THE NEED TO REVISE THE CODES OF HYGIENIC PRACTICE TO TAKE INTO ACCOUNT THE HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP)

- 17. The Committee noted that HACCP, which had been briefly discussed at its last session (see ALINORM 85/13, paras 30-33), had also been considered by the Executive Committee for introduction into Codex Codes of Practice, especially those which had been published some time ago and might need revision.
- 18. The Executive Committee had noted that the Committee had already begun the elaboration of Codes of Hygienic Practice along HACCP lines and had agreed that there was a need to review and possibly revise those Codes of Practice which did not follow the HACCP concept. However, it foresaw a heavy workload and requested the Codex Committee on Food Hygiene to examine the problem and to report to the Commission how the work could be accomplished.
- 19. The Committee agreed to discuss the matter in detail under the appropriate agenda item (see paras 113-124).

OTHER CODEX COMMITTEES

Codex Committee on Vegetable Proteins (CCVP) (Third Session, ALINORM 85/30)

- 20. The above Committee had considered hygiene provisions in the following standards:
- Draft General Standard for Vegetable Protein Products
- Draft Standard for Soy Protein Products
- Draft Standard for Wheat Gluten

- 21. The CCVP noted the general opinion of the Delegation of Argentina that the requirement to be "free from pathogenic micro-organisms" would need costly and expensive analytical work and that control should concentrate on pathogenic micro-organisms which could be present in each type of product.
- 22. The Delegation of The Netherlands was also of the opinion that end-product specifications should be established for VPP.
- 23. The CCVP noted these opinions and decided not to proceed with end-product specifications but to include the general texts for hygienic provisions which had been elaborated by the Committee.

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV) (17th Session - ALINORM 85/20)
Revised Draft Standard for Canned Palmitos

24. In discussing the hygiene section of the above Standard, the Delegation of France was of the opinion that an equilibrium pH of below 4.6 was necessary to inhibit spores of C. botulinum. France subscribed generally to a pH limit of 4.5 as a safety measure for all products concerned. The CCPFV was informed that the present text reflected the position which CCFH had established generally and CCFH decided to leave the provision unchanged.

JOINT ECE/CODEX ALIMENTARIUS GROUP OF EXPERTS ON STANDARDIZATION OF FRUIT JUICES (CCFJ)
(16th Session - ALINORM 85/14)

Aseptic Packaging

25. The Delegation of India drew attention to the increasing use of aseptic packaging for fruit juices and pulps and to the potential problems of contamination through the use of sanitizers. CCFJ had agreed that this subject would be of relevance to many Commodity Committees and agreed to refer it to the CCFA and CCFH for the possible elaboration of a Code of Practice covering aseptic packaging. The Committee noted that such provisions were already included in the "Low Acid Canned Foods" Code.

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS (CCFFP) (16th Session - ALINORM 85/18)

Microbiological Criteria for Precooked Frozen Shrimps and Prawns

26. The CCFFP had noted that the specifications recommended by the Committee at its last session (see ALINORM 85/13, paras 116-122) should be attached to the Code of Hygienic Practice for Shrimps and Prawns as end-product specifications and agreed with this point of view (see also paras 41-46).

Microbiological Specifications for Frozen Cooked Crabmeat

27. The Committee noted that an ad-hoc Working Group of the CCFFP had considered the above and had proposed that the microbiological limits already recommended for Precooked Frozen Shrimps and Prawns should also apply to Frozen Cooked Crabmeat. These recommendations would be circulated to governments for comment and would be considered by the Committee at its next session.

CODEX COMMITTEE ON PROCESSED MEAT AND POULTRY PRODUCTS (CCPMPP) - (12th Session - ALINORM 83/16)

Recommended International Code of Hygienic Practice for Processed Meat and Poultry Products

28. The Committee recalled that at its last session it had made recommendations to

the CCPMPP concerning Sampling and Inspection Procedures for the Microbiological Examination of Meat Products in Hermetically Sealed Containers (ALINORM 83/16, Appendix III and ALINORM 85/13, paras 61-74) which was annexed to the above Code.

- These recommendations would be considered at the next session of the CCPMPP later this month, and it was the hope of that Committee that the Code could be finalized at its next session and submitted to the 16th Session of the Commission in July 1985 without further consideration by this Committee.
- 30. The Committee noted the general opinion of the delegates that, in view of the importance of this Code and the changes that have been made throughout the text, it should be reviewed by this Committee before submission to the Commission.
- 31. The Committee agreed that the usual course of action should be followed and that it would review the Code at its next session.

ENDORSEMENT OF HYGIENE PROVISIONS IN CODEX STANDARDS

Coordinating Committee for Europe

Draft African Regional Standard for Gari at Step 8

- 32. The Committee was informed that the hygiene provisions in the regional standard for Gari, a fermented and toasted cassava product, required endorsement.
- 33. The Committee agreed to Section 6.1 but did not agree with the wording of Section 6.2 (a)(b)(c). It decided that Section 6.2 of the wheat flour standard was more appropriate from the public health point of view. The text recommended reads as follows:
 - 6.1 Unchanged
 - 6.2 When tested by appropriate methods of sampling and examination the gari shall be:
 - 6.2.1 to the extent possible in Good Manufacturing Practice, free from objectionable matter,
 - 6.2.2 free from micro-organisms, substances originating from micro-organisms or other poisonous substances in amounts which may reasonably represent a hazard to health.

34. Codex Committee on Vegetable Proteins

- Draft Codex General Standard for Vegetable Protein Products (VPP) (Step 5)
- Draft Codex Standard for Soy Protein Products (Step 5)
- Draft Codex Standard for Wheat Gluten (Step 5)

The Committee endorsed the following provision for the above standards:

6. HYGIENE

- 6.1 It is recommended that the products covered by the provisions of this Standard be prepared in accordance with the appropriate sections of the Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 1).
- 6.2 To the extent possible in good manufacturing practice, the products shall be free from objectionable matter.

- 6.3 When tested by appropriate methods of sampling and examination, the product:
 - (a) shall be free of micro-organisms which may represent a hazard to health
 - (b) shall not contain any substances originating from micro-organisms in amounts which may represent a hazard to health; and
 - (c) shall not contain any other poisonous substances in amounts which may represent a hazard to health.
- 35. Joint ECE/Codex Alimentarius Group of Experts on Standardization of Fruit Juices
 - Draft Codex Standard for Pulpy Mango Products (Step 8)
 - Draft Codex Standard for Guava Nectars (Step 8)
- 36. The Committee noted that CCFJ had examined the above standards and had included the same hygiene provision as in other standards for fruit juices and nectars.
- 37. The Committee endorsed the hygiene provisions in the above standards.
- 38. Godex Committee on Cereals and Cereal Products (CCCP) (ALINORM 85/29)
 - Draft Codex Standard for Whole Maize Meal (Step 8)
 - Draft Codex Standard for Degermed Maize Meal and Grits (Step 8)
- 39. The Committee noted that the hygienic provisions were identical to those already endorsed in the Standard for wheat flour and agreed to endorse the provisions.

Draft Codex Standard for Certain Pulses (Step 5)

40. The Committee noted that the hygiene provisions were identical to those already endorsed in the Standard for Maize and agreed to endorse the provisions.

Consideration of Microbiological Criteria for Pre-Cooked Frozen Shrimps and Prawns at Step 4

41. The WHO Representative introduced the previous discussion on this topic and in particular recalled that at its 19th Session the Committee had agreed to accept the following microbiological criteria for the Code of Hygienic Practice for Shrimps and Prawns. (Methods to be added later):

Mesophilic aerobic bacteria n = 5, c = 2, $m = 10^5$, $M = 10^6$ Staphylococcus aureus n = 5, c = 2, m = 500, M = 5000Salmonella n = 5, c = 0, m = 0

It was the general consensus of the Committee to recommend the above microbiological criteria as end-product specifications (not guidelines) and circulate them to governments at Step 3 of the Procedure (ALINORM 85/13, paras 116-122).

- 42. At its 16th Session, CCFFP agreed with the recommendations of the Committee on the proposed microbiological limits as end-product specifications to be attached to the Code of Hygienic Practice for Shrimps and Prawns (ALINORM 85/18, paras 46-53).
- 43. Written comments on the document had been received from Ireland, the UK and Sweden.

The Committee noted that Ireland in its written comments was "strongly in favour of keeping the criteria as guidelines for the present." Since this matter was thoroughly discussed previously (ALINORM 85/13, paras 116-119), the Committee confirmed its former decision to recommend the criteria as end-product specifications.

- The Delegation of the United Kingdom confirmed these criteria as end-product specifications to be used in association with a code of hygienic practice at the point of manufacture. From extensive testing done in the United Kingdom, 50% of the batches of warm water shrimps and prawns would fail the mesophilic aerobic count limit in this draft specification but there had not been a serious outbreak of food poisoning attributed to shrimps and prawns.
- The Delegation of Sweden expressed some concern with regard to the proposed figures for Staphylococcus aureus, but after discussion it withdrew its proposal to change the limits already recommended.
- The Delegation of France suggested the inclusion into end-product specifications of a new criterion, namely faecal coliforms as a simpler test of faecal contamination. The Delegation of the United Kingdom reminded the Committee that the addition of faecal coliforms into end-product specifications had been considered by the FAO/WHO Expert Committee on Microbiological Specifications for Foods. The findings were summarized in "Microbiological Criteria for Foods Summary of Recommendations of FAO/WHO Expert Consultations and Working Groups 1975–1981", WHO document VPU/83.54, as follows: "The available data on the occurrence of enterobacteriaceae, coliforms, faecal coliforms and E. coli in precooked frozen shrimps and prawns were reviewed. It was concluded that testing for these organisms offered no added benefit in deciding lot acceptability". The Committee believed that this statement was still valid and agreed to advance the microbiological end-product specification to Step 5 of the Procedure with a recommendation to omit Steps 6 and 7, and adopt them at Step 8.

Recommended International Code of Hygienic Practice for Desiccated Coconut (CAC/RCP 4-1971)
- Consideration of Amendment of Section V (Microbiological End-Product Specifications)

47. The WHO Representative introduced the previous discussion on microbiological specifications for desiccated coconut. In particular, it was recalled that at its 19th Session the Committee had decided that the above Code should be amended as follows (ALINORM 85/13, paras 111-114):

"Section V - End-Product Specifications:

- (A) Salmonellae: Salmonella organisms should not be recovered from any of the 25-gram samples examined when the test is carried out according to the method described (n = 10, c = 0, m = 0). Appropriate Method; ISO 3565-1975.
- (B) The product should not contain any substances originating from micro-organisms, particularly mycotoxins, in amounts which exceed the tolerances or criteria established by the official agency having jurisdiction."
- The 31st Session of the Executive Committee <u>agreed</u> to the measures taken by the committee with regard to the amendment of the End-Product Specifications in the Code of Hygienic Practice for Desiccated Coconut (ALINORM 85/3, paras 143-149).
- 49. The Delegations of U.S.A., Thailand and Japan expressed themselves in favour of the amendment and recommended its advancement to the next step of the Codex procedure. The Delegation from Thailand noted that at the present time ISO had elaborated a general method

for isolation of Salmonella (ISO 6579-1981) which was more appropriate than that cited in the proposed amendment (ISO 3565-1975). the ISO Representative <u>supported</u> the proposal of the Delegation of Thailand to change the reference which <u>was accepted</u> by the Committee.

Status of End-Product Specifications

50. The Committee $\underline{\text{decided}}$ to advance the above amendment to Step 5 with omission of Steps 6 and 7 for adoption by the Commission at Step 8 of the Procedure.

Consideration of Draft Code of Practice for the Salvaging of Damaged Canned Goods at Step 4

- 51. The Committee had before it the above document as contained in Appendix VII to ALINORM 83/13 and comments thereon from Ireland, Switzerland, Thailand and United Kingdom (CX/FH 84/3).
- The Delegation of Canada acting as rapporteur referred to the written comment of the United Kingdom which requested that the term "damaged canned products" should be clarified in the scope. The rapporteur also indicated that the Committee should consider whether the original intent of the document mainly to apply to foods damaged by calamity (fire, flood, shipping accidents) should be expanded to other cases such as sorting of lots where canned seam damage had been detected at the manufacturing stages.
- 53. The Delegation of The Netherlands was of the opinion that this Code should be of a general nature and should not cover details for specific products. Furthermore this code should not attempt to give instructions for the canning process as such.
- The Delegation of the Federal Republic of Germany questioned the feasibility of drawing up a Code for the salvaging of canned goods since in its opinion there was a large variety of products and types of distress and it would not be possible to cover every enventuality in the code. It also pointed to the need for a sampling plan to separate salvageable and non-salvageable cans and possibly microbiological tests. At present no methods or sampling plans were available. The delegation was of the opinion that the Code should only apply to salvaging of canned goods in cases of calamity.
- 55. The Committee <u>noted</u> the view of the rapporteur that this document could cover many useful aspects for the salvaging of damaged canned goods. It <u>also noted</u> the opinion of the Chairman that problems which arose during manufacture could be considered in connection with the Code of Practice for Low Acid and Acidified Low Acid Canned Foods.
- 56. The Committee <u>agreed</u> to reconvene the Working Group on the above code to examine in detail the written comments and the proposals as reflected in paras 51-54 above, and to report their findings back to the plenary session.

Provisions for the Visual Inspection Examination of Canned Foods

The Committee recalled that at its previous session it had decided to prepare two documents, one on Visual Inspection of Canned Foods and one on Microbiological Examination and Methods. The Rapporteur, Dr. I.E. Erdman (Canada), reported on the progress made so far. He indicated that the Working Group on Visual Inspection of Canned Foods had met in Chipping Campden in April 1984 and had considerably improved the illustrated document. However, the work had not yet been completed. The Committee noted that the U.K. had submitted a note on sampling plans and acceptance criteria for visual can examination (CX/FH 84/4) and decided to refer this matter also to the Working Group with an instruction to report back to the plenary session. The United Kingdom's note is attached as Appendix IV to this report.

- The Committee also <u>noted</u> that the FAO/WHO Working Group on Microbiological Specifications and Examination of Canned Foods had met from 24-28 September 1984 in Washington and that the report of that Working Group would be available later in the session.
- The Committee <u>agreed</u> to attach the report to the final report of this session to give governments an opportunity to comment on the findings of the Working Group. (See Appendix X).

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

- 60. The Rapporteur of the Working Group which met in Chipping Campden, as indicated in para. 57 stated that the primary purpose of the Working Group had been to propose amendments to the above Code based on the instructions of the Committee at its 19th Session. The report of the Working Group containing the amendments had been submitted to this Committee. (See Appendix V). The Committee noted that Governments had not yet been able to examine the proposal and decided therefore to refer it first to the Working Group which had been established to meet during this session (see para. 56).
- 61. The Committee <u>expressed</u> its appreciation for the valuable work carried out by the different Working Groups on these matters and <u>acknowledged</u> the special contributions made by Dr. Erdman.

BACKGROUND DOCUMENT ON THE ELABORATION OF MICROBIOLOGICAL CRITERIA FOR:

- (a) Bottled Drinking Waters other than Mineral Waters;
- (b) Soy Products
- (c) Dried Fish and Fishery Products
- 62. The Committee recalled that the Delegation of the United States had at its 19th Session agreed to prepare a background paper on the above topics and had accepted the delegation's offer.
- 63. The Delegation of the United States informed the Committee that it had sent a questionnaire to participants at the previous session of the Committee. The six replies received were summarized in Working Paper CX/FH 84/12.
- The Committee considered the need for microbiological criteria in the light of the information received.

A. Bottled Drinking Water Other Than Mineral Water ___ __

- The Delegation of Canada stated that the use of such waters was increasing for several reasons, among them unsuitability of local ground water. He also pointed out that this type of water was used for the cleaning of contact lenses in the widespread belief that such waters were sterile. An established flora could be introduced in the bottling system through the use of ion exchange and this could lead to high bacterial counts in the final product. The Delegation of Canada, therefore, proposed to begin work on microbiological criteria for bottled drinking water.
- 66. The Delegation of The Netherlands questioned whether there was a significant international trade in such products and stated that the microbiological specifications for these products should be not less stringent than those for drinking water.

- 67. The Delegation of France explained that in its country both bottled table water and mineral water were used. It indicated that it was not of commercial interest to ship bottled table water and, therefore, it was not necessary to develop specifications.
- 68. The Delegation of Norway indicated that while it had a small export of bottled table water, it did not see a reason to develop specifications for such products. The Delegation of the United States pointed out that there was international trade in countries outside Europe and USA. This was supported by the Federal Republic of Germany which, however, felt that the WHO International Guidelines on Drinking Water should apply.
- 69. The Chairman pointed out that the product was sold without refrigeration and that a frequent problem was the proliferation of bacterial growth followed by lysis and regrowth and was such that it was difficult to meet the drinking water standard.
- 70. Several of the delegations were of the opinion that bacterial growth could be limited either by light chlorination or pasteurization.
- 71. The Committee <u>decided not to proceed</u> with the elaboration of microbiological criteria for bottled drinking water within Codex.

Soy Products

- 72. The Delegation of Canada indicated that there was extensive trade in soy products but more difficulties had been encountered with extraneous matter such as insects than with microbiological contamination. The Delegation of the USA held the view that certain types of soy products were covered by the "Low Acid" Code; however, refrigerated products (e.g., bean curd and fermented soy products) were not covered. The Delegations of the USA and Canada stated that they were in favour of the elaboration of microbiological criteria for soy products.
- 73. The Delegation of The Netherlands supported by Norway stated, that due to their very short shelf life, these products did not enter international trade.
- 74. The Committee <u>noted</u> the proposal that it might be appropriate to await the dewelopments in the Codex Committee on Vegetable Proteins (CCVP).
- 75. The Secretariat pointed out that in that Committee the terms of reference covered vegetable protein products where the protein content had been increased and that it was doubtful whether bean curd or similar products would fall within the remit of the CCVP.
- 76. The Committee <u>decided not to commence</u> work on microbiological criteria for soy products.

Dried Fishery Products

- 77. The Delegation of the Netherlands was of the opinion that the Committee on Fish and Fishery Products (CCFFP) should be requested to examine the possibility of developing a Code of Practice on these very important products and at a later stage the Committee could then consider the question of microbiological criteria.
- 78. The Delegation of Norway supported the view that the CCFFP should consider work on dried fishery products.

The Committee concurred with the views expressed above.

CONSIDERATION OF AMENDMENT TO CODE OF HYGIENIC PRACTICE FOR EGG PRODUCTS TO INCLUDE "MELANGE" AT STEP 4 (Agenda Item 11)

- 79. The Committee had before it the above amendments contained in Appendix V to ALINORM 85/13. The Delegation of The Netherlands, acting as Rapporteur, stated that no comments at Step 3 had been received on Appendix V.
- 80. The Committee <u>concluded</u> that the proposed amendment was acceptable and advanced it to Step 5 of the Procedure. The Committee also <u>decided</u> to recommend to the 16th Session of the Commission to omit Steps 6 and 7 and to adopt the amendments at Steps 5 and 8. The proposed amendment to the Code of Practice of Hygienic Practice for Egg Products to include "Melange" is contained in Appendix V to ALINORM 85/13.
- 81. The Delegation of the USA informed the Committee that the USA does not permit the product as produced on the farm.

AMENDMENT OF CODE OF GENERAL PRINCIPLES OF FOOD HYGIENE

- 82. The Committee noted that at its last session it had been agreed that the amendment of the General Principles of Food Hygiene should be initiated to include certain provisions for "lot" including an amended definition and lot identification. (See ALINORM 83/15, para. 151).
- 83. It had also agreed to an amendment of section 4.3.1 referring to building and facilities by adding the following sentence "All construction materials should be such that when construction is completed, they do not emit toxic vapours" and to refer to "insect" screens in section 4.3.7 (windows). The Committee noted that the Delegation of The Netherlands had proposed a further series of amendments which was presented for consideration at the present session in document CX/FH 84/13.
- 84. The Delegations of Australia, New Zealand, and the United Kingdom questioned whether it was timely to introduce these further amendments since the "General Principles" Code had already been published as a Step 8 document. They were of the opinion that the amendments to the Code should be confined to those agreed at the Committee's last session. (See paras 82 and 83 above). The Committee noted that since it had already agreed to the amendment of the Code at its last session as indicated above, the amendments proposed by The Netherlands could also be considered for inclusion in the amended document which would be submitted to the Commission at its 16th Session.
- 85. The Committee <u>agreed</u> to consider these further proposed amendments, which were presented by the Delegation of The Netherlands, on this basis.

Section III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA

86. 3.1.1 Unsuitable growing or harvesting areas

It was proposed to amend this provision to include "areas", that is, to read: "Food should not be grown on or harvested from areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in the food".

- 87. the Committee did not consider that such an amendment would add to the information already in the provision and made no change.
- 88. 3.1.2 Protection from Contamination by Wastes

The Delegation of The Netherlands proposed to change the provision since in its

opinion the present first sentence, which could be interpreted as prohibiting the use of organic fertilizers, was in conflict with the second sentence which could be taken to refer only to industrial and environmental wastes.

- 89. Several delegations were of the opinion that there was no contradiction in the present text and saw no advantage in changing the provision. The Committee <u>agreed</u> with this point of view.
- 90. 3.1.4 The Delegation of The Netherlands questioned whether pest or disease control should be required to be undertaken by personnel who had a "thorough understanding" of the potential hazards to health involved.
- 91. The Committee <u>agreed</u> that it would be sufficient to require that such control measures be carried out under the supervision of such personnel. The Committee <u>agreed</u> to delete the term "by or". It was also <u>agreed</u> to end the first sentence after "hazard to health".
- 92. 4.1 The Delegation of the Netherlands pointed out that in densely populated areas it was increasingly difficult to comply with the requirements in Section 4.1 and proposed to amend the provision to read "Establishment should <u>preferably</u> be located ...". This was not agreed.
- 4.3.7 The Delegation of The Netherlands was of the opinion that the requirement that floors be made of non-toxic materials was too restrictive. It was understood that food should not come into contact with floors. It felt, however, that a requirement for non-toxic materials for walls was valid since food could come into contact with walls. The Committee agreed with the Delegation of Norway that the point could be covered by amending 4.3.1 in the following way: "All construction materials should be such that they do not transmit any undesirable substances to the food." It was also agreed to delete the term "non-toxic" from Section 4.3.7 "Floors and Walls".
- 74. The Delegation of Switzerland pointed out that it had been proposed in the Mass Catering Code to include a provision in 4.3.7 "Walls" that walls should be "sealed and free of insects." this was not agreed. An amendment was made to "Windows" replacing the term "insect screens" by "insect-proof screens". (See also para. 83).

