

**CANNED TUNA QUALITY
MANAGEMENT MANUAL**

**ASEAN CANADA FISHERIES
POST-HARVEST TECHNOLOGY PROJECT - PHASE II**

ASEAN-CANADA FISHERIES POST-HARVEST TECHNOLOGY PROJECT - PHASE II

TUNA QUALITY MANUAL

The ASEAN-Canada Fisheries Post-Harvest Technology Project (Phase II) was started in April 1992. The Project's objectives are to strengthen and upgrade fisheries product quality and fish inspection services within ASEAN countries; to assist in the development and implementation of improved methods and technologies in fish processing, preservation and packaging through regional collaborative efforts; and to facilitate the transfer/adoption of appropriate technologies to the fish processing industries through training and extension services.

The Project activities are coordinated and administered by the ASEAN Executing Agency (AEA), which is housed at the Marine Fisheries Research Department (MFRD) of the Southeast Asian Fisheries Development Center (SEAFDEC) in Singapore. In cooperation with the ASEAN governments, the Project established Regional Centres for Fish Processing Technology (RC-FPT, Singapore), Fish Inspection and Quality Control (RC-FIQC, Indonesia), and Information Preparation and Dissemination (RC-IPD, Malaysia) and developed work programs of national importance and regional interest for all ASEAN countries.

Each ASEAN member country except Malaysia conducts two activities on either seafood processing or quality control in order to develop technical training manuals/materials and assist the RC-IPD in the production of extension materials based on these Projects activities. The technologies developed are then transferred to the fish processing industries in the region through end-of-activity seminar/demonstrations and dissemination of information/training materials by government and private sector extension personnel.

The contribution of the Canadian International Development Agency (CIDA) for providing funds to assist the development of the Project and its publications is gratefully acknowledged.

AUTHORS:

Ms Sirilak Suwanrangsi, Ms Suwimon Keerathiviriyaporn, Ms Krissana Sophonphong, Mrs Supapun Briliantes and Mr Leonard G. Limpus.

PRINTER:

Regional Centre for Information Preparation and Dissemination, Department of Fisheries Malaysia, 5th Floor Wisma Awal, Jalan Raja Muda Abdul Aziz, Kg. Baru, 50300 Kuala Lumpur, MALAYSIA

LIAISON OFFICE:

ASEAN Executing Agency, ASEAN-Canada Fisheries Post-Harvest Technology Project - Phase II, Changi Fisheries Complex, 300 Nicoll Drive, Singapore 498989.

Copyright 1995. ASEAN Executing Agency, ASEAN-Canada Fisheries Post-Harvest Technology Project - Phase II. Copyright will be transferred to the Marine Fisheries Research Department, Southeast Asian Fisheries Development Centre¹, upon successful completion of the Project.

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise without the prior written permission of the publisher. However, reproduction or translation of this publication, in whole or in part, by any method or process, for purely research and non-profit purposes is allowed. The reproduction or translation must include a statement acknowledging the support and financial contribution of the Canadian International Development Agency (CIDA) for the development and production of this publication. A letter stating the purpose of the reproduction or translation must also be sent to the copyright holder.

¹Marine Fisheries Department
Southeast Asian Fisheries Development Centre
Changi Fisheries Complex
300 Nicoll Drive
Singapore 498989

ISBN: 981-00-7608-8

FOREWORD

Thailand is the world's leading exporter of canned tuna and is currently the largest source of imported canned tuna in US, Canada, Japan and European markets. Canned tuna is also an important export commodity of ASEAN nations such as the Philippines, Indonesia, Malaysia and Singapore.

Quality and safety of tuna and tuna products is a major concern of the Department of Fisheries, Thailand. Since 1985 which is during the ASEAN-Canada Fisheries Post-Harvest Technology Project - Phase I, the Department had put in effort in building up personnel and quality system so as to maintain the image of quality and safety and the inspection system. During the Phase II Project, Thailand carried out the pilot project on *Controlling Decomposition of Tuna and Tuna Products* to specifically build up expertise on quality control, inspection and quality grading of tuna products. The Project has provided inputs in terms of operation costs, specialists from the Department of Fisheries and Oceans of the Government of Canada, and in-Canada attachment training. Pilot project with the industry on application of Good Manufacturing Practice and development of HACCP quality system have been carried out. Training and workshops have been conducted for the government inspectors, quality controllers of private sector from both Thailand and ASEAN member countries.

The support of Canadian International Development Agency in this project is greatly appreciated, it should be recognized that benefit is provided to the tuna industry of not only of Thailand, but through this manual ASEAN nations will all benefit from the output of the Project. On the other hand, Canada who is one of the major importer of canned tuna from this region indirectly gain benefit from the betterment of quality and safety of the products.

Dr Plodprasop Suraswadi
Director General
Department of Fisheries
Thailand

ACKNOWLEDGEMENT

The coordinator of the pilot project would like to express the sincere gratitude to the ASEAN Executing Agency, Canadian International Development Agency and the Canadian Supplies and Services Agency in providing administrative support to the activities taken under this pilot project.

The Department of Fisheries and Oceans (DFO) of the Government of Canada especially Mr B. J. Emberly and Mr Stewart Law are highly appreciated in their continual support of the program by providing specialists to work with the project. The specialists on retort monitoring and container integrity and tuna grading, and chemists have been allowed to work with the project in providing guidance and training. They are Mr Ian Devlin, Mr Klaus Schallié, Mr Clive Cosham, Mrs Karen Fernback and Mr David MacLachlan. DFO is to be acknowledged for allowing the use and development of Canadian Tuna GMP to be included in the Manual.

Sincere appreciation to co-authors of the manual namely Ms Suwimon Keerathiviriyaporn, Ms Krissana Sophonphong, Mrs Supapun Briliantes and Mr Leonard G. Limpus.

Special thanks to the Thai tuna processors for this manual will not be completed without their support, the companies involved in the preparation of this manual include Pataya Food Industries Co., Ltd., International Seafood Associates Co., Ltd. and King Fisher Holding Co., Ltd.

The Regional Centre for Information Preparation and Dissemination in Malaysia has continually working on the design and finishing of the manual. The efforts of all its staff is highly appreciated.

Ms Sirilak Suwanrangsi
Chief, Fish Inspection Center (Bangkok)
Thailand Country Coordinator

CONTENTS

<i>FOREWORD</i>	v
<i>ACKNOWLEDGEMENT</i>	vi
<i>INTRODUCTION</i>	2
CHAPTER 1: GOOD MANUFACTURING PRACTICES FOR THE CANNING OF TUNA	5
Section I - Receipt, Examination, Handling And Storage Of Raw Fish	6
Section II - Thawing	13
Section III - Butchering, Racking and Staging	15
Section IV - Precooking	19
Section V - Cooling The Pre-Cooked Fish	22
Section VI - Cleaning	23
Section VII - Packing	30
Section VIII- Retorting	42
Section IX - Can Cooling	48
Section X - Labelling	52
Section XI - Casing	53
Section XII - Product Storage	54
Section XIII- Quality Control	55
CHAPTER 2: HACCP PLAN FOR CANNED TUNA	59
CHAPTER 3: INSPECTION/VERIFICATION OF A TUNA CANNERY	73
CHAPTER 4: SENSORY EVALUATION OF TUNA	93
CHAPTER 5: CHEMICAL EVALUATION METHOD FOR QUALITY AND SAFETY	115
Appendix Code Of Practise	145

INTRODUCTION

This manual is based in part on Canada's *Good Manufacturing Practices Canned Tuna, Handbook of Compliance* (Draft #4, September 15, 1987) of the Inspection Directorate, Department of Fisheries and Oceans of the Government of Canada.

The manual summarizes practices which, if applied in the production of canned tuna, should result in products which are safe, wholesome and of good quality.

The design and application of Good Manufacturing Practice (GMP) guidelines aim at the prevention of problems by controlling the quality of the raw material and packaging materials and the manufacturing processes involved, rather than the identification of problems in finished products. Finished product inspection suffers from the weakness that once a food product has been manufactured, little can be done to alter its quality. It can only be accepted or rejected; faults cannot be put right. In practice, of course, it is seldom possible to guarantee fully complete control over raw materials and processing conditions, and thus a certain amount of finished product inspection is necessary to confirm the effectiveness of the controls. Nevertheless, the application of effective GMP guidelines is of major importance in assuring the quality of finished food.