Section .4.4.1 - Water Supply

- 95. 4.4.1.1 The Delegation of The Netherlands was of the opinion that the water supply should always be protected against contamination, and proposed, therefore, to delete the term "adequate".
- 96. The Delegation of the United Kingdom pointed out that Section 7.3 permitted the use of different types of water and, therefore, it was appropriate to retain "adequate". The Committee made no change.
- 97. Section 4.4.1.2 <u>Ice.</u> The Committee <u>agreed</u> that reference to this section should be to 7.3.1. The Committee <u>agreed</u> that there was no need to permit specific substances to prevent adhesion of ice flakes.
- 98. Section 4.4.3 The Delegation of The Netherlands pointed out that a provision for "properly trapped waste pipes leading to drains" which appeared in Section 4.4.4 should also apply to Section 4.4.3.
- 99. The Delegation of the United Kingdom was of the opinion that the provisions should

not be changed without expert advice as to the nature of trapping systems in different installations. the Committee agreed with this point of view.

- 100. It was pointed out that Section 4.4, "Sanitary facilities" included provisions for lighting and ventilation which were not appropriate to the heading. It was <u>agreed</u> to continue the numbering under 4.3 "<u>Buildings and Facilities</u>" and to delete the reference to "Sanitary Facilities".
- 101. 4.4.7 <u>Ventilation</u>. The Delegation of The Netherlands held the view that adequate ventilation could not prevent dust, and air flow should never be from a dirty to a clean area. The Delegation of the United States felt that this provision related to the accumulation and distribution of dust.
- 102. The Committee <u>agreed</u> to relate this provision to the "build up" of heat, steam, etc. It <u>also agreed</u> to clarify the following sentence by providing for air flow "within the plant".
- 103. Section 5.7 Pest Control. The Committee agreed to make the same change as in Section 3.1.4.
- 104. Section 7.3.3 Recirculated Water. The Delegation of The Netherlands pointed out that recirculated water could be either potable or non-potable depending on the way in which it was treated. Only water which represented a hazard to health should have a separate distribution system. Several delegations stated that certain processes resulted in water which was not representing a hazard to health but which was, nevertheless, not potable for organoleptic reasons.
- 105. The Delegation of The Netherlands thought that such water should be re-treated to make it potable. To clarify the text the Committee <u>agreed</u> to a proposal made by the International Federation of Grocery Manufacturers' Associations to amend the fourth sentence in 7.3.3 to read "Non-potable re-circulated water should have a separate distribution system which can be readily identified".

Section 7.4 - Processing

106. 7.4.4 The Delegation of The Netherlands proposed to replace the term "preservation" by prevention. Several delegations pointed out that this would change the intention of this provision and the Committee <u>decided</u> to make no change.

APPENDIX I - CLEANING AND DISINFECTION

Section 2.4 - Drying after Cleaning

- 107. 2.4.2 The Committee agreed that this section should be editorially corrected.
- 108. 2.4.3 The Delegation of The Netherlands was of the opinion that disinfection of equipment should be carried out immediately after use and that disinfecting film should be rinsed off before the next use. The Delegation of Canada pointed out that such a procedure could allow the build-up of bacteria and that provisions for re-disinfection were then required. The Delegation of the Federal Republic of Germany advised that disinfectants were often corrosive and damaged equipment under prolonged contact time.
- 109. The Delegation of Canada pointed out that Section 5.2.2 of the main Code provided general guidance on cleaning and disinfecting.

- 110. The Committee decided to make no change to this provision.
- 111. The Committee noted that the amendments that had already been agreed to at its last session and those discussed above would be submitted to the 16th Session of the Commission with a request to approve amending the Code in accordance with the established procedure.
- 112. The amendments proposed are attached as Appendix VI to this report.

HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP) - GENERAL CONSIDERATION FOR INCLUSION IN CODEX CODES OF HYGIENIC PRACTICE (Agenda Item 15)

- 113. The committee noted the discussions which took place at the 31st Session of the Executive Committee (ALINORM 85/3, paras 75-80) as a result of which it had agreed that there was a need to review and possibly revise those Codes of Hygienic Practice which did not yet follow the HACCP concept. However, it had foreseen a rather heavy workload and had concluded its discussions by requesting the Committee to examine the problem and report to the 16th Session of the Commission on how the work could be accomplished.
- 114. The Committee noted that, at its previsous session (ALINORM 85/13, paras 30-33) it had briefly discussed the HACCP System. It was pointed out that the "Low Acid Canned Foods" Code had been elaborated along HACCP lines and it had agreed that in the elaboration of future codes such as the proposed Draft Code for Precooked Meals in Catering and in the revision of existing codes the HACCP approach should be borne in mind.
- 115. It also noted the CCPMPP had revised the Code of Hygienic Practice for Processed Meat and Poultry Products using the HACCP System.
- 116. The Delegation of Canada pointed out that the HACCP System was a two stage process: one in which the hazard analysis was made and a second where the critical control points were identified. The overall system would vary with the products involved and even between factories making the same end-products. This point of view was supported by other delegations.
- 117. The Delegation of the United Kingdom emphasized that to revise the existing codes of practice would be an enormous undertaking and questioned whether in view of the expertise required it would be feasible to do so.
- 118. It was pointed out by the Delegation of the USA that in most cases the codes of practice had been elaborated by the Commodity Committee concerned with the product and that their advice should be sought before embarking on the actual review.
- 119. Other delegations pointed out that the Codes were intended to apply generally and that the nature of HACCP was such that it could be difficult to apply. The most that might be achieved would be a general classification of critical control points without a detailed hazard analysis.
- 120. The Committee agreed that HACCP could not be applied to the General Principles of Food Hygiene document which provided standard texts for certain sections of all other Codes.
- 121. The Committee also agreed that this discussion should be brought to the attention of Commodity Committees. It recognized that in their review Codex Commodity Committees needed some guidance on the principles of HACCP and its intended application.
- 122. It was pointed out that there had been a WHO/ICMSF Meeting on HACCP in Food Hygiene

and that the report (VPH 82/37) was available. The Committee noted that ICMSF was preparing a handbook on the principles and application of HACCP.

- 123. The Secretariat informed the Committee that the introductory volume to the publication of Codex Codes included standard general texts and could also make reference to the WHO/ICMSF report.
- 124. The representative of WHO was of the opinion that the introduction of HACCP in the Codes presently under elaboration could serve as an example to Commodity Committees on how to proceed in the case of revising the existing codes.

CONSIDERATION OF A CODE OF HYGIENIC PRACTICE FOR SPICES

- 125. The Committee had before it a background paper on the above (CX/FH 84/14) prepared by the Delegation of the Netherlands as requested at the 19th Session of the Committee (ALINORM 85/13, paras 34-41).
- 126. The Delegate of the Netherlands Dr. K. Buchli introduced the document.
- 127. He stated that in his opinion there were too many different types of spices to include in only one Code unless the scope was confined to spices used in processed meat products. From the definition standpoint, spices and herbs were, in his opinion, inseparable and only a few spices gave difficulties in end-products. Concerning microbiological contamination, different methods of elimination would have to be considered, such as gas treatment (ethylene oxide) and irradiation or an extruder method. He indicated that each of these methods presented certain difficulties such as residue problems in the case of ethylene oxide.
- 128. The Delegation of Denmark stated that spices did not present a problem in the home preparation of foods since such foods were eaten soon after preparation. International trade in processed meat products had, however, experienced problems with contaminated spices which had resulted in blown cans.
- 129. The CCPMPP was of the opinion that similar situations could arise in other foods and that, therefore, this Committee should elaborate a Code.
- 130. The Delegation of the Federal Republic of Germany informed the Committee that its country no longer permitted the use of ethylene oxide and that irradiation was also not permitted. He pointed to the need for spices with a low microbial load for the food industry in general. Representatives of the food inudstry in its country had reported that for 10-20% of all commercially processed products decontaminated spices were necessary. It was pointed out that the Codex General Standard for Irradiated Foods (CODEX STAN 106-1983) required that the overall average dose absorbed by a food subject to radiation processing should not exceed 10 KGy.
- 131. The Chairman expressed the opinion that besides microbiological contamination, the elimination of filth was an important health and commercial requirement.
- 132. The Delegation of the United Kingdom thought that except for isolated cases, there was not much information on the health hazards involving spices. The Delegation proposed to concentrate on the already known problems and not to attempt complete coverage of spices under all possible conditions.
- 133. The Delegation of Canada informed the Committee that in its country there had also been cases of microbiological contamination in the home caused by spices. It pointed

out that microbiological contamination was present not only at the harvesting and production levels but often increased under poor storage conditions and there could be extremely wide variations in the types of contamination experienced and in the concentration of microorganisms reached. Ultimately the condition of spices depended on GMP and a code was not, in its opinion, a practical proposition.

- 134. The Delegation of the Federal Republic of Germany pointed out that in addition to the health aspects, the question of spoilage could not be overlooked and the two factors were often linked. In its opinion, spices which were produced on a commercial scale might be less contaminated than those produced on a small scale and the code should be limited to the handling after harvesting. This was supported by the Delegation of France.
- 135. The Delegation of The Netherlands held the view that aspects to be covered by the Code had already been provided for in the "General Principles". While this view was supported by the Delegation of the United States, the Delegations of Denmark and Norway thought that reference to the "General Principles" did not solve the problem.
- 136. The Committee agreed in principle to develop a Code of Hygienic Practice for Spices and discussed the scope, that is, whether to cover spices for general use or for use as ingredients and whether to include production and processing.
- 137. After further discussion the Committee agreed that all spices should be covered independently of whether they were ingredients or sold as such. The Code should also cover production and processing.
- 138. The Committee also agreed that the Code should recognize the HACCP system and should include provisions related to treatment.
- 139. The Committee recognized that more information was needed from producer countries with regard to possible changes in production conditions in order to decrease the amount of filth contained in spices.
- 140. The Committee agreed that in view of the complexity of the matter, the Secretariat should be requested to engage a consultant to prepare a detailed background paper and the outline of a first draft of a Code of Hygienic Practice covering the production, processing and microbiological criteria for spices and herbs and to include guidelines for treatment, if possible with maximum levels, for example, for ethylene oxide, and irradiation.
- 141. The Committee thanked the Delegation of The Netherlands for the preparation of an excellent discussion paper.

REPORT OF THE AD-HOC WORKING GROUP ON NATURAL MINERAL WATERS

- 142. The Chairman of the above Working Group, Dr. H. Illi of Switzerland introduced the report of the Working Group which had been established to review the Draft Code of Practice for the Collecting, Processing and Marketing of Natural Mineral Waters presented at Step 7, having regard to the observations and proposals made by the Codex Coordinating Committee for Europe at its 14th Session and to examine the amendment to Sub-section 5.2 (now 5.4) of the Codex European Regional Standard for Natural Mineral Waters, with a view to recommending endorsement.
- 143. The Working Group had also available comments from Thailand on the above Code and the paper CL 1984/16-CX/EURO/84/5 Part 1 on microbiological requirements for natural mineral waters which had been prepared by Switzerland and submitted to the 14th Session of the Coordinating Committee for Europe as recommended by the 19th Session of this Committee. (See

paras 75-77 of ALINORM 85/13). The Committee expressed its appreciation to the Working Group and approved the Report as contained in Appendix VIII to this Report.

- (a) Endorsement of Proposed Amendment to the Codex European Regional Standard for Natural Mineral Waters (CODEX STAN 108-1981) Section 5.4 Microbiological Requirements at Step 5 (Agenda Item 8)
- 144. The Committee <u>agreed</u> with the recommendation of the Working Group that the provision submitted by the Coordinating Committee for Europe was sound from a public health point of view and endorsed the provision as contained in Annex 2 to Appendix V for inclusion in the Codex European Regional Standard for Natural Mineral Waters.
 - (b) Consideration of the Draft Code of Hygienic Practice for the Collecting,
 Processing and Marketing of Natural Mineral Waters at Step 7 (Appendix IV
 to ALINORM 85/13) (Agenda Item 9)
- 145. The Committee noted the amendments as contained in para. 5 of Appendix V which had been proposed by the Working Group to improve editorially the text of the Code and agreed to these amendments.

Section 7.10 - Sampling and Laboratory Control Procedures

- 146. The Committee noted that the Coordinating Committee for Europe had proposed a revised version of this section which was based on the paper prepared by Switzerland. (See para. 143 above). The Delegation of Canada expressed concern on what it considered to be a misinterpretation of the original three class sampling plan.
- 147. The Chairman of the Working Group stated that in this case the plan had another purpose, namely to indicate that in-plant control should immediately be carried out, if any of the indicator organisms was found in the sample, to determine the reason for the positive results.
- 148. The Committee agreed that the term "specifications" in the second sentence should be replaced by the term "criteria", that the footnote should be reworded and that the text of Section 7.10 as contained in Section 1 as amended should replace the present Section 7.10.

Section VIII - End-Product Specifications

- 149. The Committee agreed that this section should be identical with Section 5.4 endorsed for inclusion in the European Regional Standard for Natural Mineral Waters. (See paras 144 above).
- 150. The Delegations of Canada and the United Kingdom held the view that it was necessary to state details of appropriate methods. The Chairman of the Working Group informed the Committee that ISO was working on methods and that these could be made available to the Committee as soon as they have been finalized.
- 151. The Delegation of The Netherlands drew attention to the fact that the end-product specifications under consideration differed from those stipulated by the EEC in its directive.
- The Committee noted that the mesophilic plate count had been deleted from Section VIII since it was only suitable for samples from cold sources and gave false positive results with samples from warm sources. The following information had been included in CX/EURO 84/15 Part I.

ringsmit 1 . e.

- "- Mesophilic bacteria, capable of multiplying in 10 x diluted Plate count agar at 42° C". This method had not been pursued.
- 153. The Fourth Session of the FAO/WHO Working Group had recommended this test for the recovery of mesophilic bacteria including potential pathogens. It should allow the combination of tests for fecal streptococci, spore-forming sulfite reducing anaerobes and Ps. aeruginosa within only one test. This would markedly simplify the control procedure. An inquiry made by the "Groupement européen des sources d'eaux minérales" (GESEM, European Association of Mineral Water Sources) revealed that the test for mesophilic bacteria at 42°C as prescribed in ALINORM 83/13 and in VPH 81/32 seemed not to be reliable. According to the Laboratories (private and university) which had participated in this inquiry this test showed that it was not a selective method with regard to micro-organisms indicating fecal contamination, as it allowed, in addition to the development of these micro-organisms, growth of numerous common bacterial species. This could lead to contestations which might not be well founded.
- 154. A recent study, not yet published, of Prof. Schmidt-Lorenz, Federal Institute of Technology, Zurich, showed that this method could be improved by reducing the incubation time from 48 to 24 hours and by not counting pin-point colonies (<1 mm). But some problems still occurred, mainly with mineral water from thermal springs. It could not be excluded, that in these mineral waters the original microflora consist of mesophilic carbotolerant bacteria which were able to grow on diluted plate count agar at 42°C. This method had not been yet fully evaluated and could not guarantee correct results under all circumstances. It seemed therefore that in fact the test of mesophilic bacteria at 42°C could create more difficulties that it would eliminate.
- 155. The Committee decided to amend Section VIII as recommended by the Working Group.

Status of the Code

156. The Committee <u>decided</u> to advance the Draft Code of Hygienic Practice for the Collecting, Processing and Marketing of Natural Mineral Waters to Step 8 of the Procedure and submit it to the 16th Session of the Commission. Several delegations indicated that they would have preferred to retain the Code at Step 6 for a further round of comments. The amended text of the Code is contained in Appendix VII to this report.

CONSIDERATION OF PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRECOOKED MEALS IN MASS CATERING AT STEP 4 (Agenda Item 10)

- 157. The Committee noted that the Delegation of Belgium had revised the above Code as agreed at the 19th Session of the Committee (CX/FH 84/7) and that comments thereon had been received from the United States and from WHO.
- 158. The Committee decided that the above Code be examined by a working Group and referred back to the plenary session.
- 159. The Chairman of the Working Group, Mr. H.J. Beckers of The Netherlands, introduced the report of the Working Group and informed the Committee that the Working Group had decided to retain the title of the Code as presently drafted. He also indicated that the Working Group had been of the opinion that the Scope section was not in conformity with the title of the Code. The Working Group had therefore decided to recommend that the Code be limited to cooked and pre-cooked meals and had excluded the other foods e.g. ices and ice creams.
- 160. The Chairman of the Working Group indicated that the question of microbiological

guidelines had been left for discussion in plenary session and placed in brackets.

- 161. The Delegation of The Netherlands proposed to delete microbiological guidelines from the Code. This was supported by several delegations for the following reasons: guidelines would be impracticable because of the wide variety of foods involved and the consequent requirement for different criteria for different foods
- 162. The Delegation of France was in favour of retaining the guidelines in order to provide guidance to manufacturers and caterers. The Delegation also pointed out that the Code could not apply to cold products since there was a requirement to bring dishes to 65°C and this would require separate treatment of cold dishes in general. The Committee agreed that government comments should be sought on this point.
- 163. The Delegation of Canada supported the view expressed above that guidelines for individual foods were not practicable but proposed that the Committee might consider a general requirement that foods covered by the Code be free of frank pathogene such as Salmonellae.
- 164. The Chairman of the Working Group informed the Committee that the Working Group had not been able to discuss all comments and incorporate them in the draft code. The Committee accepted the kind offer of the Chairman of the Working Group to finalize a revised text of the draft code and forward it to the Secretariat for distribution and government comments. The Committee agreed to attach the Working Group Report as Appendix VII to this Report.

Status of the Code

165. The Committee <u>decided</u> to retain the above code at Step 3 of the Procedure. The revised text will be distributed separately (see para. 164 above).

REPORT ON AD HOC WORKING GROUP ON ITEMS 5-7

- 166. The Chairman of the Working Group Dr. I.E. Erdman, reported on the progress made by the reconvened Working Group (see paras 49-50).
- 167. With regard to the Salvaging Code particular attention had been paid to the scope and definitions but the review had not yet been completed. The Chairman undertook to finalize the Working Group report and to make the consequent revisions of the Salvaging Code. The amended document would be forwarded to the Secretariat for distribution and for government comments. The Committee decided to retain the Code at Step 3 of the Procedure.
- 168. Concerning the proposed publication of an illustrated document on visual inspection and on teardown, the Chairman of the Working Group confirmed that additional booklets on the matters were available and that it would be desirable to include certain information to make the documents more comprehensive, that is, not only to catalogue the defects, but to explain their causes. The question of teardown would be handled by including a list of references to manuals. The Committee agreed to this course of action.
- 169. The Chairman of the Working Group recalled that the FAO/WHO Working Group on microbiological examination and methods had considered microbiological standards for foods as well as microbiological examination procedures. With regard to the former it had also defined commercial sterility. The committee <u>agreed</u> to attach the Report of the above Working Group as Appendix VII to this Report.
- 170. the Delegation of Denmark pointed out that no sampling plan had been included in

the Working Group report and proposed that Appendix III to Revision 83|16 which contained a table for suspect lots of meat products in hermetically sealed containers should be included or referenced as a guide to inspection agencies. Several delegations were of the opinion that this was inappropriate since it could not be used to confirm commercial sterility. Several delegations felt that this table for suspect lots was more appropriate to the salvaging of damaged canned foods and reference would be more appropriate in the "Salvaging Code". It was agreed not to propose its inclusion in the Working Group report. Comments on this aspect would however be considered at the next session of this Committee.

- 171. The Committee agreed that the amendments to the Low Acid and Acidified Low-Acid Canned Foods Code which has been prepared in Chipping Campden (see para. 57 and Appendix V) should be incorporated in the low acid foods document and forwarded to the Secretariat for distribution for further comments. The Committee agreed that the Secretariat should bring the proposed amendments to the Code to the attention of the 16th session of the Commission and request approval to initiate the amendment procedure.
- 172. The Committee expressed its appreciation to the Working Group.

OTHER BUSINESS

End-Product Specifications for Freeze-Dried Foods

- 173. The Committee had before it a written proposal from the Delegation of Italy to elaborate microbiological criteria for freeze-dried formulated foods.
- 174. The Delegation explained that these formulated foods were intended for all agegroups except infants and were also used in food aid programmes.
- 175. It had been found that some countries did not accept the products for microbiological reasons because of the lack of internationally accepted reference criteria.
- 176. Several delegations were of the opinion that more information should be made available on the type of product concerned.
- 177. The Committee decided that if a code was justified by conformity with the relevant Codex criteria it would consider the matter in more detail at its next session.
- 178. The Delegation of Italy agreed to prepare a background paper along these lines.

Microbiological Criteria for Certain Cheeses

- 179. The Delegation of the United States informed the Committee that the summary papers on the FAO/WHO microbiological consultations contained a list of priority foods which had presented certain microbiological problems and for which criteria should be considered. The list included cheese.
- 180. The Committee noted that problems have arisen with pathogenic <u>E. coli</u> in soft cheeses. The Delegation of Italy informed the Committee that IDF was presently working on microbiological criteria for milk and milk products and the Federation should be consulted so as to avoid duplication of work.
- 181. The Delegation of the USA offered to prepare a document for consideration at the next session of the Committee which would take into account work done by IDF. The Committee agreed with this proposal.

Date and Place of Next Session

- 182. The Committee was informed that its 21st Session would take place in Washington from 23-27 September 1985.
- 183. The Committee noted that many papers had to be prepared by various delegations and requested those responsible to send documents to the Secretariat for processing and distribution not later than January 1985.

LIST OF PARTICIPANTS LISTA DE PARTICIPANTES

Chairman

Dr. R.B. Read, Jr.
Director
Division of Microbiology
Center for Food Safety and Applied Nutrition
Department of Health & Human Services
200 C Street, S.W.
Washington, D.C., 20204, USA

MEMBER COUNTRIES

ARGENTINA ARGENTINE

Delegates

Mr. Roberto Jorge Frasisti Minister Counselor Economic and Commercial Affairs Embassy of Argentina 1600 New Hampshire Ave., N.W. Washington, D.C. 20009 USA

Mr. Gustavo Ferrari Second Secretary Economic and Commercial Affairs Embassy of Argentina 1600 New Hampshire Ave., N.W. Washington, D.C. 20009 USA

Observer

Dr. Silvia Michanie
Department of Agriculture § Livestock
National Service of Animal Health
Laboratory Services
Gorostiaga 2248
(1426) Buenos Aires
Argentina

AUSTRALIA AUSTRALIE

Delegates

Dr. D. H. Murphy
Food Technologist
Food Standards Section
Department of Primary Industry
Canberra A.C.T. 2600
Australia

Dr. W.G. Murrel Chief Research Scientist CSIRO, Division of Food Research P.O. Box 52 North Ryde NSW 2113 Australia BRAZIL BRESIL BRASIL

Delegate

Dr. Adalberto Bezerra de Alcántara Medical Veterinary Ministry of Agriculture Esplanada dos Ministerios, Bloco D - Anexo Brasilia/DF

CANADA

Head of Delegation

Mr. I.E. Erdman Chief, Evaluation Division Bureau of Microbial Hazards Health Protection Branch Health and Welfare Canada Ottawa, Ontario KIA OL2

Delegates

Dr. B.E. Brown
Scientific Evaluator
Evaluation Division
Bureau of Microbial Hazards
Health Protection Branch
Health and Welfare Canada
Ottawa, Ontario K[†]A OL2

Dr. D.S. Clark
Director
Bureau of Microbial Hazardz
Health Protection Branch
Health and Welfare Canada
Ottawa, Ontario K1A OL2

Ms. K. Miedzybrodzka
Project Officer, Program Division and
Evaluation Division
Field Operations Directorate
Health and Welfare Canada
Ottawa, Ontario K1A OL2

CANADA (CONT.)

Dr. Ian Kirk Chief, Regulations and Procedures Meat Hygiene Division Food Production and Inspection Branch Agriculture Canada Ottawa, Ontario K1A 0Y9

Mr. Charles Robbins (Industry Adviser) Consultant 3082 Balmoral Avenue Burlington, Ontario L7N 7E4

Mr. Adrien Gervais Chief Technical Services Division Inspection Branch Fisheries and Oceans Ottawa, Ontario KJA 0E6

CHINA CHINE CHINA

> Dr. Chen Yaojun Associate Research Fellow Institute of Food Safety Control and Inspection Ministry of Public Health Beijing

Dr. Zue Wenkui Director Shenyang Institute of Food Safety Control and Inspection Shenyang

Mr. Chen Xihao
Senior Engineer
Scientific Research Institute of Food
and Fermentation Industry
Ministry of Light Industry
San Li Tun
Beijing, China

Mr. Yan Ding Guo
Engineer
Guangdong Import and Export Commodities
Inspection Bureau
370 Huanshi Road
Guangzhou, China

Mr. Li Chaowei Assistant Engineer State Administration for Inspection of Import and Export Commodities Building 17 Yongandongli Jianguomenwai, Beijing, China

ALINORM 85/13A APPENDIX I

DENMARK DANEMARK DINAMARCA

Delegate

Mr. Kaj Haaning Senior Veterinary Officer Veterinary Services Laboratory Kongensgade 16, Postbox 93 4100 Ringsted

FINLAND FINLANDE FILANDIA

Delegates

Dr. Pekka Pakkala Senior Supervising Officer The National Board of Health Haapaniemenkatu 3 - 5 00530 Helsinki

Dr. Jorma Hirn Head of the Department of Food Hygiene National Veterinary Institute Box 368 00101 Helsinki

Dr. Erkki Petaja Director Customs Laboratory Tekniikantie 13 02150 Espoo

FRANCE FRANCIA

Head of Delegation

Dr. Pierre Veit
Inspecteur de la répression des fraudes
Secrétariat d'Etat chargé de la consommation
Direction de la consommation et de la répression des fraudes
13, rue Saint-Georges
75009 Paris

Delegates

Professor Henri LeClerc Directeur de l'Unité INSERM U.146 Domaine du CERTIA 369, rue Jules Guesde 59650 Villeneuve d'Ascq FRANCE (CONT.) FRANCIA

Delegates

Dr. Catherine Bouvier Vétérinaire Inspecteur Direction de la Qualité Ministère de l'Agriculture 175, rue du Chevaleret 75646 Paris Cedex 13

Mr. Guy Piclet Chercheur - Inspecteur IFREMER Les Sables de Thalamot 29000 Concarneau

Mr. Georges Thomas Consultant Confédération française de la conserve 3, rue de Logelbach 75017 Paris

GERMANY (FED.REP. OF) ALLEMAGNE (REP.FED.) ALEMANIA (REP.FED.)

Delegate

Dr. P. Teufel Bundesgesundheitsamt Wissenschaftlicher Oberrat Postfach 33 00 13 D-100 Berlin 33

ITALY ITALIE ITALIA

Delegate

Mr. Riccardo Monacelli Instituto Sanita Viale R. Elena 299 00161 Rome

JAPAN JAPON

Delegates

Dr. Kazutaka Ichikawa Director of Food Chemistry Division Environmental Health Bureau Ministry of Health and Welfare Tokyo JAPAN (CONT.) JAPON

Mr. Toshihiko Namihira
Deputy Director of Food Sanitation
Division
Environmental Health Bureau
Ministry of Health and Welfare
Tokyo

Mr. Hiroyoshi Miyamoto Technical Representative Japan Food Hygiene Association Tokyo

NETHERLANDS PAYS-BAS PAISES BAJOS

Head of Delegation

Dr. K. Buchli Ministry of Welfare, Health and Cultural Affairs Foodstuffs Division P.O. Box 439 2260 AK Leidschendam

Delegate

Mr. H.J. Beckers
Ministry of Welfare, Health and
Cultural Affairs
National Institute of Public Health
and Environmental Hygiene
P.O. Box 1
3720 BA Bilthover

NEW ZEALAND NOUVELLE-ZELANDE NUEVA ZELANDIA

Head of Delegation

Dr. A.I. McKenzie
Assistant Director-General (Technical
Services)
Meat Division
Ministry of Agriculture and Fisheries
Private Bag
Wellington

NORWAY NORVEGE NORUEGA

Delegates

Mr. Atle Orbeck Sorheim Assistant Deputy Director-General Directorate of Health P.O. Box 8128 Dep. 0032 Oslo 1 NORWAY (CONT.) NORVEGE NORUEGA

Mr. Ronald Jorgensen
Director
The Official Norwegian Quality Control
Institute for Canned Fish Products
P.O. Box 329
4001 Stavanger

SPAIN ESPAGNE ESPANA

Head of Delegation

Dr. Juán Ponz Marín Director-General for Consumer Affairs Ministry of Health and Consumer Protection Madrid

Delegate

Dr. Pedro A. García González Assistant Director-General for Market Data Ministry of Health and Consumer Protection Madrid

SWEDEN SUEDE SUECIA

Head of Delegation

Professor Torsten Nilsson Head of Food Hygiene Department The National Food Administration Box 622 S-751 26 Uppsala

Delegate

Dr. Stig-Olov Florin Head of Food Handling Division The National Food Administration Box 622 S-751 26 Uppsala

SWITZERLAND SUISSE SUIZA

Head of Delegation

Dr. H. Illi Section of Bacteriology Federal Office of Public Health Haslerstrasse 16 CH-3008 Berne SWITZERLAND (CONT.) SUISSE SUIZA

Delegate

Dr. J. C. de Man Central Quality Assurance Laboratory Nestec Case postale 88 CH-1814 La Tour-de-Peilz

THAILANDE THAILANDE TAILANDIA

Head of Delegation

Mr. Thamrong Chamdermphadejsuk
Director
The Office of the Consumer Protection
Board
Secretariat of the Prime Minister
Baan Manangkghasila
Larn - Luang Road
Bangkok 10300

Delegates

Mr. Chana Yoosaeng
Director of One Stop Service Center
Department of Industrial Works
Ministry of Industry
Rama VI Road
Bangkok 10400

Miss Metanee Sukontarug
Scientist
Office of the National Codex Alimentarius
Committee of Thailand
Thai Industrial Standards Institute
Rama VI Road
Bangkok 10400

TRINIDAD AND TOBAGO LA TRINITE-ET-TOBAGO TRINIDAD Y TABAGO

Delegate

Mr. Errol Small Agricultural Attache Embassy of Trinidad and Tobago 1708 Massachusetts Avenue, N.W. Washington, D.C., USA UNITED KINGDOM ROYAUME-UNI REINO UNIDO

Delegates

Dr. Helen Murrell Senior Medical Officer Department of Health and Social Security Alexander Fleming House Elephant and Castle London, SE 16BY

Dr. A.C. Baird-Parker Scientific Adviser Unilever Research Colworth House Sharnbrook Bedford, MK44 1LQ

Dr. Richard Harding Principal Scientific Officer Ministry of Agriculture, Fisheries and Food Room 430, Great Westminster House Horseferry London, SW1P 2AE

UNITED STATES OF AMERICA ETATS-UNIS D'AMERIQUE ESTADOS UNIDOS DE AMERICA

Head of Delegation

Mr. C. W. McMillan
Assistant Secretary for Marketing and
Inspection Services
Room 242-E, Administration Building
Department of Agriculture
Washington, D.C. 20250

Delegate

Dr. George J. Jackson Chief Food and Cosmetics Microbiology Branch Division of Microbiology Food and Drug Administration Washington, D.C. 20204

Alternate Delegate

Dr. Robert W. Weik
Special Assistant for Codex Alimentarius
Center for Food Safety and Applied
Nutrition
Food and Drug Administration
Washington, D.C. 20204

UNITED STATES OF AMERICA (CONT.) ETATS-UNIS D'AMERIQUE ESTADOS UNIDOS DE AMERICA

Government Advisers

Mr. E. Spencer Garrett
Laboratory Director
National Seafood Inspection Laboratory
National Marine Fisheries Service, NOAA
Department of Commerce
Post Office Drawer 1207
Pascagoula
Mississippi 39567

Mr. Barry Wentz Microbiologist Food and Cosmetics Microbiology Branch Division of Microbiology Food and Drug Administration Washington, D.C. 20204

Dr. George P. Hoskins Biologist Division of Microbiology Food and Drug Administration Washington, D.C. 20204

Dr. John E. Kvenberg Assistant to the Director Division of Microbiology (HFF 232) Food and Drug Administration Washington, D.C. 20204

Dr. Joseph M. Madden
Microbiologist
Food and Cosmetics Microbiology
Branch (HFF 234)
Division of Microbiology
Food and Drug Administration
Washington, D.C. 20204

Dr. Thomas Mulvaney
Special Assistant to the Director
(HFF-210)
Division of Food Technology
Food and Drug Administration
Washington, D.C. 20204

Mr. Stephen H. Spinak
Staff Officer
Canned Products Branch
Processed Products Inspection Division,
MPITS, FSIS
Department of Agriculture
Washington, D.C. 20204

Observers

Mr. Cleve Denny Director Research Services National Food Processors Association 1401 New York Avenue, N.W. Washington, D.C. 20035 UNITED STATES OF AMERICA (CONT.) ETATS-UNIS D'AMERIQUE ESTADOS UNIDOS DE AMERICA

Mr. Richard V. Lechowich Manager Microbial Research General Foods Corporation 250 North Street White Plains, New York 10625

Mr. William V. Eisenberg Private Consultant (US Delegate Emeritus) 6408 Tone Drive Bethesda, Maryland

Mr. Hugh W. Symons Deputy Director-General International Frozen Foods Association 1700 Old Meadow Road, Suite 100 McLean, Virginia

Ms. Gloria E. S. Cox Cox and Cox Investments 12006 Auth Lane Silver Spring, Maryland 20902

Mr. Lowrie Beacham Advisor to the President National Food Processors Association 1401 New York Avenue, N.W. Washington, D.C. 20005

Mr. Gary L. Yingling President Food and Drug Law Institute Suite 380 1200 New Hampshire Avenue, N.W. Washington, D.C. 20036

Dr. Jorge Alonso CPC International International Plaza P.O. Box 8000 Englewood Cliffs, New Jersey 07632

Dr. D. Archer
Deputy Director
Division of Microbiology (HFF-230)
Food and Drug Administration
Washington, D.C. 20204

Mr. Donald A. Kautter Microbiologist Division of Microbiology (HFF-234) Food and Drug Administration Washington, D.C. 20204

Mr. Fred A. Phillips
Special Assistant for Low-Acid Canned
Foods (HFF-310)
Food and Drug Administration
Washington, D.C. 20204

UNITED STATES OF AMERICA (CONT.) ETATS-UNIS D'AMERIQUE ESTADOS UNIDOS DE AMERICA

Ms. R. Creitz NOAA Department of Commerce Washington, D.C. 20235

Mr. G. Blaufarb NOAA Department of Commerce Washington, D.C. 20235

Mr. Robert R. Jule

c/o Mr. A.A. Kopetz Vice President for Research and Develop- MANUFACTURERS ASSOCIATIONS (IFGMA) ment, Metal Packaging American Can Company Barrington Technical Center 433 N. Northwest Highway Barrington, Illinois 60010

Ms. Rhonda Nally Office of the Executive Secretariat Room 332E Department of Agriculture Washington, D.C. 20250

Ms. Linda Wood Office of the Administrator Policy and Program Planning Room 4435, South Building Department of Agriculture Washington, D.C. 20250

Ms. Deborah Young Secretary to Liaison Officer Food and Drug Administration 200 C Street, S.W. Washington, D.C. 20204

Dr. S.L. Nightingale Assistant Commissioner for Health Affairs 600 Fisher Lane Food and Drug Administration Rockville, Maryland

Ms. Tanya Roberts Economist Economic Research Service Department of Agriculture 500 12th Street, S.W. Washington, D.C. 20204

Mr. Melvin R. Johnston Chief, HFF Food and Drug Administration 200 C Street, S.W. Washington, D.C. 20204

INTERNATIONAL ORGANIZATIONS ORGANISATIONS INTERNATIONALES ORGANIZACIONES INTERNACIONALES

COMMISSION OF THE EUROPEAN COMMUNITIES (EEC)

Mr. Gilbert Vos Principal Administrator-General Directorate III Commission of the European Communities Rue de la Loi 200 Brussels 1049 Belgium

INTERNATIONAL FEDERATION OF GROCERY

Dr. Andrew B. Moore Science Associate Grocery Manufacturers of America Inc. 1010 Wisconsin Avenue, N.W. Washington, D.C. 20007 USA

Mr. Gregory Gorman Intarnational Affairs Associate I.F.G.M.A. 1010 Wisconsin Avenue, N.W. Washington, D.C. 20007 USA

INTERNATIONAL ORGANIZATION FOR STANDARDS (ISO)

. Mrs. J. Gantois Association française de normalisation (AFNOR) Tour Europe Cedex 7 92080 Paris la Défense France

FAO PERSONNEL PERSONNEL DE LA FAO PERSONAL DE LA FAO

FAO Liaison Officers and Rapporteurs

Mr. J. M. Hutchinson
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the
United Nations
Via delle Terme di Caracalla
00100 Rome
Italy

Ms. Barbara Dix
Food Standards Officer
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the
United Nations
Via delle Terme di Caracalla
00100 Rome
Italy

WHO Liaison Officer

Dr. A. Kouliskovskii
Food Hygienist
Veterinary of Public Health
Division of Communicable Diseases
World Health Organization
1211 Geneva 27
Switzerland

WHO Representative

Dr. Primo Arambulo III
Regional Advisor in Veterinary Public
Health
Pan American Health Organization
525 23rd Street, N.W.
Washington, D.C. 20037
USA

CHRONIC ASPECTS OF DIARRHEAL DISEASE

Dr. Douglas L. Archer
Deputy Director
Division of Microbiology
Center for Food Safety and Applied Nutrition
Food and Drug Administration

The Codex Committee on Food Hygiene (CCFH) of the FAO/WHO Codex Alimentarius Commission is charged "to ensure a safe, sound and wholesome product fit for human consumption". I will address the safety issues dealt with by the CCFH. Many persons believe that the acute diarrheal disease caused by enteric pathogens is unpleasant but not serious and in most cases certainly not life threatening. However a growing body of literature indicates that enteric pathogens and their attendant diarrheal disease may lead to chronic diseases such as allergy, autoimmune disorders, neoplasia and malnutrition with attendant immunologic dysfunction.

The first question I would like to pose is: Why are newly emerging pathogenic species only now being recognized? Several explanations are possible: (1) altered food sources for humans, (2) genetic interchanges among species, (3) improved detection methods (a commonly proposed explanation), or (4) evolutionary/selective processes. I propose that evolutionary/selective processes may be the most important explanation. Several bacteria are known to be able to rapidly alter their antigenic makeup; these include <u>Borrelia recurrentis</u>, <u>Campylobacter fetus</u>, <u>Vibrio cholerae</u>, <u>Escherichia coli</u>, and <u>Streptococcus spp. (1)</u>. The ability to rapidly alter surface antigens has been ascribed in part to a selection of minority bacterial populations with surface antigens different from those of a majority population, against which an antibody response is mounted. It has recently been proposed, however, that this process may be due to switching on the bacterium's genes that code for surface components, perhaps in some systematic order (2). The invading organism finds it advantageous to rapidly alter its surface antigens and even more advantageous if these antigens mimic human tissue antigens. In his "Cross Tolerance Hypothesis", Ebringer (3) divides the possible interactions between host and bacterium into three possible combinations: (1) Complete cross-reactivity between host and bacterium; in this situation no immune response can be mounted and the host is destroyed. (2) No cross-reactivity between host and bacterium; in this case the bacterium is eliminated efficiently by the immune system. (3) Partial cross-reactivity between host and bacterium; in this case survival between host and bacterium is balanced, since only a suboptimal immune response is mounted. From an evolutionary viewpoint, the latter situation is of greatest advantage to the bacterium because it enables maximum population density to be attained and permits the longest time for dissemination from the host (2). Thus, it would seem logical that enteric pathogens would tend to mimic host tissue antigens and cause protracted diarrhea. An example of a new pathogen exhibiting this tendency is the recently reported noninvasive Escherichia coli 0111:K58:H2, which causes protracted diarrhea in infants (mean duration 25+15 days) and produces none of the toxins or colonization factors usually ascribed to pathogenic E. coli (4). No information regarding this organism's ability to mimic host antigens is yet published. Partial cross-reactivity of microbial antigens with human tissue antigens has long been thought to contribute to the causation of autoimmune disorders (e.g., E. coli 0:14 elicits in humans an antibody that cross-reacts with colonic epithelium and gives rise to ulcerative colitis).

The CCFH has little control over evolutionary/selective pressures; however, it has a profound impact on another factor influencing antigenic variation: the global distribution of microorganisms.

There is strong evidence that three autoimmume diseases - reactive arthritis, Reiter's syndrome, and ankylosing spondylitis - are triggered by infections with enteric pathogens (5, 6). These infections may occur without overt diarrhea (7). The reactive arthritis, particularly that caused by Yersinia, may persist for more than four years and lead to permanent joint damage (8, 9). Y. enterocolitica serotypes 0:3 and 0:9, which give rise to reactive arthritis in Europe, are only rarely encountered on the North American continent.

In addition to the bacterial "trigger", there is a genetic component to the three diseases mentioned previously. Persons carrying the histocompatibility antigen HLA-B27 are particularly susceptible to these three diseases and to others of the so-called seronegative spondarthritis group (10, 11). Reviews (12, 13) concerning the HLA system with regard to disease predeliction and bacteria as triggers point out that many HLA-linked diseases are of unknown etiology in that the "triggers" remain undetermined.

of the seronegative spondarthropathies, the mechanisms involved in ankylosing spondylitis are best understood. Much of the pioneer work has been conducted in Australia. The basis of the underlying causative mechanisms involves the ability of certain enteric pathogens of the general Klebsiella, Shigella, Campylobacter, Salmonella, Escherichia and Yersinia to modify the HLA-B27 antigen and render it susceptible to lysis by normal immune mechanisms (14). The modifying factor has been purified, and the ability of a bacterium to produce it resides on a plasmid (15). Furthermore, there is good circumstantial evidence that the bacteria carrying the modifying factor-coding plasmid may be able to transfer the factor to host cells in which it may be stably incorporated; thus, the host cells become a permanent source of the modifying factor (16, 17). This is the first such disease mechanism described in which genetic material is transferred from prokaryotic to eukaryotic cells. This mechanism may be operative, at least in part, in reactive arthritis and Reiter's syndrome (16). In Belgium it has been proposed that joint diseases caused by Y. enterocolitica may be the leading cause of chronic disease (18) in that country.

At one time, the suggestion that bacteria (or other microbes except viruses) might play a causative role in cancer would have been thought absurd. However, very recent work indicates that bacteria may in fact play such a role. Normal anaerobic flora, under certain dietary conditions, produce powerful mutagens of the fecapentaene family (19). The yeast Candida albicans can cause the formation of the carcinogen benzylmethylnitrosamine from two harmless chemicals (20). Microbial toxins, metabolites, or whole organisms may act as tumor promoters or cocarcinogens (21-24): one such organism is viable E. coli (25).

Acute disease may also lead to chronic disease by inducing malabsorption with resultant malnutrition and loss of immune competence, thus predisposing to the host secondary infection (26). Recently, an ultrastructural study of the small intestine of well-nourished individuals during a diarrheal episode was conducted in Brazil, the first such study ever reported that did not involve severely malnourished individuals (27). The electron micrographs of the absorptive epithelium of the small bowel provide impressive evidence that severe damage to the intestinal villi and absorptive epithelium occurs during a diarrheal episode. The authors also discuss the probable uptake of macromolecules during such an episode, an event that can lead to food allergy (27) as previously shown by Gruskay and Cooke (28).

Malabsorption of nutrients caused by enteric pathogens, including Salmonella, Shigella, Giardia lamblia, and enteroviruses, is well-documented (29, 30). The nutrient loss caused by enteric infections has been reviewed (26). Even the loss of single essential nutrients (31) let alone the loss of multiple nutrients which may occur during diarrhea, can cause loss of immune competence (32, 33) resulting in an increased susceptibility to infections, prolonged infections, and increased severity of infections.