In preparing these GMP guidelines, it was assumed that they are intended to deal with issues of quality, safety and wholesomeness in canned tuna. There can be no compromise with regards to safety and wholesomeness; they must be assured insofar as is humanly possible, and there must be no deviation from the highest standards of assurance. On the other hand, products which are safe and wholesome may differ in quality. There is a legitimate place in the market for products which differ in quality, so long as their wholesomeness and safety are not in doubt, and the manufacture and sale of the products involved does not result in consumers being misled as to their character, quality, value, merit or composition. Within the framework of the need to assure safety and wholesomeness, the current guidelines attempt to set forth practices which will result in the production of canned tuna which is of acceptable commercial quality.

It is essential that any GMP guidelines produced for canned tuna be subject to periodic review and amendment, as required. Furthermore, the guidelines must not be written in such a way that they freeze the technology at current levels. Rather, they must be flexible and permit technological changes which result in greater cost efficiency or utilize new techniques and procedures.

It must also be recognized that, although guidelines for GMP in the production of canned tuna represent a subset of more general guidelines for canned fish, they do not apply without change to the canning of other species of fish. The principles involved are undoubtedly generic in nature.

Extensive attention has already been paid by national and international agencies and organizations to the requirements which must be met to assure safety in low-acid hermetically sealed canned products, such as canned tuna. In general, when issues of safety and wholesomeness arise in the guidelines for GMP presented below, reference is made to already existing documents bearing on the matter. These include the following:

- a) *Codex Alimentarius Commission Code of Practice - General Principles of Food Hygiene,*
- b) *Codex Alimentarius Commission Recommended International Code of Practice for Canned Fish,*
- c) *Canadian Food Industry Code of Practice for Heat Processing Low-Acid Products in Hermetically Sealed Containers; Canadian Food Processors Association/Meat Packers Council/Fisheries Council of Canada/Fisheries Council of British Columbia,*
- d) *Regulations Respecting the Inspection of Processed Fish and Processing Establishments (the "Fish Inspection Regulations") revised from time to time; Queens Printer, Ottawa,*
- e) *Codex Alimentarius Commission recommended International Code of Hygiene Practice for Low and Acidified Low Acid Canned Foods,*
- f) Borgstrom, G. *Fish as Food.* Academic Press 1965.

In structuring recommendations, the major steps in processing canned tuna were identified and some of these were designated to be of critical importance (Critical Control Points) with respect to quality and/or safety. These are given below:

PROCESSING STEPS	CRITICAL IMPORTANCE	
Receipt and storage	Quality	Safety
Thawing frozen tuna for processing	Quality	
Butchering, racking and staging	Quality	
Precooking Cooling precooked fish	Quality	
In-process storage Cleaning	Quality	
Packing	Quality	Safety
Seaming and washing		Safety
Retorting		Safety
Can cooling	Quality	Safety
Labelling, casing and storing		Safety

In addition to the original GMP guidelines, the highlighted CRITICAL CONTROL POINTS IN TUNA PROCESSING were addressed. This is the result of a Workshop on Principle and Application of HACCP organized by the Department of Fisheries, Thailand between the years 1991 - 1993, and also the result of development studies on controlling decomposition of tuna and tuna products funded under the ASEAN-Canada Fisheries Post-harvest Technology Project - Phase II.

Additionally, information on the sensory evaluation of tuna, inspection of tuna canneries and some chemical analytical techniques for tuna which have been investigated under the Project and are used by Thailand are presented.

Sirilak Suwanrangsi,
 Coordinator PP-Thailand
 ASEAN-Canada Fisheries Post Harvest Technology Project - Phase II

CHAPTER 1

**GOOD MANUFACTURING PRACTICES
FOR
THE CANNING OF TUNA**

SECTION I
RECEIPT, EXAMINATION, HANDLING
AND STORAGE OF RAW FISH

The quality of the raw fish is one of the most important factors in determining the quality of the finished product. If the raw product is of inferior quality, it is not possible for the canned product to be of high quality. Each step in processing has the potential to lower the quality; none can raise it.

GMP 1.1 Each delivered shipment of raw or frozen tuna shall be inspected to determine its condition and quality. The condition of the fish shall be noted on receipt. The name of the supplier, the temperature and appearance of the fish and the number of rejects (smashed, sours, decomposed) shall be recorded on a suitable report.