In conclusion, through its activities, the CCFH plays a vital role world-wide in preventing both acute and chronic diseases in humans by (1) preventing the occurrence of pathogens in food and (2) preventing global redistribution of pathogens indigenous to, and evolving within, separated geographic regions.

 $\overline{\text{NOTE}}$: A complete review of the role of enteric pathogens in rheumatoid disease with $\overline{\text{80}}$ references has been submitted for publication in the Journal of Food Protection. If accepted for publication, it should appear in 6-9 months. The reference list will be supplied to interested persons on request.

REFERENCES

- 1. Smith, H. Microbial surfaces in relation to pathogenicity. Bacteriol. Rev. 41:475-500, 1977.
- Gotschlich, E.C. Thoughts on the evolution of strategies used by bacteria for evasion of host defenses. Rev. Infect. Dis. 5(Suppl 4):S778-S783, 1983.
- 3. Ebringer, A. The cross-tolerance hypothesis, HLA-B27 and ankylosing spondylitis. B. J. Rheumatol. 22:(Suppl 2):53-66, 1983.
- 4. Lacroix, J., Delage, G., Gosselin, F., and Chicoine, L. Severe protracted diarrhea due to multiresistant adherent <u>Escherichia coli</u>. Amer. J. Dis. Child. 138:693-696, 1984.
- Keat, A. Reiter's syndrome and reactive arthritis in perspective. N. Engl. J. Med. 309:1606-1615, 1983.
- 6. Eastmond, C. J. Gram-negative bacteria and B27 disease. B. J. Rheumatol. 22(Suppl. 2):67-74, 1983.
- 7. Dunk, A.A., Dobbie, D. T., and Pitkeathly, D.A. Reactive arthritis following asymptomatic <u>Yersinia</u> infection. Scott Med. J. <u>25</u>:327-328, 1980.
- 8. Luzar, M. J., Caldwell, J. H., Mekhjian, H., and Thomas, F.B. <u>Yersinia enterocolitica</u> infection presenting as chronic enteropathic arthritis. Arthritis Rheum. 26:1163-1165, 1983.
- 9. Kalliomaki, J. L. and Leino, R. Follow-up studies of joint complications in yersiniosis. Acta Med. Scand. <u>205</u>:521-525, 1979.
- 10. Wright, V., Neumann, V., Shinebaum, R., and Cooke, E. M. Pathogenesis of seronegative arthritis. B. J. Rheumatol. 22(Suppl. 2):29-32, 1983.
- 11. Ebringer, R., Spondylarthritis and the post-infectious syndromes. Rheumatol. Rehabil. 18:218-226, 1979.
- 12. Carpenter, C. Autoimmunity and HLA. J. Clin. Immunol. 2:157-165, 1982.
- 13. Peter, J. B. and Hawkins, B. R. HLA antigens and disease. Diagn. Med. (Jan/Feb) 1-8, 1983.
- 14. Prendergast, J. K., Sullivan, J. S., Geczy, A., Upfold, L. I., Edmonds, J. P., Bashir, H. V., and Reiss-Levy, E. Possible role of enteric organisms in the pathogenesis of ankylosing spondylitis and other seronegative arthropathies. Infect. Immun. 41:935-941, 1983.
- 15. Sullivan, J., Upfold, L., Geczy, A. F., Bashir, H.V., and Edmonds, J. P. Immunochemical characterization of Klebsiella antigens which specifically

- modify an HLA-B27-associated cell-surface component. Human Immunol. 5:295-307, 1982.
- 16. Geczy, A. F., Alexander, K., Bashir, H. V., Edmonds, J. P., Uphold, L. and Sullivan, J. HLA-B27, <u>Klebsiella</u> and ankylosing spondylitis: biological and chemical studies. <u>Immunol</u>. Rev. <u>70</u>:23-50, 1983.
- 17. Orban, P., Sullivan, J. S., Geczy, A. F., Upfold, L. I., Coulits, N. and Bashir, H.V. A factor shed by lymphoblastoid cell lines of HLA-B27 positive patients with ankylosing spondylitis, specifically modifies the cells of HLA-B27 positive normal individuals. Clin. Exp. Immunol. 53:10-16, 1980.
- 18. Larsen, J. H. Yersinia enterocolitica infections and rheumatic diseases. Scand. J. Rheumatol. 9:129-137, 1980.
- 19. Baptista, J., Bruce, W. R., Gupta, I., Krepinsky, J. J., VanTassell, R. L. and Wilkins, T. D. On distribution of different fecapentaenes, the fecal mutagens, in the human population. Cancer Lett. 22:299-303, 1984.
- 20. Hsia, C-C., Sun, T-T., Wang, Y-Y., Anderson, L. M., Armstrong, D. and Good, R. A. Enhancement of formation of the esophageal carcinogen benzylmethyl nitrosamine from its precursors by <u>Candida albicans</u>. Proc. Nat. Acad. Sci. USA. 78:1878-1881, 1981.
- 21. Moore, R. E. Toxins, anticancer agents, and tumor promoters from marine prokaryotes. Pure Appl. Chem. <u>54</u>:1919-1934, 1982.
- 22. Fujiki, H., Mori, M., Nakayasu, M., Terada, M. and Sugimura, T. A possible naturally occurring tumor promoter, teleocidin B from Streptomyces. Biochem. Biophys. Res. Comm. 90:976-983, 1979.
- 23. Mizutani, T. and Mitsuoka, T. Effect of intestinal bacteria on incidence of liver tumors in gnotobiotic C3H/He male mice. J. Nat. Cancer Inst. 65:1365-1369, 1979.
- 24. Scott, P.M. and Stoltz, D. R. Mutagens produced by <u>Alternaria alternata</u>. Mutat. Res. 78:33-40, 1980.
- 25. Higgy, N.A., Verma, A. K. and Bryan, G.T. Introduction of rat urinary bladder ornithine decarboxylase by <u>E. coli</u> infection. Proc. AACR (Abstr #593) 150, 1984.
- 26. Archer, D. L. Diarrheal episodes and diarrheal disease: acute disease with chronic implications. J. Food Prot. 47:322-328, 1984.
- 27. Fagundes-Neto, U., Pacheco, I. P., daSilvo Patricio, F. R. and Wehba, J. Ultrastructural study of alterations in the small intestinal epithelium of children with acute diarrhea. J. Ped. Gastroenterol. Nutr. 3:510-515, 1984.

- 28. Gruskay, F. L. and Cooke, R. E. The gastrointestinal absorption of unaltered protein in normal infants and infants recovering from diarrhea. Pediatrics 26:763-767, 1955.
- 29. Rosenberg, I. H., Solomons, N.W. and Schneider, R. E. Malabsorption associated with diarrhea and intestinal infections. Am. J. Clin. Nutr. 30:1248-1253, 1977.
- 30. Gracey, M.S. Nutrition, bacteria and the gut. B. Med. Bull. 37:71-75, 1981.
- 31. Beisel, W. R., Edelman, R., Nauss, K. and Suskind, R.M. Single-nutrient effects on immunologic functions. J. Am. Med. Assoc. <u>245</u>:53-58, 1981.
- 32. Chandra, R. K. The nutrition-immunity-infection nexis: the enumeration and functional assessment of lymphocyte subsets in nutritional deficiency. Nutr. Res. 3:605-615, 1983.
- 33. Chandra, R. K., Immunodeficiency in undernutrition and overnutrition. Nutr. Rev. 39:225-231, 1981.

LIST OF THE EXISTING DOCUMENTS IN THE FIELD OF FOOD PRODUCTS MICROBIOLOGY COMING UNDER SC 9 AND OF THE SECTOR COMMITTEES BASED DOCUMENTS "PRODUCTS"

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

- ISO 4831-1978 General guidance for the enumeration of coliforms Most probable number technique at 30 °C
- ISO 4832-1978 General guidance for enumeration of coliforms Colony count technique at 30 °C
- ISO 4833-1978 General guidance for enumeration of micro-organisms Colony count technique at 30 °C
- ISO 6579-1981 General guidance on methods for the detection of Salmonella
- ISO 6887-1983 General guidance for the preparation of dilutions for microbiological examination
- ISO 6888-1983 General guidance for enumeration of Staphylococcus aureus Colony count technique
- ISO 7667-1983 Standard layout for methods of microbiological examination
 - DIS 7218 General guidance for microbiological analysis
 - DIS 7251 General guidance for the enumeration of presumptive Escherichia coli Most probable number technique after incubation at 35-37 °C then 45 °C
 - DIS 7402 General guidance for enumeration of Enterobacteriaceae without resuscitation Most probable number technique at 35-37 °C and colony count technique at 35-37 °C
- DIS 7937 General guidance for enumeration of Clostridium perfringens Colony count technique at 35-37 °C

Cereals and cereals products - Sub-Committee ISO/TC 34/SC 4

DP 7698 - Enumeration of microorganisms

Milk and milk products - Sub-Committee ISO/TC 34/SC 5

DIS 6610 - Milk - Enumeration of microorganisms - Colony count technique at 30 °C

- DIS 6730 Milk Enumeration of psychrotrophic microorganisms Colony count technique at 6,5 °C
- DIS 6785 Hilk and milk products Detection of Salmonella
- DP 5541/1 Milk and milk products Enumeration of coliforms Part 1:

 Most probable number technique
- DP 5541/2 Milk and milk products Enumeration of coliforms Part 2 : Colony count technique
- DP 5944 Dried milk Detection of coagulase positive staphylococci -
- DP 6611 Milk and milk products Enumeration of yeasts and moulds Colony count technique at 25 °C
- DP 7889 Yogurt Enumeration of characteristic microorganisms Colony count technique at 37 °C
- DP 7924 Dried milk, dried whey, lactose Enumeration of microorganisms Colony count technique at 30 °C
- DP 8198 Casein and caseinates Enumeration of microorganisms Colony count technique at 30 °C
- DP 8261 Milk and milk products Preparation of samples and dilutions for microbiological examination
- DP 8552 Milk Enumeration of psychrotrophic microorganisms Colony count technique at 21 °C
- DP 8553 Milk Enumeration of microorganisms Plate loop technique at 30 °C

Meat and meat products - Sub-Committee ISO/TC 34/SC 6

- ISO 2293-1976 Aerobic count at 30 °C (Reference method) (under revision)
- ISO 3100/3 Sampling Part 3: Treatment of primary sample for microbiological analysis (under revision)
- ISO 3565-1975 Detection of Salmonellae (Reference method) (under revision)
- ISO 3811-1979 Detection and enumeration of presumptive coliform bacteria and presumptive Escherichia coli (Reference method)
- ISO 5552-1979 Detection and enumeration of Enterobacteriaceae (Reference methods)
- DIS 5551 Enumeration of Staphylococcus aureus Colony count technique
- DIS 6649 Detection and enumeration of Clostridium perfringens (Reference method)
- DP 6391 Enumeration of Escherichia coli Colony count technique at 44 °C using membranes

UNITED KINGDOM NOTE ON SAMPLING PLANS AND ACCEPTANCE CRITERIA FOR VISUAL CAN EXAMINATION

These discussions and proposals were produced after meetings with the UK Canned Food Manufacturers and Importers in response to the report of the Codex Working Group on the Visual and Tear-down Inspection of Cans for Defects (CX/FM/83/3), the subsequent Food Hygiene Committee in September 1983 and the Codex Working Group Meeting on Low Acid Canned Foods in April 1984.

Current UK position

All the importers consulted used visual can inspection for external defects in low acid canned foods. However, acceptance of lots was based on evidence and on experience of the application of good manufacturing practices (GMP) at the cannery, obtained by factory inspection by trained specialists and by the availability of production and control records. End-product inspection was thought to be of limited value as it alone could not give the necessary assurances about public health risks.

Nevertheless, end-product inspection does have a number of uses and was used by some importers on all imported lots. It is often felt to be very important psychologically to use some form of independent check to ensure that the producer was continually aware of the importers' concern over the critical nature of can integrity. Things do occasionally go wrong and the occasional lot is found with excessive can faults. End-product inspection has reduced the risk of the importers' selling defective product and the subsequent investigations have resulted in a tightening up of GMP at the canner's premises.

However, it is felt very strongly that end-product examination for visual defects should not be over emphasized as it could divert attention from those GMPs which cannot be checked by visual end-product examination. This might also encourage the regrettably common practice of manual sorting of batches and removal of the defective cans so that the batches just met the prescribed standard.

Any standard or sampling plan for visual inspection should have a high probability of detecting defect levels which would indicate a lack of control at the cannery. A slack standard could have the opposite effect to that intended, in that processors could reduce their level of maintenance, control and inspection to the point where lots are just past the standard.

It was known that many importers do not carry out thorough technical factory inspections or do visual can examination. It was most important that any scheme for end-product examination does not in any way imply that such examinations can be used as the only basis for judging product to be fit for release for human consumption.

Sampling plans

The companies present used different sampling plans. These included general viewing of the consignment and multiple sampling with sample numbers usually in excess of 1,000 cans and with very strict acceptance numbers. The sample size of 240 cans as recommended by the Codex Working Group was only thought to be adequate in a limited number of situations. These were, when sampling small lots or individual code lots or when there was a very low risk associated with that product such as when intended for manufacturing purposes only where the product will be throroughly recooked.

The acceptance level of 5 class II major defects (can abnormalities which do not show signs of having leaked but are of such magnitude that they may leak) was considered as being much too high. In such a small sample size it should be 0.

The construction of sampling plans to evaluate consignment for visual defects requires the definition of defects, agreement on acceptable and unacceptable numbers of cans with visual defects, and an appreciation of the purpose and limitation of such tests.

The sampling plans are based on random sampling. The practicalities of dealing with a large shipment make random sampling virtually impossible. As the defects are often not uniformily distributed this could seriously bias the results and the plans' calculated probabilities will not hold.

If one of the purposes of carrying out the test is to protect the consumer from infected products, the sample size should vary according to the lot size. With a variable lot size and constant sample size, although the proportion of defectives released will remain constant at the critical defect level concentrations, there are more defectives in a large batch; therefore, the larger the batch size the greater the number of defectives that will be released for sale. This increases the risk to the whole population of consumers of this type of canned food.

Definition of defects

There are many types of visual defects with many different degrees of severity. Some work has been done on relating the type of visual defect to the risk of infection of the contents of the can, but this work has only been done for one product in one can size produced in one part of the world. This relationship may not be the same in other situations and we have no information on the quantitative effect of the severity of defects. Whilst different types and severities of defects will affect the risk of infection, this does not necessarily give any further indication of the degree of control on the manufacturing line. The presence of any visual defect in a small sample size may be an indication that non-visual defects may be present or that GMP may be lax in other areas. When investigating a batch which fails the initial visual defect check, the severity of a defect may influence the subsequent action to be taken; however, until that stage is reached, it is not necessary to take a decision on the severity of the defect or the precise classification of the defect. Therefore, all cans which are blown, leaking, holed, or showing visual defects which could affect their integrity, may be simply classified as "defective". The pictorial manual of seam defects should be very useful in training inspectors, but it must be appreciated that it is very difficult to determine if some types of seam abnormalities do in fact affect container integrity, especially side seam abnormalities.

Defect levels

There is very little information available on visual defect levels in canned foods produced when GMPs are operated. These defect levels were thought to be very low, probably much better than 1 in 10,000 for cylindrical cans. Routine visual examination of UK production usually revealed no defects, but occasionally batches were found where several cans had visual defects and on an average basis these could give a false impression of the norm.

The Canadian study of 230,000 Salmon cans revealed a total of 344 cans with abnormalities, that is 1 can in 668. The UK trial on USA half pound Salmon cans was carried out on batches which were expected to have high levels of visual defects and which cannot be regarded as representative. The defect level found of 214 in 250,000, that is 1 in 1,168 cans, is the same order of magnitude as in the Canadian study. Ninety two per cent of those defects came from 3 of the 5 batches which had on average a defect rate of 1 in 761 cans; incidentally these three batches were rejected.

It is therefore recommended that visual defect levels in excess of 1 in a 1,000 cans are not entirely acceptable. The proposed sampling plan which is designed to accept 5 major defects in 240 cans, that is 2.1%, is completely unacceptable and if promulgated in a Codex document is likely to lead to a serious relaxation of existing practices. We believe that it is better that importing authorities check batches less frequently, than that we adopt a standard which is lower by an order of magnitude than that which can easily be achieved with good manufacturing practices. A defect level of 1%, that is 10 in a 1,000 cans, is considered gross bad practice and should have an extremely low probability of being accepted. A defect of 1 in 300 cans should be readily recognised and rejected 9 times out of 10. As we have already said, a defect level of 1 in 1,000 cans is not entirely satisfactory, but as it is not too abnormal it may be accepted perhaps more frequently than it is rejected. A defect level of 1 in 10,000 cans is in keeping with good manufacturing practice and should have very little chance of being rejected.

Lot definition

The occurrence of visually defective cans may be due to many different failures to maintain GMPs or to combinations of these failures. However, when GMPs are maintained, the levels of defects will be very low and randomly dispersed. When errors in GMP do occur and result in visually defective cans it is usually confined to a single cannery line where there was a problem due to, for example, abuse or bad filling or to a poor seaming operation. Sometimes, when the defects are related to an empty can fault it may affect production from all lines that are using that can size, but will usually be confined to a relatively short production period.

In canneries which normally operate GMPs, the distribution of visual seam defects is usually related to a particular line and to a particular production period, that is if it is code-related. Ideally therefore each code lot should be inspected. This is normally not economically practical but an attempt must be made to limit the number of codes in a lot (preferably not more than 10 codes) and to include any 1 product, can size, cannery and production season. The numbers of cans in a lot should not exceed 300,000 and preferably less than 100,000 and come from a short production period, e.g. not more than 4 weeks. To do this, it is necessary to have information available on the codes present in the consignment.

Selection of sampling plans

A range of sampling plans may be used, each of which will have its own particular operating characteristics and may be chosen according to the level of assurance required. This will vary depending on the risk associated with a particular product and manufacturing operation and the market for which it is intended. The selection will be futher influenced by the size and homogeneity of the lot and the probability of failing acceptable samples. As examples, 3 simple sampling plans are illustrated in Table 1.

The first sampling plan gives very low consumer protection but may be used for certain packs not sold to the general public and not consumed without cooking. It will not detect, with any certainty, the defect levels associated with an out-of-control situation, but as defects may be code-related the 240 can sample plan may prove adequate for checking lots with only one or two codes present.

The second plan with a sample size of 720 has the minimum size of sample which will give the required assurances of detecting lots with unacceptable numbers of visually defective cans. However, with a zero tolerance for defects there is a relatively high risk of acceptable lots being rejected.

The third sampling plan was considered to be the most useful and is a reasonable compromise in giving a good probability of detecting high defect levels, yet giving no chance of failing a lot with 0.01% defectives.

Considering the number of different production, lots arriving at most busy ports, it is doubtful if many port authorities would be able to carry out even the first plan, other than very occasionally.

Treatment of batches in which any defects are found

The classification of defects according to the probability of loss of the seal cannot be used alone in the assessment of the risk to the health of the consumer. Consideration also has to be given to the probable presence and concentration of pathogens in the environment to which the cans have been exposed. If the cans are likely to have come into contact with high concentrations of very virulent foodborne pathogens, it may not be possible to accept any defect, whatever its class.

Depending on the number and type of defects found, an increased sampling level may then be necessary to determine the extent of the fault, including the inspection of individual code lots. As the presence of certain types of defect may be an indication of a general lack of GMP during the manufacturing operation, the supplier should be contacted and the appropriate evidence of good GMP should be sought. Other defects may indicate mishandling in storage or transport and enquiries would then need to be directed to the appropriate areas. This would probably need to be undertaken by central national authorities rather than by local portal authorities.

All such investigations require a detailed knowledge of canning technology and trade practices. It is therefore necessary that appropriate skilled staff are responsible for the assessment of the problem and for further investigations.

Summary

- 1. Visual examination of cans for external defects will not ensure freedom from either understerilisation or leaker infection. Infected cans frequently do not "blow" and cans without visual defects may be infected.
- 2. Control of visual seam quality is just one of a series of controls relating to good manufacturing practices. All controls must ensure that the level of contamination with microorganisms is within acceptable limits and that the risk of food poisoning is minimised.
- 3. The use of sampling plans needs to be considered in relation to their intended purpose and to the acceptable and unacceptable limits of visual can defects defined.
- 4. All types of visual defect which are likely to affect container integrity or which indicate a loss of integrity or of control during can closure should be treated with equal weight when using a routing monitoring sampling plan, particularly with the necessary low acceptance numbers.
- 5. Major visual defects are undesirable at levels greater than 1 in 10,000 and completely unacceptable at 1 in 100. Levels in excess of 1 in 1,000 may indicate an out-of-control situation leading to concern about the effectiveness of GMP controls that have been applied.
- 6. The proposal in CX/FM/83/3 for a sample size of 240 and an acceptance number of 5 major defects is totally unacceptable. There is only a 90% probability of rejecting batches with 4% defectives. What is even worse, it could lead to a reduction in present standards for visual seam defects and divert attention away from all other aspects of GMP.
- 7. A sample size of 240 cans with an acceptance number of 0 (for major and critical defects) is here proposed for special circumstances, such as monitoring individual

code batches of a low risk product. For routing monitoring the proposal is a sample size of 1,200 with an acceptance number of 1.

Table 1

	Sample size	Accept	Retain	Probability of accepting batch with defect levels			
				1/100	1/300	1/1,000	1/10,000
1)	240	0	1	8.96%	44.91%	78.7 %	97.6 %
2)	720	0	1	0.072%	9.06%	48.66%	93.1 %
3)	1,200	1	2	0.008%	9.15%	66.3 %	99.3 %

REPORT TO THE FOOD HYGIENE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION BY THE LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS WORKING GROUP

In compliance with a request of the Food Hygiene Committee as recorded in paragraph 61 of the Report of the Nineteenth Session held in Washington in September 1983 (Alinorm 85/13) a meeting of the LACF Working Group was convened to prepare amendments to the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979), First Edition. The Working Group is composed of delegates and representatives from Canada, the Federal Republic of Germany, the Netherlands, Norway, the United Kingdom and the United States of America. The Working Group is chaired by Mr. I.E. Erdman of Canada.

The meeting was held from 16 April, 1984 to 20 April, 1984, inclusive, at the Campden Food Preservation Research Association (C.F.P.R.A.) in Chipping-Campden, U.K. The delegates and representatives attending are listed in Appendix II to this report. While the primary purpose of the meeting was to formulate proposed amendments to the Code, a secondary purpose was to give further consideration to the visual and tear-down examination and evaluation of canned foods.

1. Amendments to the Code

The consideration of amendments to the Code were greatly facilitated by the submission of a detailed working paper on the subject by the United Kingdom. This represented considerable work and thought on the part of the United Kingdom and its delegates should be commended. The amendments proposed are given in detail in Appendix I of this report. Amendments were made to the following sections;

- 1. Introduction
- 2. Table of Contents
- 3. Sections 7, 8, 9, & 10

As will be seen, the main thrust of the amendments concern container integrity and defects as well as hygienic practices to minimize the risk of post-

processing contamination. These amendments along with the pictoral manual of commonly occurring defects, both visual and tear-down, will strenghthen the Code. Wherever an amendment has been made, the entire Sub-Section has been reproduced in Appendix I with the changes or additions underlined to facilitate identification. Underlining is not possible for deletions.

2. Defect Nomenclature and Classification

The defect pictoral manual and classification presented at the last meeting of the Food Hygiene Committee was reviewed in conjunction with similar manuals, one prepared by the C.F.P.R.A. and the other by Fisheries and Oceans, Canada. While these latter manuals did not attempt to classify the defects as to their seriousness, they did include a written description of each and a list of the causes with each picture or illustration. The Working Group agreed that any Codex manual should include these added features. Since both these latter manuals are, with some editorial changes, ready for publication, it may be more feasible to have Codex adopt one or the other or perhaps a combination of the two. This will be considered at the next meeting of the Working Group.

The question of defect classification was discussed, but no consensus was attained. This subject as well as sampling plans and acceptance criteria are still controversial and will be discussed at the next meeting.

The Working Group wishes to thank the U.K. Delegation for its preparation of the excellent working paper on the amendments to the Code and to the C.F.P.R.A. for the use of its facilities and their generous hospitality.

Dr. B.E. Brown Canada Rapporteur

ANNEX I

1. The following to be added to become the final paragraph of the introduction, (p. iv).

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

7.4 Packaging

7.4.1 Storage and characteristics of containers

All packaging material should be stored in a clean and sanitary manner. The material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product objectionable substances beyond the limits acceptable to the official agency having jurisdiction. The packaging material should be sound and should provide appropriate protection from contamination. The product containers should be sufficiently durable to withstand the mechanical, chemical and thermal stresses encountered during normal distribution. (An overwrap may be necessary for flexible and semi-rigid containers.) With laminates particular attention should be paid to ensure that the combination of processing requirements and product characteristics does not cause delamination as this may result in loss of integrity. The sealant material chosen must be compatible with the product as well as the container and closure systems. The closures for glass containers are particularly susceptible to mechanical damage which may result in a temporary or permanent loss of hermetic seal. The closures of sealed jars should therefore be contained within the glass body diameter to avoid closure to closure contact of the sealed jars.

2. 7.4.2 Inspection of empty product containers

7.4.2.1 Appropriate sampling and inspection schemes should be used by both container manufacturer and canner to ensure that containers and closures are in compliance with jointly agreed specifications and any requirements of the

agency having jurisdiction that may apply. As a minimum these should include those inspections and measurements given in Sub-Section 7.4.8 of this Code. (Empty containers are particularly subject to damage by faulty operation of depalletizers and by badly designed or controlled conveyors to filling and seaming machines.)

7.4.2.2 (No changes made.)

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

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

3. 7.4.5 Filling of product containers

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

7.4.5.2 The filling of containers, either mechanically or by hand, should be controlled so as to meet the filling and headspace requirements as specified in the scheduled process. It is important to achieve a constancy of filling, not only for economic reasons, but also because both the heat penetration and the container integrity may be affected by excessive fill variation. In

rotationally processed containers the headspace should be accurately controlled and sufficient to ensure consistent and adequate agitation of the contents. When flexible packaging is used, variations in <u>product particle size</u>, fill-weight and/or headspace may lead to variations in the filled pouch dimensions (thickness) which <u>may</u> adversely affect the heat penetration.

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

4. 7.4.6 Exhausting of containers

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

5. 7.4.7 Closing operations

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

7.4.7.2 For heat sealing, seal jaws should be plane-parallel to each other with one or both jaws being heated. The temperature of the jaws should be maintained at the specified temperature over the whole seal area. Pressure build-up on the jaws should be fast enough and final pressure high enough to allow product to be squeezed away from the seals before bonding commences. Flexible pouches are normally sealed in the vertical position. The requirements for the control and operation of sealing equipment are similar to those for semi-rigid containers. The seal area should be free from product contamination and the width of the seal should not be less than 3 mm.

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

6. 7.4.8 Inspection of closures

7.4.8.1 Inspection for external defects

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

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

7.4.8.1.2 Inspection and tear-down of double seams

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

(Note: References to standard texts or manuals dealing with methods for the tearing down of double seams shall be inserted here.)

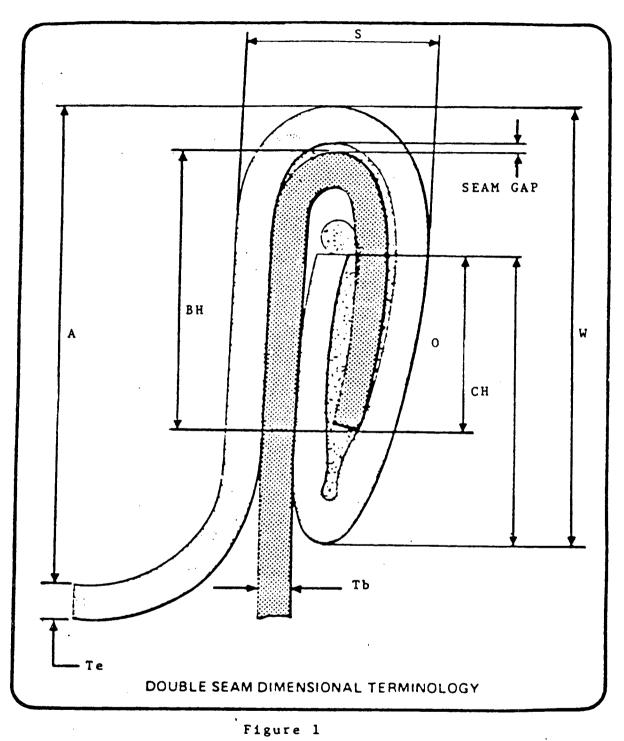
7.4.8.1.2.1 Cylindrical cans

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

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

Countersink depth - A

Double seam length - W



Double seam thickness - S
Body hook length - BH
Cover hook length - CH
End plate thickness - Te
Body plate thickness - Tb

As well as measuring the seam thickness, the double seam should be stripped down and evaluated for tightness, pressure ridge (chuck impression) and for other visual characteristics, such as juncture rating, internal droop, etc. The overlap (0) can be calculated by the following formula:

$$0 = (CH + BH + Te) - W$$

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

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

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

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

7.4.8.1.2 Other than cylindrical cans

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

(Note: Figure 2 has been deleted.)

7.4.8.1.3 Inspection of heat seals

Appropriate visual inspections and tests should be conducted daily by competent, trained and experienced personnel at intervals of sufficient frequency to ensure consistent reliable hermetic sealing. Records of such tests and corrective action required should be maintained.

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

7.4.8.1.5 Closure defects

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

7. 7.4.9 Handling of containers after closure

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

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

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

8. 7.4.10 Coding

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

9. 7.4.11 Washing

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

7.4.11.3 (This Sub-Section is deleted.)

10. 7.5.2 Establishing a scheduled process

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

Products and <u>filling</u> specifications, including any restrictions on ingredient changes;

Container size (dimensions) and type;

Container orientation and spacing in retort where appropriate; Ingoing weight of product(s) including liquor where appropriate; Air content, where applicable;

Minimum initial temperature;

Venting procedures, where applicable, should be determined on fully loaded retorts:

Type and characteristics of heat processing system;

Sterilization temperature;

Sterilization time;

Overpressure, where applicable;

Cooling method.

Any changes in the product specifications should be evaluated as to their effect on the adequacy of the process. If the scheduled process is found to be inadequate it must be re-established.

7.5.2.9 (This Sub-Section has become 7.4.5.3.)

11. 7.6.8 Cooling

To avoid thermophilic spoilage and/or organoleptic deterioration of the product, the containers should be cooled as rapidly as possible to an internal temperature of 40°C (105°F). In practice, water cooling is used for this purpose. Further cooling is done in air to evaporate the adhering water film. This aids in preventing both microbiological contamination and corrosion. Unless otherwise indicated, extra pressure should be applied during cooling to compensate for the internal pressure inside the container at the beginning of cooling, to prevent the deformation or leakage of containers. This can be minimized by equating the over pressure with the internal container pressure. When the integrity of the container is not adversely affected, water or air under atmospheric pressure may be used for cooling. Extra pressure is commonly achieved by introducing water or compressed air into the retort under pressure. The container and closure manufacturers' instructions should be followed. To reduce thermal shock to glass containers the temperature of the cooling medium in the retort should be reduced slowly during the initial cooling phase.

(The next paragraph has been moved to 7.6.8.1)

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

7.6.8.1 Cooling water quality

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

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

7.6.8.2 To ensure effective disinfection, chlorine must be thoroughly mixed with the water to a level which will minimize the risk of contamination of the can contents during cooling: a 20 minute minimum contact time at suitable pH and temperature is normally considered adequate.

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

- a) the presence of a measurable residual free chlorine in the water at the end of the contact time; and
- b) detectable amounts of residual free chlorine in the water after it has been used for cooling containers. (Residual free chlorine content of 0.5 to 2 p.p.m. are usually considered adequate. Chlorine levels in excess of this may accelerate corrosion of certain metallic containers.)
- c) a low microbial content of the water at the point of use. The temperature and pH of the water should be measured and recorded for reference.

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

The amount of chlorine required for adequate disinfection will depend upon the chlorine demand of the water, its pH and temperature. Where water with a high level of organic impurity, (e.g., surface water) is used as a source of supply, it will usually be necessary to provide suitable treatment for separation of impurities, prior to disinfection by chlorine thereby reducing

excessive chlorine demand. Recirculated cooling water may gradually increase in organic load and it may be necessary to reduce this by separation or other means. If the pH of cooling water is greater than 7.0 or its temperature is above 30°C it may be necessary to increase the minimum contact time or concentration of chlorine to achieve adequate disinfection. Similar actions may be necessary with water disinfected by means other than addition of chlorine.

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

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

12. 7.7 Post Process Container Handling

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

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

- 2) conveying systems and equipment are designed to minimize abuse; and
- 3) conveyor and equipment surfaces are effectively cleaned and disinfected.

Glass jars may be similarly affected.

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

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

7.7.1 Retort crate unloading

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

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

7.7.2 Container drying

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

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

The drying of batch processed containers may be accelerated by dipping the filled retort crates in a tank of a suitable wetting agent. After Immersion (15 seconds) the crates should be tipped and allowed to drain. It is essential that the solution of wetting agent be kept at not less than 80°C to avoid microbial infection and be changed at the end of each shift.

7.7.3 Container abuse

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

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

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

7.7.4 Post process cleaning and disinfection

Any container conveyor or equipment surface that is wet during production periods will permit rapid growth of infecting microorganisms unless it is effectively cleaned at least once every 24 hours and, in addition, regularly disinfected during production periods. The chlorine in the cooling water deposited on these surfaces from cooled cans is not an adequate

disinfectant. Any cleaning and disinfection program that is instituted should be carefully evaluated before being adopted as a routine procedure. For example, properly treated surfaces should have a mesophilic aerobic bacterial level of less than 500 c.f.u. per 26 cm² (4 in). The assessment of the continuing effectiveness of post process cleaning and disinfection programs can only be established by bacteriological monitoring.

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

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

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

7.7.5 When containers are to be overwrapped the secondary wrap should be placed on dry containers only. Generally, flexible and semi-rigid containers should be overwrapped.

13. 8.2.3 Water quality records

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

8.2.5 (This subsection is to be renumbered as 8.3.)

14. 8.3 Retention of Records

The records specified in Sub-Sections 7.6, 7.7, 8.1 and 8.2 should be retained for a period of not less than 3 years to assist investigation of problems should they arise. They should be held in a manner which will permit ready reference.

15. 8.2.1 Process records

Recorder charts should be identified by date, code lot and other data as necessary, so they can be correlated with the written record of lots

processed. Each entry of the record should be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and the retort or processing system operator or such designated person should sign or initial each record form. Prior to shipment or release for distribution, but not later than one working day after the actual process, a representative of plant management who is competent should review and ensure that all processing and production records are complete and that all product received the scheduled process. The records, including the recorder thermometer chart, should be signed or initiated by the person conducting the review.

16. 9 Storage and Transport of Finished Product

Conditions of storage and transport should be such that the integrity of the product container and the safety and quality of the product are not adversely affected. Attention is drawn to common forms of damage such as that caused by improper use of fork lift trucks.

9.3 Labels or label adhesives which are hygroscopic and therefore liable to promote rusting of timplate should be avoided as should pastes and adhesives that contain acids or mineral salts.

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

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

- 9.5 The storage conditions, including temperature, should be such as to prevent deterioration or contamination of the product. Rapid temperature changes during storage should be avoided as this may cause the condensation of moist air on the containers and thus lead to container corrosion.
- 9.6 Any of the above conditions may necessitate reference to the code of hygienic practice for salvage of distressed canned foods, (currently under preparation).

17. 10 Laboratory Control Procedures

10.1 It is desirable that each establishment should have access to laboratory control of the <u>processes used as well as the products packed</u>. 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.

ANNEX II

1. CANADA

1. Mr. I.E. Erdman, Chairman,

2. Dr. B.E. Brown, Rapporteur,

3. Mr. C.G. Robbins

Health & Welfare

Health & Welfare

Representing Canadian

Canning and Can Manufacturers

2. The NETHERLANDS

1. Ms. H.M.C. Put

Thomassen & Drijver -

Verblifa N.V.

3. NORWAY

1. Mr. R. Jorgensen

The Official Norwegian Quality

Control Institute for Canned Fish

4. The UNITED KINGDOM

1. Dr. R.H.G. Charles

Department of Health and

Social Security

2. Mr. E.W. Kingcott

Department of Health and

Social Security

3. Mr. D.A. Jones

Ministry of Agriculture,

Fisheries and Food

4. Dr. A.C. Baird-Parker

Unilever Research

5. Dr. D. Shapton

Libby, McNeil & Libby

6. Mr. R.H. Thorpe

C.F.P.R.A.

7. Mr. D. Atherton

C.F.P.R.A.

5. The UNITED STATES OF AMERICA

1. Dr. G.J. Jackson

2. Dr. T.R. Mulvaney

3. Mr. S.H. Spinak

4. Mr. C. Denny

5. Mr. R.R. Jule

Food & Drug Administration

Food & Drug Administration

Department of Agriculture

N.F.P.A.

American Can Manufacturers

Institute

PROPOSALS FOR AMENDMENTS TO THE RECOMMENDED INTERNATIONAL CODE OF PRACTICE GENERAL PRINCIPLES OF FOOD HYGIENE

(CAC/VOL A - Ed.1)

3.1.4 Pest and disease control

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

4.1 Location

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

4.3 Buildings and facilities

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

4.3.7 In food handling areas:

- Floors where appropriate, should be of water-proof, non-absorbent, washable, and non-slip materials, without crevices, and should be easy to clean and disinfect. Where appropriate, floors should slope sufficiently for liquids to drain to trapped outlets.
- Walls where appropriate, should be of water-proof, non-absorbent and washable materials sealed and free of insects and should be light-coloured. Up to a height appropriate for the operation, they should be smooth and without crevices, and should be easy to clean and disinfect. Where appropriate angles between walls, between walls and floors, and between walls and ceilings should be sealed and coved to facilitate cleaning.
- Windows and other openings should be so constructed as to avoid accumulation of dirt and those which open should be fitted with insect-proof screens. Screens should be easily movable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.

Renumber 4.4.1 to 4.4.8 to read 4.3.12 to 4.3.19.

4.3.12 Water supply

4.3.12.1 An ample supply of water, in compliance with section 7.3 of this Code, under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination.

4.3.18 Ventilation

Adequate ventilation should be provided to prevent excessive build up heat, steam condensation and dust and to remove contaminated air. The direction of the air flow within the plant should never be from a dirty area to a clean area.

Ventilation openings should be provided with a screen or other protecting enclosure of non-corrodible material. Screens should be easily removable for cleaning.

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 under direct supervision of personnel who have a thorough understanding of the potential hazards to health resulting from the use of these agents, including those hazards which may arise from residues retained in the product. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

7.5.4 Lot identification

Each container shall be embossed or otherwise permanently marked in code or in clear to identify the producing factory and the lot. A lot means a definitive quantity of a commodity produced under essentially the same conditions.

Appendix 1 - Cleaning and disinfection

2.4.2 Adequate drainage points should be provided in equipment that cannot be dismantled and drying racks provided for small pieces of equipment that are dismantled for the purpose of cleaning.

DRAFT CODE OF HYGIENIC PRACTICE FOR THE COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATER

(Advanced to Step 8)

SECTION I - FIELD OF APPLICATION

This code recommends appropriate general techniques for collecting natural mineral water, its treatment, bottling, packaging, storage, transport, distribution and sale for direct consumption, so as to guarantee a safe, healthy and wholesome product.

SECTION II - DEFINITIONS

- 2.1 For the purpose of this code the following expressions have the meaning stated:
 - 2.1.1 Natural mineral waters all waters meeting the requirement of the European standard for Natural Mineral Waters (CAC/RS 108-1979).
 - 2.1.2 Adequate sufficient to accomplish the intended purpose of this code.
 - 2.1.3 Cleaning the removal of soil, food residues, dirt, grease or other objectional matter.
 - 2.1:4 Contamination the occurrence of any objectionable matter in the product.
 - 2.1.5 <u>Disinfection</u> the reduction, without adversely affecting the natural mineral water, 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 natural mineral water.
 - 2.1.6 Establishment any building(s) or areas in which matural mineral water is handled after collection and the surroundings under the control of the same management.
 - 2.1.7 Handling of natural mineral water any manipulation with regard to collecting, treating, bottling, packaging, storing, transport, distribution and sale of natural mineral water.
 - 2.1.8 Food Hygiene all measures necessary to ensure the safety, soundness and wholesomeness of natural mineral water at all stages from its exploitation and processing until its final consumption.
 - 2.1.9 Packaging Material any containers such as cans, bottles, cartons, boxes, cases, or wrapping and covering material such as foil, film, metal paper and wax-paper.
 - 2.1.10 Pests any animals capable of directly or indirectly contaminating natural mineral water.
 - 2.1.11 Containers any bottle, carton, can or other container to be filled with natural mineral water, properly labelled and intended for sale.
 - 2.1.12 Aquifers any solid permeable mass of rocks (layer) containing natural mineral water.
 - 2.1.13 Spring any natural mineral water discharging genuinely from the ground.

SECTION 111 - PRESCRIPTIONS OF THE RESOURCES OF NATURAL MINERAL WATERS

A. Protection of alimentary reservoirs and aquifers

3.1 Authorization

Any spring, well or drilling intended for the collection of natural mineral water should be approved by the official authority having jurisdiction for this region.

3.2 Determination of the genesis of natural mineral water

As far 'as it is methodologically possible in each case, a precise analysis should be carried out on the origin of natural mineral waters, the period of their residence in the ground before being collected and their chemical and physical qualities.

3.3 Perimeter of protection

If possible areas wherein natural mineral water might be polluted or its chemical and physical qualities otherwise deteriorated should be determined by a hydrologist. Where indicated by hydrogeological conditions and considering the risks of pollution and physical, chemical and biochemical reactions, several perimeters with separate dimensions may be provided for.

3.4 Protective measures

All possible precautions should be taken within the protected perimeters to avoid any pollution of, or external influence on, the chemical and physical qualities of natural mineral water.

It is recommended that regulations be established for the disposal of liquid, solid or gaseous waste, the use of substances that might deteriorate natural mineral water (by agriculture e.g.) as well as for any possibility of accidental deterioration of natural mineral water by natural occurrences such as a change in the hydrogeological conditions. Particular consideration should be given to the following potential pollutants: bacteria, viruses, fertilizers, hydrocarbons, detergents, pesticides, phenolic compounds, toxic metals, radioactive substances and other soluble organic or inorganic substances. Even where nature provides apparently sufficient protection against surface pollution, potential hazards should be taken into consideration, such as mining, hydraulic and engineering facilities etc.

B. Hygiene prescriptions for the collection of natural mineral water

3.5 Extraction

The withdrawal of natural mineral water (from springs, galleries, genuine or drilled wells) must be performed in conformity with the hydrogeological conditions in such a manner as to prevent any other than the natural mineral water from entering, or, should there be pumping facilities, prevent any extraneous water from entering by reducing the supply. The natural mineral water thus collected or pumped should be protected in such a way that it will be safe from pollution whether caused by natural occurrence or actions of neglect or ill will.

3.6 Materials

The pipes, pumps or other possible devices coming into contact with natural mineral water and used for its collection should be made of such material as to guarantee that the original qualities of natural mineral water will not be changed.

3.7 Protection of the extraction area

In the immediate surroundings of springs and wells, precautionary measures should be taken to guarantee that no pollutant whatsoever can enter the extraction area, that is, an area surrounding the source within a radius of about 60 m. The extraction areas to be established therefore should at least be identical with the areas allocated at the time of construction. These extraction areas should be inaccessible to non-authorized people by providing adequate devices (e.g. enclosure). Any use not aiming at the collection of natural mineral water should be forbidden in these areas.

3.8 The exploitation of natural mineral water

The condition of the extraction facilities, areas of extraction and perimeters of protection as well as the quality of the natural mineral water should periodically be checked. To control the stability of the chemical and physical particulars of the natural mineral water derived - besides the natural variations - automatic measurements of the typical characteristics of water should be carried out and notified (e.g, electrical conductance, temperature, content of carbon dioxide) or frequent partial analyses should be done.