GMP 1.2 Each lot of raw fish shall be graded. A lot shall be rejected if it fails to meet guidelines for acceptable quality. Rejected lots and individual rejected fish shall be removed from the area; they shall not be further processed for human food.



Grading frozen whole tuna



Frozen tuna



Frozen Tonggol

REASON

Since the quality of the final product depends upon the quality of the raw material, each delivered shipment of raw or frozen tuna shall be inspected and graded to determine its condition so that no tainted, decomposed, or unwholesome tuna are utilized, and to ascertain if all fish have been handled in a clean and sanitary manner.

It is essential that records of the quality of the fish in each shipment be maintained in order to identify lots which may not meet specifications.

Records of the quality and condition of the shipment, containing the following information, are made and kept for a period not less than 3 years after the shipment has been processed:

- a) species,
- b) date of receipt of shipment,
- c) name of supplier,
- d) name of delivery vessel or transport company,
- e) the average temperature of the fish,
- f) the grade of each fish inspected as per the Raw or Frozen Whole Tuna Grade Standard, including the reason or reasons for such grade, and
- g) the lots of final products identified by can codes which were produced from the particular lot of raw material.

NOTE: Culling of reject fish from a lot may be permitted in processing areas at the discretion of an Inspector, provided the rejected lots and individual rejected fish are physically segregated and there is no possibility that they can be combined with tuna of acceptable quality that is being thawed, butchered, or otherwise prepared for processing.

Grade standards for whole or butchered tuna intended for processing are given in Table 1, and a sampling plan is given in Chapter 2.

Table 1

**GRADE STANDARD
WHOLE OR BUTCHERED TUNA INTENDED FOR PROCESSING**

Grades are assigned to each sample unit examined using the combination of factors given below. The assigned grade cannot be higher than the lowest grade for any of the grading factors. Table 3 describes a sampling plan. The grade(s) assigned to the lot are determined by the percentage of each grade of the sample units in the lot. A lot of fish shall be rejected if the number of reject fish exceeds the acceptance number in Table 3. A reject lot may be culled and is subject to re-inspection.

<i>Grade Factors</i>	<i>Grade 'A' or '1'</i>	<i>Grade 'B' or '2'</i>	<i>Grade 'C' or '3'</i>	<i>Reject</i>
ODOUR Belly cavity and cut through flesh at nape	Fresh characteristic odours.	No odour.	Slightly stale odour or uncharacteristic odours not associated with taint or decomposition.	Any detectable odour associated with taint or decomposition such as ammonia, bilge, sour.
BELLY CAVITY Internal organs and belly wall	Smooth, bright, no evidence of burn; organs bright, firm, characteristic colour.	Slight burn, slightly rough peritoneum; organs slightly soft with loss of lustre, red discolouration evident.	Breakdown of belly wall, no holes to skin, excessively rough peritoneum; organs bleached and soft; 10% of belly wall affected by protruding bones; cracks if bent 90°.	Burns through to skin, greater than 10% of belly wall has protruding bones; organs show liquifaction, and/or grey or green colours evident.
PHYSICAL DAMAGE Edible portion of fish	No evidence of mutilation or damage.	Slight mutilation or deformation; no evidence of splitting.	Slight splitting; less than 10% of fish slightly smashed or broken to expose muscle.	Greater than 10% of the fish is split, smashed or mutilated to expose muscle.
TEXTURE	Firm and elastic.	Slightly soft.	Soft.	Excessively soft and mushy.
EYES	Clear, bright, protruding.	Sunken, cloudy-white or reddish.	Sunken, dull white or red. Center of eye liquified.	Not assigned.
SKIN	Characteristic lustre and colour, clear and bright.	Dull colour.	Absence of characteristic colour and lustre; breaks in skin.	Gross discolouration of skin, skin decomposed, broken with decomposed muscle visible.
GILLS	Characteristic odour and blood red appearance.	No odour; pale red to brown red colour.	Uncharacteristic odours not associated with taint or decomposition; dark brown to yellow brown colour.	<i>Grade 'D' or '4'</i> Detectable odours associated with taint and decomposition; white-yellow colour and slimy appearance.

GMP 1.3 On receipt, fish shall be tested for mercury, histamine and other chemical parameters related to safety and quality

REASON

Histamine is formed through the action of naturally occurring spoilage bacteria on the histidine in tuna. Histamine, when ingested in sufficient quantities, may give rise to “scombroid poisoning”. Heavy metals such as mercury, if present in amounts exceeding permissible levels, can pose a severe health threat. These tests are necessary to ensure the health and safety of the consumer.