C. Maintenance of extraction facilities

3.9 <u>Technical aspects</u>

Methods and procedures for maintaining the extraction facilities should be hygienic and not be a potential health hazard to humans or a source of contamination to natural mineral water. From the hygiene standpoint, servicing of the extraction installations should meet the same standards as those required for the bottling or treatment.

3.10 Equipment and reservoirs

Equipment and reservoirs used for extraction of natural mineral water should be constructed and maintained in order to minimize all hazards to human health and to avoid contamination.

3.11 Storage at the point of extraction

The quantity of natural mineral water stored at the point of extraction should be as low as possible. The storing should furthermore guarantee protection against contamination or deterioration.

D. Transport of natural mineral water

3.12 Means of transport, piping and reservoirs

Any vehicle, piping or reservoir used in the processing of natural mineral water from its source to the bottling facilities, the latter included, should comply with the necessary requirements and be made of inert material such as ceramic and stainless steel which prevents any deterioration, be it by water, handling, servicing or disinfection; it should allow easy cleaning.

3.13 Maintenance of vehicles and reservoirs

Any vehicle or reservoir should be properly cleaned and if necessary disinfected

and kept in good repair so us not to present any danger of contamination to natural mineral water and of deterioration of the essential qualities of natural mineral water.

SECTION IV - ESTABLISHMENT FOR PROCESSING NATURAL MINERAL WATERS - DESIGN AND FACILITIES

4.1 Location

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

4.2 Roadways and areas used by wheeled traffic

Such roadways and areas serving the establishment which are within its boundaries or in its immediate vicinity should have a hard paved surface suitable for wheeled traffic. There should be adequate drainage and provision should be made for protection of the extraction area in accordance with sub-section 3.7 where appropriate and to allow for cleaning. Adequate road signals may be provided to call the attention of road users to the existence of a natural mineral water extraction area.

4.3 Buildings and Facilities

4.3.1 Type of construction

Buildings and facilities should be of sound construction in accordance with the provisions of Sub-section 3.7 and maintained in good repair.

4.3.2 - Disposition of holding facilities

Rooms for recreation, for storing or packaging of raw material and areas for the cleaning of containers to be re-used should be apart from the bottling areas to prevent the end-product from being contaminated. Raw and packaging materials and any other additions which come into contact with natural mineral water should be stored apart from other material.

- 4.3.3 Adequate working space should be provided to allow for satisfactory performance of all operations.
- 4.3.4 The design should be such as to permit easy and adequate cleaning and to facilitate proper supervision of natural mineral water hygiene.
- 4.3.5 The buildings and facilities should be designed to provide separation by partition, location or other effective means between those operations which may cause cross-contamination.
- 4.3.6 Buildings and facilities should be designed to facilitate hygienic operations by means of a regulated flow in the process from the arrival of the natural mineral water at the premises to the finished product, and should provide for appropriate temperature conditions for the process and the product.

4.3.7 Natural mineral water handling, storing and bottling areas

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

- Walls, where appropriate, should be of water-proof, non-absorbent, washable and non-toxic materials and should be light coloured. Up to a height appropriate for the operation they should be smooth and without crevices, and should be easy to clean and disinfect. Where appropriate, angles between walls, between walls and floors, and between walls and and ceilings should be sealed and coved to facilitate cleaning.
- Ceilings should be so designed, constructed and finished as to prevent the accumulation of dirt and minimize condensation, mould development and flaking, and should be easy to clean.
- Windows and other openings should be so constructed as to avoid accumulation of dirt and those which open should be fitted with screens Screens should be easily movable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.
- Doors should have smooth, non-absorbent surfaces and, where appropriate, be self-closing and close fitting.
- Stairs, lift cages and auxiliary structures such as platforms, ladders, chutes, should be so situated and constructed as not to cause contamination to food. Chutes should be constructed with inspection and cleaning hatches.
- Piping for natural mineral water lines should be independent of potable and non-potable waters.
- 4.3.8 In natural mineral water handling areas all overhead structures and fittings should be installed in such a manner as to avoid contamination directly or indirectly of natural mineral water and raw materials by condensation and drip, and should not hamper cleaning operations. They should be insulated where appropriate and be so designed and finished as to prevent the accumulation of dirt and to minimize condensation, mould development and flaking. They should be easy to clean.
- 4.3.9 Living quarters, toilets and areas where animals are kept should be completely separated from and should not open directly on to natural mineral water handling areas.
- 4.3.10 Where appropriate, establishments should be so designed that access can be controlled.
- 4.3.11 The use of material which cannot be adequately cleaned and disinfected, such as wood, should be avoided unless its use would clearly not be a source of contamination.

4.3.12 Canalisation, drainage lines

Canalisation and drainage and used water lines as well as any possible waste storage area within the protected perimeter should be built and maintained in such a manner as not to present any risk whatsoever of polluting aquifers and springs.

4.3.13 Fuel storage area

Any storage area or tank for the storing of fuels such as coal or hydrocarbons should be designed, protected, controlled and maintained in such a manner as not to present a risk of aquifers and springs being polluted during the storage and manipulation of these fuels.

4.4 Hygiene Facilities

4.4.1 Water supply

- 4.4.1.1 An ample supply of <u>potable</u> water in compliance with Section 7.3 of the Codex Code of Practice General Principles of Food Hygience (CAC/RCP1 1969 Rev. 1) under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination. 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 Natural mineral water, potable water, non potable water for steam production or for refrigeration or any other use should be carried in completely separate lines with no cross connection between them and without back siphonage. It would be desirable that these lines be identified by different colours. Steam used in direct contact with natural mineral water and natural mineral water contact surfaces should contain no substances which may be hazardous to health or may contaminate the food.

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 natural mineral water handling areas. Hand washing facilities with warm or hot and cold water, a suitable hand-cleaning preparation, and with suitable hygienic means of drying hands, should be provided adjacent to toilets and in such a position that the employee must pass them when returning to the processing area. Where hot and cold water are available mixing taps should be provided. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near to each washing facility. Care should be taken that these receptacles for used paper towels are regularly emptied. 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 natural mineral water processing areas

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

4.4.5 Disinfection facilities

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

4.4.6 Lighting

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

540 lux (50 foot candles) at all inspection points

220 lux (20 foot candles) in work rooms

110 lux (10 foot candles) in other areas.

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

4.4.7 Ventilation

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

4.4.8 Facilities for storage of waste and inedible material

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

4.5 Equipment and Utensils

4.5.1 Materials

All equipment and utensils used in natural mineral water handling areas and which may contact the natural mineral water 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. Surface should be smooth and free from pits and crevices. The use of wood and other materials which cannot be adequately cleaned and disinfected should be avoided except when their use would clearly not be a source of contamination. The use of different materials in such a way that contact corrosion can occur should be avoided.

4.5.2 Hygienic 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.

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, Revised Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 1 (1979)).
- 5.2.2 To prevent contamination of natural mineral water, all equipment and utensils should be cleaned as frequently as necessary and disinfected whenever circumstances demand.
- Adequate precautions should be taken to prevent natural mineral water from being contaminated during cleaning or disinfection of rooms, equipment or utensils, by water and detergents or by disinfectants and their solutions. Detergents and disinfectants should be suitable for the purpose intended and should be acceptable to the official agency having jurisdiction. Any residues of these agents on a surface which may come in contact with natural mineral water should be removed by thorough rinsing with water in corpliance with 7.3 of the Recommended International Code of Hygienic Practice General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 1 (1979)) before the area or equipment is again used for handling natural mineral water.
- 5.2.4 Either immediately after cessation of work for the day or at such other times as may be appropriate, floors, including drains, auxiliary structures and walls of natural mineral water handling areas should be thoroughly cleaned.
- 5.2.5 Changing facilities and toilets should be kept clean at all times.
- 5.2.6 Roadways and yards in the immediate vicinity of and serving the premises should be kept clean.

5.3 Hygiene Control Programme

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

5.4 Storage and Disposal of Waste

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

contact with the waste should be cleaned and disinfected. The waste storage area should also be cleaned and disinfected.

5.5 Exclusion of Animals

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

5.6 Pest Control

- 5.6.1 There should be an effective and continuous programme for the control of pests. Establishments and surrounding areas should be regularly examined for evidence of infestation.
- Should pests gain entrance to the establishment, eradication measures should be instituted. Control measures involving treatment with chemical, physical or biological agents should only be undertaken by or under direct supervision of personnel who have a thorough understanding of the potential hazards to health resulting from the use of these agents, including those hazards which may arise from residues retained in the natural mineral water. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.
- 5.6.3 Pesticides should only be used if other precautionary measures cannot be used effectively. Before pesticides are applied, care should be taken to safeguard natural mineral water, equipment and utensils from contamination. After application, contaminated equipment and utensils should be thoroughly cleaned to remove residues prior to being used again.

5.7 Storage of Hazardous Substances

- 5.7.1 Pesticides or other substances which may represent a hazard to health should be suitably labelled with a warning about their toxicity and use. They should be stored in locked rooms or cabinets used only for that purpose and dispensed and handled only by authorized and properly trained personnel or by persons under strict supervision of trained personnel. Extreme care should be taken to avoid contaminating natural mineral water.
- 5.7.2 Except when necessary for hygienic or processing purposes, no substance which could contaminate natural mineral water should be used or stored in natural mineral water handling areas.

5.8 Personal Effects and Clothing

Personal effects and clothing should not be deposited in natural mineral water handling areas.

SECTION VI - PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene Training

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

6.2 Medical Examination

Persons who come in contact with natural mineral water in the course of their work should have a medical examination prior to employment if the official agency having jurisdiction, acting on medical advice, considers that this is

necessary, whether because of epidemiological considerations or the medical history of the prospective natural mineral water handler. Medical examination of natural mineral water 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 natural mineral water handling area in any capacity in which there is any likelihood of such a person directly or indirectly contaminating natural mineral water 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 natural mineral water or natural mineral water 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, while on duty in a natural mineral water handling area, should wash his hands frequently and thoroughly with a suitable hand cleaning preparation under running warm water in compliance with Section 7.3 of the Codex Code of Practice - General Principle of Food Hygiene (CAC/RCP 1-1969 Rev. 1 (1979)). 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 natural mineral water handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor. During periods where natural mineral water is manipulated by hand, any jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in natural mineral water handling.

6.7 Personal Behaviour

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

6.8 Visitors

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

6.9 Supervision

Responsibility for ensuring compliance by all personnel with all requirements of Sections 6.1 - 6.8 inclusive should be specifically allocated to competent supervisory personnel.

SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

To guarantee a good and stable quality of natural mineral water, certain criteria should be monitored regularly, e.g.

- 7.1.1 Spring discharge, temperature of the natural mineral water;
- 7.1.2 Appearance of the natural mineral water;
- 7.1.3 Odour and taste of the natural mineral water;
- 7.1.4 The conductance of natural mineral water or any other adequate parameter;
- 7.1.5 The microbiological flora.
- 7.2 Should there be a perceptible lack in meeting the standards, the necessary corrective measures are immediately to be taken.

7.3 Treatment

The treatment may include decantation, filtration, airing and where necessary application or offtake of carbon dioxide (CO₂).

- 7.3.1 Processing should be supervised by technically competent personnel.
- 7.3.2 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.
- 7.3.3 Rough treatment of containers should be avoided to prevent the possibility of contamination of the processed product.
- 7.3.4 Treatment 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.
- 7.3.5 All contaminated equipment which has been in contact with raw materials should be thoroughly cleaned and disinfected prior to being used in contact with the end-products.

7.4 Packaging material and containers

7.4.1 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. Only packaging material required for immediate use should be kept in the packing or filling area.

7.4.2 Product containers should not have been used for any purpose that may lead to contamination of the product. Used containers, also new containers if there is a possibility that they have been contaminated, should be cleaned and disinfected. When chemicals are used for these purposes, the container should be rinsed as prescribed under 5.2.3. Containers should be well drained after rinsing. Used and, when necessary, unused containers should be inspected immediately before filling.

7.5 Filling and Sealing of Containers

- 7.5.1 Packaging should be done under conditions that preclude the introduction of contaminants into the product.
- 7.5.2 The methods, equipment and material used for sealing should guarantee a tight and impervious sealing and not damage the containers nor deteriorate the chemical, bacteriological and organoleptic qualities of natural mineral water.

7.6 Packaging of Containers

The packaging of containers should protect the latter from contamination and damage and allow appropriate handling and storing.

7.7 Lot Identification

Each container shall be permanently marked in code or in clear to identify the producing factory and the lot. A lot is a quantity of natural mineral water produced under identical conditions, all packages of which should bear a lot number that identifies the production during a particular time interval, and usually from a particular "line" or other critical processing unit.

7.8 Processing and Production Records

Permanent, legible and dated records of pertinent processing and production details should be kept concerning each lot. These records should be retained for a period that exceeds the shelf life of the product. Records should also be kept of the initial distribution by lot.

7.9 Storage and Transport of the End-Product

The end-product should be stored and transported under such conditions as will preclude 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 natural mineral water which is fit for human consumption is despatched and that end-product specifications should be complied with when they exist.

7.10 Sampling and Laboratory Control Procedure

The following are intended as guidelines for testing the water at the source and at critical control points:

Natural mineral water should contain no parasites and should meet the following criteria:

		n	С	m	М	Method
1,	Coliforms	5x250 m1	1	0	1*	ISO/TC 147/SC 4/GT 2
2.	Faecal streptococci	5x250 m1	1	0	1*	ISO/TC 147/SC 4/GT 4 (ISO/DIS 7899/2)
3.	Spore-forming sulfite-reducing					
	anaerobes	5x250 m1	1	0	1*	ISO/TC 147/SC 4/GT 5 (DP 6461/2)
4.	Pseudomonas aeruginosa	5x250 m1	0	0	_	ISO/TC 147/SC 4/GT 3 (DP 8360/2)
5.	Aerobic microbial count	: The max	imum ne ur	perm nique	missil e char	ble total aerobic counts per milliliter racteristics of the source and should

^{*} In cases of positive results (M \geq 1) additional samples should be examined to determine the reason for the positive results.

SECTION VIII - END-PRODUCT SPECIFICATIONS

During marketing, natural mineral water:

- (i) shall be of such a quality that it will not represent a risk to the health of the consumer (absence of pathogenic micro-organisms);
- (ii) furthermore it shall be in conformity with the following microbiological specifications:

First Examination		Decision		
Coliforms* Group D Streptococci P. aeruginosa	1x250 m1) 1x250 m1) 1x250 m1))	if absent	t <u>1</u> /	

Second Examination (4x250 ml)		$\frac{-}{c}\frac{2}{-}$	m	М	
Coliforms*	,	1	0	2) ISO
Group D Streptococci		1	0	2) Methods
P. aeruginosa		0	0	0) 3/

* Shall not be E. coli.

 $[\]frac{1}{2}$ The second examination shall include detection of coliforms, Group D Streptococci and P. aeruginosa.

^{2/} Results of the first and second examination

^{3/} Methods to be elaborated

REPORT OF THE AD HOC WORKING GROUP ON NATURAL MINERAL WATERS

- 1. An Ad Hoc Working Group was established on natural mineral waters under the chairmanship of Dr. H. Illi (Switzerland). Members of the following delegations took part: Argentina, Brazil, Canada, China, France, Italy, Japan, the Netherlands, Spain, Sweden, the United Kingdom, the United States of America, the observer from the European Community and the observer from the International Standards Organization. Dr. R. Harding (UK) was appointed as rapporteur.
- 2. The Chairman presented the tasks before the Working Group to review the draft Code of Practice for the Collecting, Processing and Marketing of Natural Mineral Waters, having regard to the observations and proposals made by the Codex Co-ordinating Committee for Europe at its 14th Session, and to examine the amendment to Sub-section 5.2 (now 5.4) of the Codex European Regional Standard for Natural Mineral Waters, with a view to recommending endorsement.
- 3. The following changes to the draft Code of Hygienic Practice were agreed:
 - 2.1.8 The words "... production or manufacture..." were replaced by "... exploitation and processing...".

Section IV

Title now reads: "Establishment for Processing of Natural Mineral Waters - Design and Facilities".

- 7.3.4 The words 'Methods of preservation..." were replaced by "Treatment..."
- 7.4.2 The third sentence now reads: "When chemicals are used for these purposes, the container should be rinsed as prescribed under 5.2.3."
- 7.7 In the second sentence, the word "food" was replaced by the words "natural mineral water."
- 7.8 The words "but unless a specific need exists they need not be kept for more than two years" were deleted from the English text. This followed an agreement of the Committee at its 19th Session, and brought the English and Spanish texts in line with the French text.
- 7.10 Sampling and Laboratory Control Procedure
- 4. The Working Group was invited to consider the proposal (Annex I) made by the Codex Co-ordinating Committee for Europe at its 14th Session. France pointed out that a sample size of 50 ml for sulphite reducing Clostridia (rather than 250 ml) would be in practice more convenient. The observer of the European Community indicated that there were discrepancies between the European Community Directive on Natural Mineral Waters and the proposed text, but recognized that it was a code of practice of an advisory nature. The Working Group agreed with the proposal as contained in Annex I and recommended that the Plenary Session include it in the Code of Practice.

Section VIII - End-Product Specifications

5. The Chairman drew to the attention of the Working Group the recommendations of both this Committee at its previous session and the Co-ordinating Committee for Europe that Section VIII should be identical with Section 5.4 of the Codex European Regional Standard for Natural Mineral Waters. The Working Group so agreed.

Section 5.4 (Microbiological criteria)

- 6. The Chairman explained in detail the proposal from the 14th Session of the Codex Co-ordinating Committee for Europe (Annex 2), making particular mention of the two step sampling plan. The observer of the European Community pointed out that there were discrepancies between the European Community Directive on Natural Mineral Waters and the proposal (see the Report of the 14th Session of the Codex Co-ordinating Committee for Europe, paragraphs 104 to 107), and therefore all countries of the European Community would have to abstain from endorsing them.
- 7. The Working Group <u>agreed</u> unanimously that the proposal was sound from a public health point of view, and recommended that the text contained in Annex 2 should replace both Section VIII in the Code of Practice (see paragraph 5), and be endorsed by the Plenary Session for inclusion in Section 5.4 of the Codex European Regional Standard for Natural Mineral Waters.

ANNEXE 1

7.10 Sampling and Laboratory Control Procedure

The following are intended as guidelines for testing the water at the source and at critical control points:

Mineral Water should contain no parasites and should meet the following specifications:

	n	С		M	method
1. Coliforms	5x250 ml	1	0	1*	ISO/TC 147/SC 4/GT 2
2. Fecal streptococci	5x250 ml	1	0	1*	ISO/TC 147/SC 4/GT 4 (ISO/DIS 7899/2)
3. Spore-forming sulfite					·
reducing anaerobes	5x250 mL	1	0	1*	ISO/TC 147/SC 4/GT 5 (bP 6461/2)
4. Pseudoxonas aeruginosa	5x250 mL	0	0	-	ISO/TC 147/SC 4/GT 3 (0° 8360/2)
5. Aerobic microbial count	The maxim	um pe	ermiss	ible t	otal aerobic counts per milliliter at
	20-22 °C a	nd 37	oc qet	pend an	the unique characteristics of the source uthority having jurisdiction.

^{*} In cases of positive results (M \geq 1) additional samples should be examined for the specific criteria.

ANNEX 2

5.4 Microbiological Requirements

During marketing, natural mineral water:

- shall be of such a quality that it will not represent a risk to the health of the consumer (absence of pathogenic microorganisms);
- (ii) furthermore it shall be in conformity with the following microbiological specifications:

First Examination		Decision
	1 x 250 ml) 1 x 250 ml)	if absent accepted if > 1 or 24 second examination is carried out 1/ if > 2 rejected
P. aeruginosa :	1 x 250 ml)	if absent accepted rejected

	c _2/	ш.	М		
Coliforms *	1	0	2∦)	ISO	•
Group D Streptococci	1	0	2)	Methods	
P. aeruginosa	0	0	0).	3/	1

The second examination shall include detection of coliforms, Group D Streptococci and P. aeruginosa.

^{2/} Results of the first and second examination.

^{3/} Methods to be elaborated.

^{*} Shall not be E. coli.

REPORT OF WORKING GROUP, 2 OCTOBER, 1984

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-COOKED AND COOKED MEALS IN MASS CATERING

Present: Netherlands (Chairman)

Canada (Rapporteur)

Argentina Australia Brazil Denmark Finland France Japan Norway Sweden Switzerland

United Kingdom

U.S.A.

People's Republic of China

WHO Representative

General Remarks

Some concern expressed over editorial errors in text.

Title

After some discussion, the following title was adopted "Draft Code of Hygienic Practice in Catering".

Objection from Sweden, and Australia prefers to limit scope of code and leave title as it is.

"... for pre-cooked and cooked meals in mass catering".

Explanatory Preface

Sweden's suggestion to change text of B 2 carried first sentence:

'Mass catering provides food that is generally perishable and that is eaten at the same time by a large number of people".

Similarly B 3 carried

Add

"persons suffering from allergies or hyper-sensitivity"

Scope

Much discussion that scope as written does not reflect title of code.

Sweden and Switzerland suggested we limit code only to cooked and pre-cooked meals otherwise scope too vast to deal with.

Change first sentence:

"prep. (of pre-cooked and cooked) food which..."

Last sentence:

"and serving of (pre-cooked and cooked) meals.

Definitions

2.4(a) Sweden, France feel many foods cannot be kept at 65 degrees C without adverse effects to the food. Finland disagrees, should remain at 65 degrees C. U.S.A. concurs with 65 degrees because of concern of pathogens as based on WHO document.

Sweden withdrew suggestion to change temperature.

UK proposed 70 degrees C, but satisfied with "at least 65 degrees C".

Netherlands and Norway suggested deletion of last 2 lines -- carried.

Also delete (ultimate) consumer -- carried.

- 2.4(d) Much discussion as to need. Canada suggested combining 2.4(c) and (d) which basically are the same.
- 2.4(c) "Cooked-frozen meal": catering system based on cooking followed by fast freezing, storage at controlled low temperature conditions below-18 degrees C or 0 degree F or below and subsequent thawing at a controlled temperature in a refrigerator at +3 degrees C or in a fast thawing unit where the circulating air temperature does not exceed 10 degrees C and thawing is complete within 6 hours.