Official methods and some methods developed and modified by Thailand are given in Chapter 5.

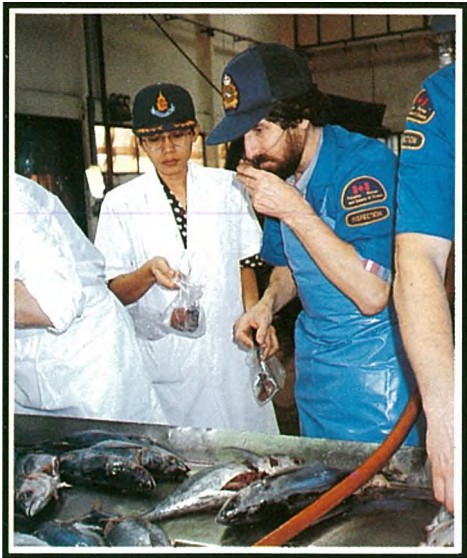
GMP 1.4 Fish which are in transit to the cold storage area shall be protected from the elements by appropriate covers on the shipping containers, and must be moved to cold storage as quickly as possible in order to keep surface thawing to a minimum.

REASON

This is necessary to prevent premature thawing between unloading and delivery to the plant, which could result in quality deterioration of the fish.



*Raw material
in
cold storage*



Collection of samples for raw material quality evaluation



Determination for histamine using Fluorometer



Determination for mercury using mercury analyser

GMP 1.5 Fish in storage shall be properly stored in sanitary containers and identified within the storage area according to the date it entered storage.



Storage of fish in stainless steel bins

REASON

This will ensure that tuna storage containers do not become a source of contamination and that stored tuna is processed as soon as possible, so that freer burn, rancidity development and, in general, quality deterioration is minimized.

GMP 1.6 Rooms in which frozen fish are stored shall be maintained at a temperature of -18°C or colder, providing that the storage time of the fish is no longer than 3 months.

REASON

Temperature fluctuations will adversely affect the quality of frozen fish. Automatic temperature recorders are highly recommended.

SECTION II

THAWING

GMP 2.1 Fish to be used immediately for canning shall be thawed in a uniform manner in safe, sanitary water which complies with the requirements of a competent authority. Recycling of water is not permitted. The temperature of the thaw water may be increased as appropriate, but if this is done, a tempering process should be carried out before introduction of the water to the thawing tank.

Note: Recycling is defined as using water for the thawing of more than one load of fish in the same thaw tank.

Tempering is a controlled warming process for frozen fish where the temperature is raised to approximately -7°C

REASON

These practices are necessary to ensure that the plant water supply will not be a source of contamination to the product and that the thawing process does not adversely affect the quality of the fish.

Thawing of fish



Thawed fish



GMP 2.2 Thaw tanks shall be of non-corrodible material, other than wood, and shall have smooth surfaces free from cracks and crevices.

REASON

This will help ensure that the thaw tanks do not become a source of contamination.

GMP 2.3 Hard frozen fish shall be sufficiently thawed to facilitate butchering. A properly thawed fish shall have a maximum internal temperature of 5°C at the butchering table.

REASON

Adherence to this section is critical to prevent rapid deterioration of the quality of the product; once the temperature of the fish exceeds 5°C, the rate of bacteriological and enzymatic spoilage begins to accelerate. If the fish are not thawed sufficiently, proper butchering may be difficult to perform and/or correct precooking temperatures at the backbone of the fish may not be attained.

SECTION III

BUTCHERING, RACKING AND STAGING

GMP 3.1 The time between thawing and the end of butchering must not exceed 2 hours for fish under 5 kg in weight, or 4 hours for fish 5 kg or greater in weight.

Note: Thawing is defined as ending when the thaw water is drained from the thawing tanks. Butchering ends when the fish are placed on the cooking racks.

REASON

In order to maintain the quality of the fish, the time between thawing and the end of butchering should be kept to a minimum and proportional to the sizes of fish under consideration. For fish weighing less than 5 kg, that time must not exceed 2 hours. For fish weighing 5 kg or more that time must not exceed 4 hours.

GMP 3.2 Fish shall be rinsed with safe, sanitary water before butchering.