Also delete below (freezing point) leave below -18 degrees C or..."

2.7 After much discussion decided to leave as is to provide some degree of uniformity between the codes.

New definition

"Potentially hazardous" to be used instead of perishable. Proposed by USA, no resolution.

Food Handling Personnel

Finland suggested the need for a definition. WHO - Catering Code - definition to be adopted.

4.3.5 CCP Note

Add to end of first paragraph:

"These rooms should be adequately equipped to ensure that no equipment or untensils need to be used for both raw and cooked foods".

Second paragraph:

"Crockery returned for washing may not be stored in the food production area nor in the kitchen itself.

The management and food inspectors should regularly check if the separation principle is well applied".

- 4.3.6 Delete in last line, the words "and humidity".
- 4.3.7 Definition to be changed in line with General Principles.
- 4.4.1.1 Te be replaced by wording of General Principles.
- 4.4.1.1 -- CCP Note

"WHO - "Guidelines for Drinking Water Quality" correct title of this text.

- 4.4.2 Add at end of paragraph: "All waste pipes should be properly trapped and lead to a drain.
- 4.4.1.2 -- CCP Note

"... at least 65 degrees C..."

"... at least 80 degrees C and cleaned by frequent changing..."

4.4.3 CCP Note

Part of second sentence missing

"The method must ensure that foods are not held a long time in the temperature range between 7.0 degrees C and..."

"Raw and cooked foods should be kept in separate refrigerators"

4.4.4 To be left as it is in the General Principles.

Page 9 last paragraph. (15 degrees C) as suggested by Sweden.

- 4.4.6 To be left as it is.
- 4.4.8 Change title as suggested by Switzerland: "Ventilation air conditioning".
- 4.5.2.1 CCP Note

Much discussion as to the meaning of this note. Will be redrafted. Australia suggested:

"The capacity of the equipment used should be adequate to permit the production of high quality food".

- 4.5.2.3 4th line: Change average to maximum
- 5.2.2 2nd paragraph, 4th line: USA does not support rinsing disinfectants and suggested "cleaned, rinsed, and disinfected".

Denmark disagreed.

9th paragraph, 1st line, add: ... or be disposable...

5th paragraph: delete "ices or ice cream"

3rd paragraph, 5th line: "clean and safe"

3rd paragraph, 4th line: (or steam) deleted.

5.2.4 Leave as it is

- 5.2.6 Leave as it is.
- 5.5 To read as in G.P., "Section 5.6" "Animals that are uncontrolled or that could be a hazard to health should be excluded from establishments."
- (6.4., 6.5.)

USA takes objection to wording and will take this up in the Plenary Session as these are taken from the G.P.

- (5.8) To be discussed further in Plenary.
- (6.2) To be discussed further in Plenary.
- (6.8) USA will discuss metal gloves and disposable gloves in Plenary.
- 7.2.1 CCP Note, 1st line include shellfish
- 7.1.4 3rd line
 "or stored at a temperature between 1 and 3 degrees C."
- 7.1.5 3rd line
 "or stored at a temperature of or below 18 degrees C."
- 7.4.1 USA favors 74 degrees C for poultry and stuffing
 Sweden supports adding a phrase to this effect at the end of the paragraph.
 Norway favors inclusion in CCP note.
 UK would like to include use of heat probes. USA also.
- 7.3.1., 7.3.2

After much discussion, the Working Group decided to keep only the first sentence of 7.3.1 in this whole section.

7.2.5 Add:

"It is preferable to have separate equipment for handling and preparation of raw and cooked foods, in particular apparatus for slicing and mincing.

7.2.3

7.4.2 Add at end of 1st paragraph:

"All thawing should be done as rapidly as possible and in such a way as to avoid any risk of cross-contamination from drip-water."

Replace defreezing by thawing.

7.4.2 CCP Note

2nd sentence added on USA recommendation:
"Large poultry, such as turkey, should never be stuffed.
Stuffing should be cooked separately.
Also note on C. perfringens in addition to Salmonella.

1st sentence: - change "turkeys" to "poultry carcasses."

(7.4.4)

Delete, same as 2.4(a)

7.4.5 "When products are grilled, roasted, browned, fried, blanched, poached, boiled, or cooked..."

Change 10 degrees C to 7.0 degrees C to be consistent with another part of code.

USA suggested chilled to 7.0 degrees within 2 hours, but this would require special equipment and therefore should go to government comment.

- 7.6.2 Denmark finds requirements unnecessarily strict. Same comments apply here as made under 7.4.5.
- 7.5.5 "and" changed to "in which".

"10 degrees C" changed to "15 degrees C" as in 4.4.8.

7.6.2 Much discussion ensued on the length of time which should be required for rapid chilling.

USA clarified the purpose of this section which is to define "rapid chiller".

Consensus to keep 7.6.2 as it is.

CC Note to explain chiller and chilling.

7.6.3 Replace "cold" with "chilled storage".

CCP Note

Replace "fish" with "seafood products".

- 7.6.4 Sweden felt that 5 days should not apply to foods treated to increase shelf-life that is, vacuum packed etc.
- 7.7.1 Second sentence, delete

"such as blast freezers..."

USA felt that speed of freezing should not be a consideration in a code of hygienic practice, as it impacts only on quality.

7.9.2 Change 2 to "1 hour" as time may be detrimental to nutritional quality of food.

(7.10.4)

Deletion guidelines supported by many

Decided to place (7.10.4) in brackets for further discussion.

7.10.5 Samples should be kept in sterile containers if to be used for testing at a later date.

REPORT OF THE FAO/WHO WORKING GROUP ON MICROBIOLOGICAL SPECIFICATIONS AND EXAMINATIONS OF CANNED FOODS

Washington, D.C. 24-28 September, 1984

CONTENTS

- Introduction
- 2. Elaboration of Microbiological Criteria for Foods
- Consideration of Microbiological Specification for Canned Foods 3.
- Microbiological Examination of Canned Foods
 - 4.1 Introduction
 - 4.2 Product identification and history information
 - 4.3 Laboratory examination
 - A. External visual examination and physical measurements
 - B. Incubation
 - C. Cleaning, disinfection and opening of container
 - D. Sampling and microbiological analysis of container contents
 - E. Direct microscopic examination

 - F. Sensory examination
 G. Measurements of pH of Measurements of pH of contents
 - н. Emptying and sterilization of container
 - I. Container integrity examination (section to be developed)
- Guidelines for the most probable interpretation of all data from the laboratory examination of a container of canned food.
- Guidelines to assist in identifying causes of non-commercial sterility 6.
- 7. Concluding remarks

APPENDIX 1	List of Participants
APPENDIX II	Flow diagram of procedures for the examination of a thermally processed food in a hermetically sealed container
APPENDIX III	An example of a product identification and history enquiry form
APPENDIX IV	Procedures for microbiological analysis of an analytical sample
APPENDIX V	Guidelines for the interpretation of results of a complete microbiological analysis
APPENDIX VI	List of Working Documents

1. Introduction

The meeting was opened by Dr. R.B. Read, Jr., Division of Microbiology, Food and Drug Administration, Department of Health and Human Services, who welcomed the participants on behalf of the Government of the United States of America.

Dr. A. Koulikovskii, speaking on behalf of the Director-General of the World Health Organization Dr. H. Mahler, expressed his thanks to the Government of the United States of America for making it possible to hold the meeting in Washington. He also expressed appreciation of the Joint FAO/WHO Secretariat to the experts for the background papers which had contributed on the topics to be discussed and for their participation at the meeting.

The participants were informed that the findings of the present Working Group on the Microbiological Specifications and Examination of Canned Foods would be reported to the Codex Committee on Food Hygiene which would be held the following week (1-5 October 1984).

2. Elaboration of Microbiological Criteria for Foods

The first Joint FAO/WHO Expert Consultation, as part of a cooperative project of the United Nations Environment Programme, was held in Geneva (7-11 April 1975). The Consultation considered the microbiological specifications for foods in relation to the FAO/WHO Food Standards Programme, and identified the foods reserving particular attention with respect to the formulation of microbiological specifications, microorganisms important in foods in international trade, and the format of such specifications. The Consultation particularly considered the microbiological specifications for egg products.

The second Consultation, held in Geneva from 21 February to 2 March 1977, discussed foods for which provisional criteria were already being considered, listed foods which appeared to warrant future consideration and, from this list, singled out six groups of foods for which more immediate action was recommended. The Consultation made some recommendations concerning general principles for the establishment of microbiological specifications for pre-cooked frozen shrimps and prawns, routine methods for the detection of Salmonella spp. in consignments of frozen raw froglegs; for ice mixes and edible ices, and for other commodities.

The third meeting on microbiological criteria for foods (Geneva, 20-26 February 1979) dealt with microbiological criteria for chilled and frozen raw meat and poultry.

The Group also considered in more detail the general principles for the establishment and application of microbiological criteria for foods which were accepted in principle with some modification of the definitions by the Codex Committee on Food Hygiene.

In November 1980, a FAO/WHO Working Group considered and elaborated microbiological specifications for dried milk and natural mineral water.

The reports of all the above-mentioned meetings were compiled in one document recently published by WHO* $\,$

The present Working Group on the Microbiological Specifications and Examination of Canned Foods was convened as a result of the discussion at the 19th Session of the Codex Committee on Food Hygiene (20-26 September 1983) which decided that the elaboration of microbiological criteria for canned food "should be given priority".

^{*} Microbiological criteria for foods. Summary of recommendations of FAO/WHO expert consultations and working groups 1975-1981. WHO document VPH/83.54.

Mr. I.E. Erdman was elected Chairman and Dr. D.A. Kautter, the Vice-Chairman of the Working Group. Dr. A.C. Baird-Parker was appointed as Rapporteur. The agenda was discussed by the participants. It was agreed that the subjects to be considered by the Working Group were:

- 1. Microbiological specifications for canned foods
- 2. Microbiological examination of canned foods
- 3. Guidelines for the most probable interpretation of all data obtained from the examination of a container of canned food
- 4. Guidelines to assist in identifying causes of non-commercial sterility

3. Consideration of Microbiological Specifications for Canned Foods

The Working Group noted that microbiological end-product specifications are intended to accompany a Code of Practice to increase assurance that the provisions of hygienic significance to the Code have been met.

In the existing Recommended International Code of Practice for low-acid and acidified low-acid canned foods (CAC/RCP 23-1979), it is stated, in the section devoted to end-product specifications, "The products should be commercially sterile, and not contain any substances originating from microorganisms in amounts which may present a hazard to health".

Participants exchanged their views with regard to this requirement in the Code. It was mentioned that in some countries, standards for canned foods contain requirements for certain groups of microorganisms to be examined (e.g. in Thailand such specifications exist for canned squid, cuttlefish, octopus and canned baby clams).

The participants recognized that such microbiological specifications may provide some additional assurance of the commercial sterility of thermally processed foods. However, it was the opinion of the Group that such specifications should not be recommended for the routine examination of canned foods since they give little assurance that the requirements in the Code of Hygienic Practice for low-acid canned foods have been met or that commercial sterility has been achieved within the lot. The Group believed that commercial sterility, defined in the Code as the "condition achieved by application of heat, sufficient alone, or in combination with other appropriate treatments, to render the food free from microorganisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during distribution and storage" formed the microbiological specification for canned foods. The Working Group agreed that commercial sterility cannot be proven by end-product sampling of a lot but can only be assured by the application of the procedures presented in the Code.

4. Microbiological Examination of Canned Foods

4.1 Introduction

The Working Group considered that there was a need to develop a procedure to examine a container of a thermally processed food that is suspected to be not commercially sterile. Such a procedure is beneficial in investigating problems of non-commercial sterility of canned foods and in identifying problems which may, by their nature, create public health hazards. Such procedures may be applied by a processor, an independent laboratory or regulatory authority.

This procedure is not intended to establish the total absence of viable organisms in a single container or to establish whether commercial sterility has been achieved in a lot of a product. It is primarily intended to investigate problems leading to spoilage but it also could be used to identify potential safety problems. If there is evidence that search for a specific pathogen is necessary, appropriate procedures should be applied.*

As spoilage of thermally processed foods can result from poor handling of raw materials prior to processing, under-processing, or post-thermal processing leaker contamination, procedures to establish the cause of spoilage should not be limited solely to examination of the food for viable microorganisms. They should include also, the physical examination of the container, and its integrity, as well as (where possible) the examination of records of the processing and shipping history of the product. The results of these should be taken into account, together with the microbiological results, in arriving at a final conclusion.

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

4.2 Product Identification and History Information (Stage 1 in Appendix II)

The Working Group agreed that it is important to compile as much information as possible about the suspect product. This should not be restricted solely to the acquisition of microbiological data. The information and data should be examined for trends and patterns before making conclusions. A check list of the information required is helpful to ensure that essential data are not missed. An example of information needed in such a check list is given in Appendix III.

4.3 Laboratory Examination

The Working Group considered the different steps in the laboratory examination of canned foods and proposed the following procedure.

^{*} For detailed descriptions of such procedures see, for example, "Microorganisms in foods. I. Their significance and methods of enumeration" 2nd edition, ICMSF, University of Toronto Press, 1978.

A. External visual inspection and physical measurements (Stages 2 in Appendix II)

- Visual examination of container should be done before removing any paper labels. Defects such as dents, visibly damaged seams, corrosion, swelling and knife cuts should be recorded.
- 2. Visual examination should be repeated after removal of the labels (if present), particularly for seam defects, tin plate faults and corrosion. Before removal, the label should be marked in a manner so that its original position on the container can be identified. This will assist in the location of defects which may be indicated by stains on the label. During examination of the container an attempt should be made to establish whether the problem is damage caused by mishandling during shipment or is a result of factory damage. All observations should be recorded.
- 3. The container should be carefully examined with the aid of a magnifying lens, under good illumination, before opening and/or attempting seam measurements. With respect to 3-piece metal cans, particular attention should be paid to examining the seams for defects such as cutovers and dents (adjacent to or on the seam), droops, spurs, pleats and lap faults. Other less noticeable defects may occur, for example, faults in the tinplate, score marks caused by the supermarket case opening knives, small pinholes in welded side seams, rust holes etc. Therefore careful visual examination of the can is essential. A list of the common visual external defects found on three-piece cans is given in Table 1.

TABLE 1

The Common Visual External Defects
Found in 3-Piece Cans*

Likely Place Where Fault Occured or Caused	Position on Can	Type of Defect
Can Manufacture	Can end/can body	Cut, hole, fracture tinplate
Cannery lap	Can body	Side seam fault, fault
	Easy-open strip	Score fracture
	Can end	Deep coding,compound squeeze out damage to key fixing
	Double seam	Cut over Droop Split droop Deformed end seam Spur Knocked down curl
		First operation roll Skidder, false seam. Knocked down flange Jumped seam, broken chuck
	Can body	Perforated, pierced, Cut dents
Filling		Peaked, flipper, springer
Cooling	•	Peaked, pannelled
Can runways		Cable burn, abrasions, dents under rim of double seam
Storage		External corrosion (rust)
Transit/Retail		Cuts, dents

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

Non-destructive measurements of seals or seams should be carried out. For example, for cylindrical cans, measurements of double seam height and thickness, and countersink should be carried out at at least 3 locations approximately 120°C apart around the double seam exclusive of the juncture with the side seam. Blown, badly distorted or damaged containers are usually only suitable for visual examination since the seams are often too distorted for proper seam measurements to be made. Tests or measurements, e.g. tap-test, countersink or center depth, can be used to give comparative measures of the internal vacuum.

Determination of Net Weight

A close approximation of the net weight can be obtained by subtracting the average net weight of empty containers, if known, from the gross weight of the container. If this is not possible, the determination of the net weight will have to be delayed until the weight of the empty container is established; see Section H.

Over-filling reduces the headspace and may adversely affect the vacuum when the container is sealed. In extreme cases it may cause containers to have a zero internal vacuum and even result in bulging of the container ends giving the appearance of a swollen can. Over-filling may decrease the effectiveness of a thermal treatment, specially when flexible containers are used, and cause excessive strain on seals or seams during processing. Net weight in excess of a reasonable tolerance of the declared net weight, or the average net weight determined by examination of a significant number of containers of normal appearance, may indicate over-filling.

Underweights may indicate that either the container was under-filled or leakage has occurred. Other evidence that leakage may be the cause of underweight should be sought, e.g. stains or product residues on the container surface, label, surrounding containers in the same carton.

B. Incubation (Stage 3 in Appendix II)

Consideration should be given as to whether the container(s) should be incubated before opening for microbiological examination of the contents. Incubation is usually unnecessary for international shipments of canned foods, unless the shipping history indicates the containers have been stored at temperatures not exceeding 20°C during transportation and storage. If this possibility exists, containers should be incubated at either 30°C for 14 days and/or 37°C for 10 days. In addition, if the product is intended to be distributed in areas of the world with a tropical climate, containers should also be incubated for 5 days at 55°C. Thermophiles may die during such incubation period, therefore it is desirable to examine containers frequently. The aim of incubation is to increase the chance of finding viable microorganisms in subsequent microbiological examinations. It is not intended to indicate whether or not product is microbiologically stable.

Swollen, punctured or holed containers must not be incubated.

C. Cleaning, disinfection and opening of containers (Stages 4 and 5 in Appendix II)

- 1. Containers should be cleaned with a detergent, rinsed and disinfected, e.g. by immersion of clean containers in 100-300 ppm chlorinated water (pH 6.8) for 10-15 minutes. Containers should be dried immediately after disinfection, using sterile disposable paper tissues.
- 2. A safety cabinet should be preferably used when opening suspected non-commercially sterile containers. Within the cabinet, swollen containers should be opened inside a bag or by using the inverted funnel method to contain any spray. Horizontal laminar flow cabinets which blow air over the operator should not be used. All containers should be handled as if they contained Clostridium botulinum toxin.

- 3. It is usual to open the non-coded end of the metal container. It is recommended that a stainless steel spike (with shield) be used for piercing the container end. For opening cans containing solid product a disc cutter should be used, or alternatively the side may be pierced and the container opened by cutting round the body. It is important to avoid damage to seams and seals when opening containers.
- 4. Flat (not swollen) containers.
- a) The end of the container which is to be opened for sampling should be decontaminated, e.g. by flooding with an appropriate aqueous alcohol/iodine solution and leaving for 20 minutes or by using 2% peracetic acid in isopropanol for 5 minutes.

Appropriate safety precautions should be taken when using any of these chemicals.

- b) The opening device should be cleaned in appropriately diluted detergent and decontaminated as described above or sterilized by wet heat in an autoclave. Open the decontaminated part of the container.
- c) Record any odour from can, but direct sniffing must be avoided.
- d) The opening should be protected with a sterile cover (e.g. half Petri dish).
- 5. Swollen containers. (The wearing of a face shield is recommended when opening swollen containers).
- a) Swollen containers may be chilled to (4^o C) before opening to reduce the pressure inside except if they are suspected of containing thermophiles.
- b) Proceed as described in Sections 2 and 4 above.
- D. Sampling and microbiological analysis of container contents (Stages 6 and 7 Appendix II)

 Sampling and inoculation of media

The procedure for the microbiological analysis of samples from the contents of a container are given in Appendix III.

1. Reference sample

A reference sample of at least 20 g or 20 ml shall be aseptically removed from the contents and transferred to a sterile container, sealed and refrigerated until required at a temperature below 10°C. The reference sample may be required to permit confirmation of results at a later stage. Care should be taken to avoid freezing the sample as this may kill a significant number of bacteria in the reference sample. If thermophiles are of concern then the reference sample should not be refrigerated. The reference sample also provides material for non-microbiological tests or analyses, should these be required, e.g., for analysis for tin, iron, lead, etc.

For solid, and semi-solid canned foods, it is advisable after sampling to transfer all the remaining contents to sterile container.

2. Analytical sample and inoculation of media

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

2.1 Liquid products

It was recommended to sample these products using suitable sterile, plugged, wide bore-tipped pipettes (pipetting by mouth should be avoided). The sample should be inoculated into liquid and solid media.

For liquid media it is recommended that each tube of each medium is inoculated with 1-2 ml of the container contents. To mix contents it is advisable to flush the pipette at least twice with contents before withdrawing the analytical unit. Liquid samples may also be mixed by agitating the container before opening.

For the inoculation of solid media each plate should be streaked with at least one loopful (approx. 0.01 ml) of container contents.

2.2. Solid and semi-solid products

For the purpose of analysis of these products core and surface samples should be taken.

For taking a core sample, a suitable sterile device (e.g. cork borer), having adequate diameter and length should be used. Take the sample by pushing the device from one surface through the geometric centre to the opposite surface of the container. With solid foods it is advisable to move the device back and forth slightly while cutting through the food to facilitate removal of the core.

Core samples should be divided into three portions, one from each end of the core and the third from the centre. Each portion should contain sufficient quantity to permit inoculation of 1 to 2 g of material into each tube of each medium used. Each portion should form a separate analytical unit, and it would be wise to transfer each portion to a separate sterile container labelled clearly to identify the portion of the core. Each portion should be chopped aseptically to reduce the particle size. It is useful to add the chopped portion to 2-5 ml of a suitable sterile diluent (e.g. 0.1% peptone water) and further comminute the portion. In any case, this latter step will be required for streaking of plates (see below).

For surface sampling the product should be removed aseptically from the container to a sterile tray. Scrape the product surface giving special attention to those areas in contact with the seams and any easy-opening feature. In many cases, it may be sufficient to swab those same areas of the container. The swab should be placed into a sterile suitable diluent, shaken vigorously and used to inoculate each medium. It is recommended that liquid and solid media be inoculated using the same procedures described in the section above dealing with liquid products. Each portion of the core sample and the surface sample should be treated as separate analytical units.

N.B. Where possible microbiological analysis should also be done on at least one normal can for comparative purposes.

E. <u>Direct microscopic examination</u> (Stage 8 in Appendix II)

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

There is an advantage in using both a wet film and a dry stain technique. There is little point in using a Gram stain because old cultures often give a variable Gram reaction.

A slide of the can contents should be prepared for examination. Control slides from sound cans should be included, particularly if the product is unfamiliar or if numbersper field are to be compared.