REASON

In order to remove all extraneous and unwanted material from the fish, they shall be rinsed thoroughly using a sanitary water system.

GMP 3.3 Thawed or fresh fish shall be properly butchered, the belly cavities thereof thoroughly washed with safe, sanitary water, and the fish inspected for defects by well-trained and qualified personnel. All fish of questionable quality shall be examined, using sensory evaluation techniques and, where fish of unacceptable quality are found, all fish of the lot(s) involved shall be examined.

Butchering of fish



Recording temperature and quality of raw material

Segregation of rejected raw material



Any fish which are decomposed or rancid, fail to meet the tuna species requirements, or are too mutilated to process shall be segregated from acceptable tuna and disposed of for other than human food.

REASON

Proper butchering and washing is necessary to prevent bacteriological and enzymatic decomposition of the flesh. The gut of the fish harbours huge populations of spoilage organisms as well as autolytic enzymes and, therefore, it is critical that internal organs and viscera be removed quickly and completely and the belly cavity thoroughly washed with safe, sanitary water to protect sound flesh from contamination and subsequent decomposition. The external surfaces of fish also contain populations of microorganisms, and during butchering these surfaces may become further contaminated. Washing significantly reduces this bacterial load.

GMP 3.4 The butchered, washed and inspected fish shall be placed in an orderly manner, belly-down, in suitable non-corrodible metal racks of sanitary design, for movement into the pre-cooker.

Reasonable consistency in size shall be maintained amongst the fish in any given rack.

The racks shall be kept in a clean and sanitary condition.

REASON

It is necessary to ensure that the fish are pre-cooked at a uniform rate and that the cooking racks do not become a source of contamination to the product. The importance of placing the fish belly down on the cooking racks cannot be overemphasized. This arrangement allows the fish juices, oils, and rancid fat to drain off the fish during the cooking process. If the fish were belly up, these juices would collect in the belly cavities of the fish thereby penetrating and tainting the edible portions of their flesh. Unless the pre-cooking racks are properly sanitized, a build-up of proteinaceous material, juices, oils, fats, and other grime will occur and possibly contaminate and taint the edible portions of the fish flesh.

GMP 3.5 *The time during which fish are kept at the staging step must not exceed two hours for fish less than 5 kg in weight, or four hours for fish 5 kg or more in weight. If the ambient temperature exceeds 22°C, the maximum permitted staging time should be reduced accordingly.*

NOTE: Staging is defined as starting when the fish are placed on the cooking racks and ends when the racks have been placed in the cooker and the steam has been turned on.

REASON

In order to reduce the extent of bacterial spoilage, the staging time between butchering and pre-cooking should be kept to a minimum. The racks shall be kept in clean and sanitary condition.



Staging of gutted fish (5 kg. or less) should not exceed 2 hours

<p style="text-align: center;">SECTION IV</p> <p style="text-align: center;">PRECOOKING</p>

GMP 4.1 The precooking units, cooking racks, pre-cookers, etc. shall be of sanitary design and be kept clean at all times. All precooking surfaces and materials coming into contact with the fish shall be clean and sanitary. No copper alloys or brass shall be used in any surface which comes into contact with the fish.

REASON

This is necessary to ensure that equipment and utensils do not become a source of bacteriological or other contamination of the product, and to prevent the greening and other discoloration of the fish flesh caused by contact with copper alloys or brass.

GMP 4.2 Cooking times and temperatures shall be adequate to remove excess fish oils and body fluids and to make the loins easy to separate from the backbone.