It is important to note the following:

- It is easy to confuse particles of product with microorganisms, it may be useful to dilute the sample.
- Pre-process spoilage or autosterilization may show up on smears at this stage but no growth is obtained on culture media.
- Do not assume that apparent absence of microorganisms on a slide means that none are present in the product.
- The entire smear should be scanned to locate areas of microbiological interest. Examine at least five fields in detail. Record observations giving approximate numbers and morphology.

F. Sensory examination (Stage 9 in Appendix II)

This procedure was considered by the Working Group as an important part of the examination of canned foods. During this procedure note should be taken of any unusual breakdown of product, unusual colour, odour or cloudy brine.

The texture of solids should be checked by feeling/squeezing product with a gloved hand. It is essential that the temperature of product should be less than 15° C and preferably not greater than 20°C.

Where it is possible, comparisons of the results of sensory examination with normal products should be done.

G. Measurement of pH of contents (Stage 10 in Appendix II)

The Working Group recommended that pH of contents should be checked and compared with normal product in accordance with existing methodology*. A change in pH may indicate microbial growth.

^{*} The recommended International Code of Hygienic Practice for Low Acid and Acidified Low Acid Canned Foods CAC/RCP 23-1979 (Appendix II)

H. Emptying and sterilization of container (Stage 11 in Appendix II)

The contents should be emptied out into a suitable container unless removed for reference sample. The container should be examined internally for evidence of corrosion or other defects.

The empty container should be washed, disinfected, dried and then weighed. It should be sterilized prior to subsequent examination by vacuum or pressure testing, seam teardown etc. (Section to be developed for these).

5. Guidelines for the Most Probable Interpretation of All Data from a Container of a Canned Food

The interpretation of the laboratory data in Tables 2 and 3* should be considered together with the overall pattern of the particular spoilage incident being investigated and the product history.

^{*} Based on M.L. Speck, Compendium of Methods for the Microbiological Examination of Foods, 1976.

TABLE 2

Interpretation of Laboratory Data Concerning a Low-Acid Food

Condition of can	Odour	Appearance***	pH*	Smear	Key** points from cultures	Possible interpretations
Swell	Sour	Frothy possibly ropy brine	Below normal	Cocci and/ or rods and/ or yeasts	Positive; aerobe and/or anaerobe; growth at 30°C and/or 37°C	Post-process leakage
Swell	Slightly off (some- times) ammoni- acal	Normal to frothy	Slightly to defi- nitely abnormal may be higher pH	Rods (spores sometimes seen)	Positive; aerobe and/or anaerobe; growth at 30°C; often pellicle formation in aerobic broths	Post-process leakage or gross under- process
Swell	Sour ·	Frothy possibly ropy brine. Food firm and uncoked	Below normal	Mixed population (often spores)	Positive; aerobe and/or anaerobe; growth at 30°C, 37° and often 55°C	No thermal process given
Swell	Normal to sour or cheesy	Pale colour or distinct colour change frothy	Slightly to defi- nitely below normal	Medium to long rods, often granular. (spores sel- dom seen)	Positive; anaerobic growth at 55°C. No growth at 30°C. Possibly growth at 37°C.	Thermophilic anaerobe; inadequate cooling or storage at elevated temperatures Clostridium spp.
Swell	Normal to cheesy to putrid	Usually frothy with disintegration of solid particles	Slightly to defi- nitely below normal	Rods (spores may be seen)	Growth and gas in anaerobic culture at 37°C and/or 30°C but no growth in aerobic cultures	Under-processing mesophilic anaerobe HIGH RISK-consider survival of Clostridium botulinum
Swell	Normal	Normal	Normal	Normal	Negative	Insufficient exhausting of can before seaming;overfill or hydrogen swell
Swell .	Little or no gas on opening	Normal	Normal to below normal	Large numbers of evenly stained cocci and/or rods	Negative	Pre-process spoilage
Swell	Sour to cheesy	Frothy	Often below normal	Poorly stained cocci and/or rods	Negative	Leaker spoilage followed by auto-sterilisation

Condition of can	Odour	Appearance***	pH*	Smear	Key** points from cultures	Possible interpretations
Apparently sound	Sulph- urous	Contents blackened	Normal to below normal	Rods	Anaerobic growth without gas at 55 [°] C only	Thermophilic sulphur stinker under processing
Apparently sound	Normal to sour	Normal to cloudy brine	Normal to below normal	Cocci and/or rods	Positive; aerobe and/or anaerobe; growth at 30°C, and usually 37°C	Post-process leakage
Apparently sound	Normal to sour	Normal to cloudy	Below normal	Rods (often granular)	No growth below 37°C. Aerobic growth without gas at 55°C; may get no growth if samples old or incubated for long period	Thermophilic aerobes (flat sour) Bacillus spp. Inadequate cooling or storage at elevated temperatures
Apparently sound	Normal to sour	Normal to cloudy	Below normal	Rod, (spores may be seen)	Positive; aerobe growth at 37°C and 30°C	Under-processing or leakage. Mesophilic aerobic spore-formers. (Bacillus spp.)
Apparently sound	Normal to sour	Normal to cloudy brine	Below normal	Granular rods	Negative	Under-processing or auto-sterili-sation; thermo-philic aerobes
Apparently sound	Normal to sour	Normal	Normal to below	Large numbers of evenly stained cocci and/or rods per field	Negative	Pre-process spoilage
Apparently sound	Normal	Normal	Normal	Negative or occasional rods and/or cocci, i.e. normal	Negative	No microbiolo- gical problem

The pH may rise particularly with microbial growth in meat or protein rich food

There may be difficulty in isolating <u>Flavobacterium</u> spp. from milk or milk-based products at 25°C as they may not grow in aerobic broths.

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

TABLE 3

Interpretation of Laboratory Data Concerning an Acidified Low-Acid canned Food

Condition of can	Odour	Appearance*	Normal pH group	Smear	Key points from cultures	Possible interpretations
Swell	Normal to metallic	Normal to frothy	4.6 and below	Normal	Negative	Hydrogen swell
Swell	Sour	Frothy - possibly ropy brine	4.6 and below	Rods and/or cocci and/or yeasts	Positive aerobe and/or anaerobe growth at 30°C	No process given or post-process leakage
Swell	Sour	Normal to frothy	4.6 and below	Rods	Growth and/or gas aerobically and/or anaerobically at 30°C	Lactobacilli; grossly insuffi- cient processing or post-processs leakage
Swell	Butyric	Normal to fosthy	4.6 to 3.7	Rods (spores may be seen)	Growth and gas in anaerobic culture at 30°C	Under-processing mesophilic aerobe (flat sour)
Apparently sound	Sour	Normal to cloudy juice	4.6 to 3.7	Rods (often granular)	Aerobic growth without gas at 37°C and/or 55°C	Thermophilic/ mesophilic aerobe (flat sour)
Apparently sound	Normal sour	Normal cloudy juice possibly mouldy	4.6 and below	Rods and/or cocci and/or moulds	Positive aerobe and/or anaerobe growth at 30°C	Leakage under- processing
Apparently sound	Normal	Normal	4.6 and below	Normal .	Negative	No microbiologica problem

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

6. Guidelines to Assist in Identifying Causes of Non-Commercial Sterility

The Group recognized the importance of considering all available data to assist in identifying causes of non-commercial sterility and proposed the following guidelines:

1. Number of Spoiled Containers

- a) Isolated container: usually random leaker but could be the result of under-processing or non-processing;
- b) Several containers: defective containers, rough handling or under-processing;
- c) Under-processing often associated with a particular batch.
- 2. Age of Product and Storage

Location of Spoilage

- a) Excessive age and for excessively high temperature may give rise to hydrogen swells;
- b) Corrosion, or damage, causing perforations of container may lead to leaker spoilage;
- c) Thermophilic spoilage may result from storage at high temperature, e.g. 37°C and above.
- d) Packs exported to hot climates may result in thermophilic spoilage.
- a) Spoilage in centre of container stacks, or near ceiling, may indicate insufficient cooling resulting in thermophilic spoilage;
- Scattered spoilage throughout stacks or cases may indicate past processing leakage or underprocessing;
- c) High numbers of spoiled containers usually indicate under-processing.

4. Processing Records

- a) Records showing poor control of thermal processing may correlate with spoilage from underprocessing;
- b) Adequate processing records may eliminate underprocessing spoilage and indicate post-process leaker contamination;
- c) Inadequate venting of retorts, leaking cooling water valves, broken thermometers and non-rotation of rotary cookers may lead to under-processing;
- d) Delays, with bad hygiene before processing, may lead to pre-processing spoilage;
- e) Leaker spoilage may occur with or without defective seams or visible dents and may be related to overcooling, inadequate chlorination, contaminated cooling water and/or dirty, wet post-processing equipment;

- f) Handling wet cans may increase likelihood of leaker spoilage;
- g) High thermophilic spore counts in blanchers may correlate with thermophilic spoilage;
- h) Changes in product formulation without reevaluation of process parameters may lead to underprocessing;
- i) Inadequate sanitation may lead to either buildup of microorganisms in product which may overwhelm a normal thermal process or lead to post-process leaker contamination.

5. Laboratory Data

See Tables 2, 3 and Appendix V.

7. Concluding Remarks

The Working Group recognized that their deliberations centered on determining of lack of commercial sterility in canned foods. Such determinations are of necessity, different from those required to prove that commercial sterility has been attained within a given code-lot of food.

The Group did not feel that it was possible to give general guidance on the disposal of lots which have been demonstrated to be not commercially sterile.

The reasons for such non-commercial sterility are many and varied. Therefore, a decision on disposal of such lots needs to be made on a case-by-case basis, utilizing much of the information obtained in assessing the status of the lot from which the container was obtained. Whether or not a lot can be salvaged will depend, for example, on factors such as the reason for non-commercial sterility, the ability and reliability of physically separating satisfactory from non-satisfactory products, etc. These factors will of course, vary widely. Therefore, the general principles outlined in the Code of Hygienic Practice for Canned Foods Suspected of being Contaminated (under development by the Codex Committee on Food Hygiene) may well apply and be used for lots in which lack of commercial sterility has been identified.

APPENDIX I

LIST OF PARTICIPANTS

Dr. A.C. Baird-Parker Colworth Laboratory Unilever Research Colworth House Sharnbrook. Bedford MK44 1LQ

Dr. B.E. Brown Evaluation Division Bureau of Microbial Hazards Health Protection Branch Health and Welfare Canada Ottawa Ontario K1A OL2 Canada

Mr. I.E Erdman Chief Evaluation Division Bureau of Microbial Hazards Health Protection Branch Health and Welfare Canada Ottawa Ontario K1A OL2 Canada

Mr. K. Haaning Veterinary Service Laboratory Ministry of Agriculture Kongensgade 16 Postbox 93 DK 4100 Ringsted Denmark

Mr. D.A. Kautter Assistant Chief, Food and Cosmetics Microbiology Branch HFF-234 Division of Microbiology Center for Food Safety and Applied Nutrition Secretariat Food and Drug Administration Public Health Service US Department of Health and Human Services Washington, D.C. 20204 USA

Dr. J.C. de Man NESTEC S.A. Central Quality Assurance Laboratory P.O. Box 88 1814 La Tour-de-Peilz Switzerland

Dr. S.C. Michanie Associate Professor of Food Microbiology Faculty of Food Engineering University of Luján Gorostiaga 2248 Buenos Aires Argentina

Dr. T. Mulvaney Division of Food Technology **CFSAN** Food and Drug Administration, PHS US Department of Health and Human Services Washington, D.C. 20204

Dr. W.G. Murrell CSTRO Division of Food Research Food Research Laboratory Delhi Road North Ryde NSW 2113 Australia

Dr. P. Teufel Institute for Veterinary Medicine (Robert von Ostertag Institute) Thielallee 88/92 Berlin (West)-33 Federal Republic of Germany

Ms. C. Wongkhalaung Chief of Quality Control Division Institute of Food Research and Product Development Kasetsart University P.O. Box 4-170Bangkok 10400 Thailand

Dr. A. Koulikovskii Food Hygienist Veterinary Public Health Division of Communicable Diseases World Health Organization Geneva Switzerland

Observers

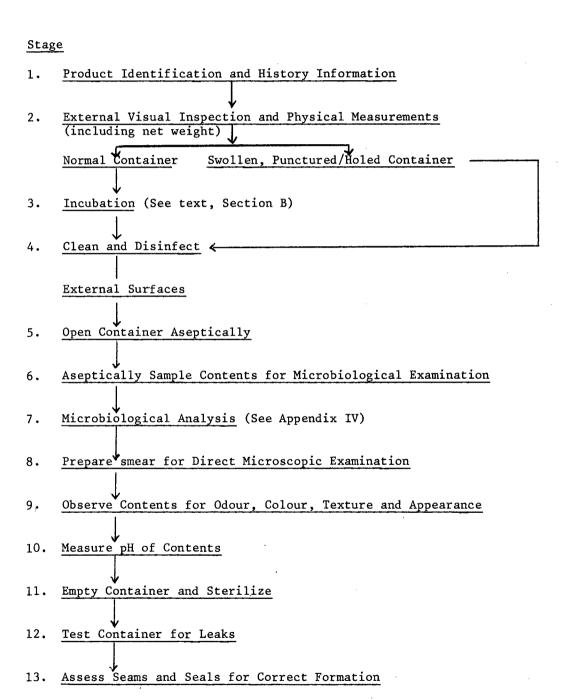
Dr. R.B. Read, Jr.
Director
Division of Microbiology
Food and Drug Administration
Public Health Services
US Department of Health and Human Services
Washington, D.C. 20204
USA

Dr. G.J. Jackson Chief Food and Cosmetic Microbiology Branch Food and Drug Administration Public Health Services US Department of Health and Human Services Washington, D.C. 20204 USA

Dr. R.W. Johnston Director Division of Microbiology, FSIS US Department of Agriculture Washington, D.C. 20250 USA

APPENDIX II

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



APPENDIX III

AN EXAMPLE OF A PRODUCT IDENTIFICATION AND HISTORY ENQUIRY FORM*

Enquiry No.

Date

(Tick or complete those parts of form applicable to the enquiry)

1. Reasons for Investigation

- 1.1 Illness
 - a. Number of persons involved
 - b. Symptoms
 - c. Time before onset of symptoms
 - d. What other foods and beverages were also ingested
 - e. Number of cans involved
- 1.2 Defects
 - a. Location of affected product
 - b. Temperature of storage
 - c. Number of defect containers
 - d. Number of normal containers
 - e. Date when defect first noted
 - f. How many swollen, burst or leaking containers
 - g. Where there consumer complaints? (If yes, give details).

2. Product Description and Identification

- 2.1 Product name and type
- 2.2 Container type and size
- 2.3 Identification (Code lot)
- 2.4 Processor
- 2.5 Supplier/Importer
- 2.6 Lot size

3. Product History Relating to Suspect Code Lot(s)

- 3.1 Product composition
- 3.2 Container supplier and specification
- 3.3 Processing data and records
 - a. Product preparation
 - b. Filling
 - c. Sealing
 - d. Thermal processing
 - e. Cooling
 - F. Additional quality control records
- * This form is only intended to be an example and may require modification for a specific investigation. For instance, the data to be collected under Section 1.1. (illness) should be expanded if food poisoning is suspected.

- 3.4 Storage and transportation
- 3.5 Current status of lot(s) under examination

4. Sample Description and History

- 4.1 Where and when was sample obtained
- 4.2 Total number of containers at site of sampling
- 4.3 Number of containers selected
- 4.4 How were containers selected
- 4.5 Number of containers having defects and rate
- 4.6 Describe type of defects
- 4.7 Conditions of storage and transportation
- 4.8 Sample identification (number assigned)

APPENDIX IV

PROCEDURES FOR MICROBIOLOGICAL ANALYSIS OF ANALYTICAL SAMPLE

A. Mesophiles

Incubation Conditions

1.	Media*	Aerobic	Anaerobic
		Liquid Solid	Liquid Solid
		- DTB -PCA	-PE2 -LVA
		- PE2	-CMM -PIA
			-LB -RCA
	•		-RCM -BA
2.	Quantity 15 ml tube	15 ml 15 ml plate tube	15 ml plate
3.	Replication > 2 tubes	⇒ 2 plates ⇒ 2 tubes ⇒ 2	plates
4.	Incubation		•
	Temperature (**) 30°C	30°C 30°C	30°C
5.	Incubation		
	Time (***) up to 14	days up to 5 days up to 1	4 days up to 5 days.

Use one medium for each series of solid and liquid media

Incubated aerobically and anaerobically

* Abbreviations used for media:

DTB - Dextrose Tryptone Broth

PE2 - Peptone, Yeast Extract Media (Folinazzo, J.F. and Troy, V.S., 1954. A simple medium for growth and isolation of spoilage organisms from canned food: Food Technol. 8:280-28

PCA - Plate Count Agar

CMM - Cooked Meat Medium

LB - Liver Broth

RCM - Reinforced Clostridial Medium

LVA - Liver Veal Agar

PIA - Pork Infusion Agar

RCA - Reinforced Clostridial Agar

BA - Blood Agar

- ** Temperature of 35°C or 37°C may be used in addition or when ambiant (room) temperature is near to or greater than 30°C or when specific organisms of concern have higher optimal growth temperatures.
- *** Examine tubes and plates periodically, e.g. at least every two days. Incubation is terminated when positive growth observed.

Verification of suspect positive tubes

All suspect positive tubes should be examined as follows:

- Carry out a direct microscopic examination of suitably prepared and stained smears.
- 2. Inoculate at least duplicate plates, and incubate aerobically and anaerobically for up to 5 days. For suitable media see above.

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

Identification of isolates

To assist in identifying the cause of non-commercial sterility it is useful to identify isolates. For this purpose standard microbiological procedures should be used (Speck, 1976; ICMSF, 1980, BAM, 1978).

B. Thermophiles

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

Incubate for up to 10 days.

Thermophilic aerobes (flat sour) - Dextrose-tryptone broth:

B. Thermoacidurans . Proteose Peptone-acid medium* (coagulans)

Anaerobes not producing H₂S - Liver broth*

C. Thermosaccharolyticum - Corn liver* medium

Anaerobes producing - Sulphite agar*

 $\mathrm{H}_2\mathrm{S}$ + reduced iron or iron citrate

C. Acid tolerant

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

1. Liquid

- a. Acid Broth (AB) (see U.S.FDA Bacteriological Analytical Manual)
- b. Man, Rogosa and Sharp (MRS) broth

While the above media have been useful for acid foods there may well be exceptions and specific media and temperatures may be required.

2. Incubation

30°C for up to 14 days.

^{*} Hersom & Hulland, 1980

APPENDIX V

Guideline to the Interpretation of results of a complete Microbiological . Analysis Using Triplicate Determinations

AEROBIC BROTH				AEROBIC PLATE			ANAEROBIC BROTH			ANAEROBIC PLATE			RESULTS
30°	37 ⁰	55 ⁰		30 ⁰	37 ⁰	55 ⁰	30 ⁰	37 ⁰	55 ⁰	30°	37 ⁰	55 ⁰	
+ + + +	+ + +	-		+ + -	+ - +	-	-	- - -	-	-	- - -	-	STRICT- AEROBE MESO- PHILIC LEAKAGE OR PERHAPS UNDER PROCESSING
+ + +	+ - +	-		+ + -	+ -+	- - -	+ + -	+ + +		+ + -	+ - +	-	MESOPHILIC FACULTATIVE ANAEROBE LEAKAGE OR UNDER PROCESSING
-	-	-		-	-	- -	+ + +	+ - +	-	+ -	+ - +	-	MESOPHILIC STRICT ANAEROBE UNDER PROCESSING OR LEAKAGE
	-	+ + +		- - -	-	+ + -	- - -	-	-	-	- - -	-	STRICT THERMOPHILIC AEROBE UNDER - PROCESSING USUALLY OR BLANCHER/RAW MATERIAL PROBLEM

									(Appendix V continued					
_	-	_	-	_	-	-	+	+	-	+	+	THERMOPHILIC STRICT /		
-	-	-	-	-	-	Ξ	+	+	<u>-</u>	-		ANAEROBE UNDER PROCESSING CESSING . USUALLY OR BLANCHER/RAW MATERIAL PROBLEMS		
-	-	-	-	-	-	-	-	-	-	-	-	CAN CULTURE DIE OUT STERILE CAN PREPROCESS SPOILAGE WRONG CULTURE MEDIA		

The preferred temperature is 30°C (See Text)

NOTE: The above table is the expected result for a pure culture (mixed cultures often occur and all cultures should be checked by examination using a microscope).

Check that all isolates will in fact grow in sound product samples and that they show similar spoilage characteristics. It is also important to cross reference incubation tests.

Refer to contents smear results earlier in flow sheet. When results do .not fit a pattern, more than one cause of spoilage may be present, or some of your ta may be inaccurate or incorrect.

Finally weigh all the possibilities of each state carefully with the information available before arriving at a conclusion. In some instances a clear answer may not emerge and further samples may be required.

Retain cultures, reference samples and cans until enquiry is completed. It may be useful for future references to retain interesting cultures and samples, otherwise, these should be autoclaved before disposal.

APPENDIX VI

LIST OF WORKING DOCUMENTS

- 1. de Man J.C., Canned foods stable under ambient conditions
- Kautter D.A., Lynt R.K., Landry W.L., Lanier F.M., Schwab H., Examination of canned foods
- 3. Michanie S.C., Control measures applied to canned meat for international trade
- 4. Murrel W.G., Christian F.H.B., Microbiological specifications for canned foods
- 5. Murrel W.G., Christian F.H.B., Microbiological examination of defective cans/containers
- 6. Teufel P., Kolb H., Microbiological examination of canned food in the Federal Republic of Germany
- 7. Wongkhalaung C., Microbiological examinations and specifications of canned foods in Thailand
- 8. Examination of suspect spoiled cans. Document prepared by the Campden Food Preservation Research Association Microbiology Panel (Chipping Campden, UK) presented to the participants by Dr.A.C. Baird-Parker
- 9. Method for the determination of presence of viable microorganisms in canned food. Project document of the Canadian Health Protection Branch, MFA-25C, May 1983, presented to the participants by Dr. I.E. Erdman