REASON

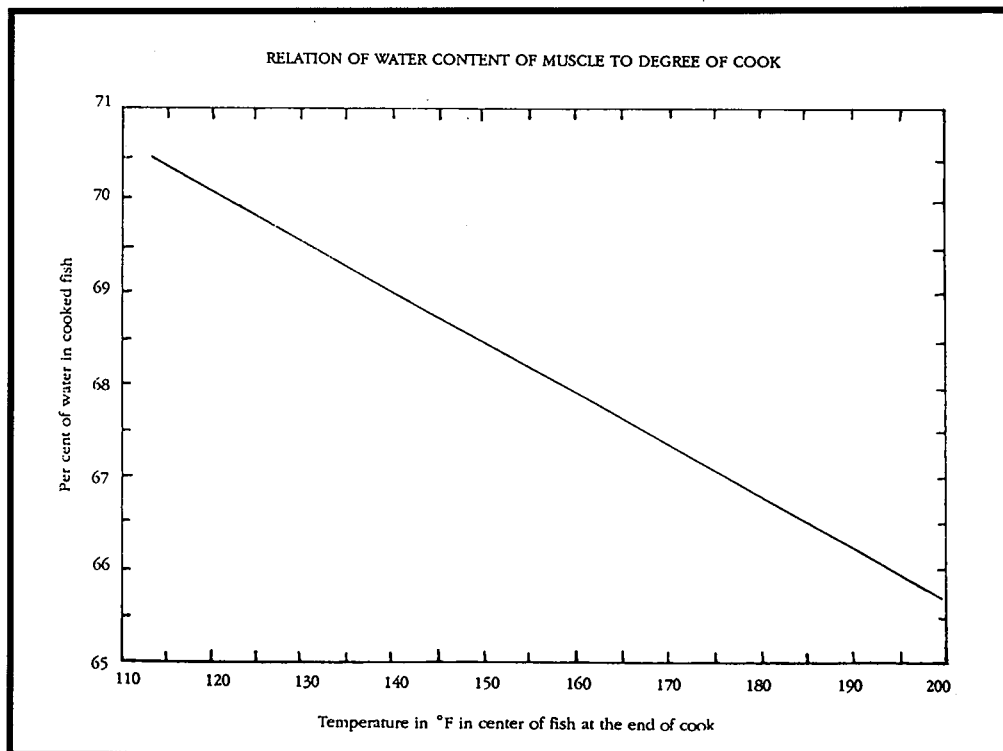
The following excerpt from *Fish as Food*, Vol. IV, Academic Press Inc., 1965, p. 226 is instructive. "As the cooking proceeds, water, and water-soluble proteinaceous material such as gelatin, nitrogen-containing extractives, and other substances are leached out of the fish and accumulate in the condensed steam which flows from the cooker continuously during the cooking operation. This condensate also contains a certain amount of oil. The steam which, during the cooking, escapes through the steam vents contains certain volatile substances that are characteristic of raw fish odour (amines). Under the influence of heat, the protein in the tuna muscle will coagulate and shrink away from the bony structure, thereby making easier the subsequent cleaning and separation of the dorsal and ventral loins which are used for canning. The precooking of tuna is,

therefore, a very important step in the over-all canning operation, as this step, perhaps more than any other, influences not only yield but quality.

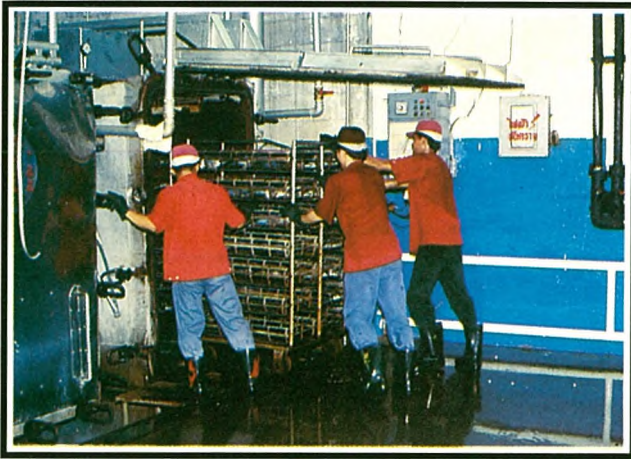
"It is known, however, that in order to obtain a good cook, the temperature of the tuna, as measured along the upper part of the spinal column, in the thickest part of the fish, must be brought up to approximately 140-150°F. Further cooking beyond this point is not only unnecessary but actually reduces both yield and flavor of the tuna meat.

"In as much as the temperature attained in the centre of the tuna is directly related to the time of pre-cook, the moisture content cooking time relationship may be expressed by a graph of similar slope.

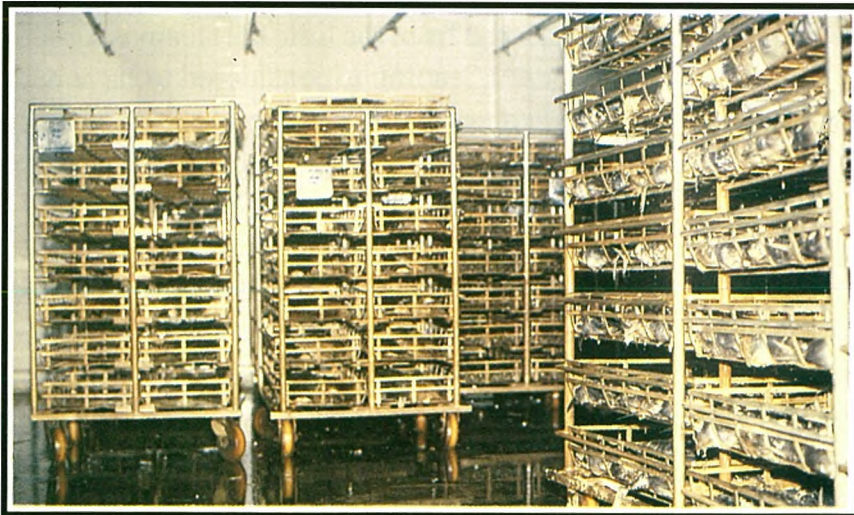
"To obtain a good cook, it is also important that the tuna be graded for uniform size, within very narrow limits. This sometimes proves difficult when the size distribution in a load of tuna is wide. Another important point to observe in connection with pre-cooking of tuna is that all the tuna must have the same temperature when entering the cooker. Tuna which has not been fully thawed will need much more heat before a temperature rise takes place in the tuna than will a fully thawed fish."



Tuna canning and Preservation of Raw Material



Cooling of fish should be under temperature and time control



After end of pre-cooking, fish should be cleaned within 6 hours

Cooking of fish, a stage of the art



<p style="text-align: center;">SECTION V</p> <p style="text-align: center;">COOLING THE PRE-COOKED FISH</p>

GMP 5.1 The precooked fish shall be cooled for a period sufficient to allow the loins to be handled. The allowable time period between pre-cooking and cleaning shall not exceed 6 hours.

NOTE: This time is measured from the time the steam is turned off to when the cleaning ends. Cleaning is considered to have ended when all the loins or flaked product from the pre-cooked lot is placed in trays or on a conveyor for delivery to the packing area.

REASON

The cooling and cleaning of pre-cooked fish should be achieved as quickly as possible. In no case should this exceed 6 hours. Reference to this process is made in *Fish As Food*, Volume IV, page 228. "The cooling is carried out in cooling rooms provided with good air circulation and screened for protection against infestation. During the cooling period, the tuna undergo some very important changes. The weight of the cooked tuna is further reduced through evaporation from the hot fish. A general drying up of the surface area of the fish often takes place. The skin on the tuna, which during cooking has loosened from the muscle tissue and which at that point may be peeled off, will, as a result of the drying during cooling, dehydrate and become leathery and reattach itself to the cooked tuna muscle. Some of the oil contained in the tuna, which during cooking has accumulated on the surface of the cooked tuna, may become oxidized."

<p style="text-align: center;">SECTION VI</p> <p style="text-align: center;">CLEANING</p>

GMP 6.1 Fish cleaning shall be done in a sanitary area. All tables, pans, cleaning surfaces, etc. shall be of non-porous materials which are non-corrodible and easily cleaned and sanitized. No wooden surfaces are permitted. All surface joints shall be smooth and watertight.

REASON

To maintain sanitary conditions at all times, all fish cleaning shall be done in an area and on surfaces easily cleaned and sanitized.

GMP 6.2 Workers shall have clean outer clothing and effective hair restraints to protect fish from foreign contamination. Employees who handle fish with their bare hands shall not wear fingernail polish.

REASON

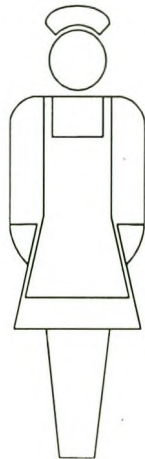
In order to prevent contamination of fish products, every person in food handling areas should maintain a high degree of personal cleanliness and should at all times wear suitable protective clothing including head covering and footwear, all of which should be cleanable unless designed to be disposed of, and should be maintained in a clean condition. Aprons and similar items should not be laid on the floor for washing. Personnel should not wear any insecure jewellery when engaged in food handling, and jewellery that cannot be adequately disinfected should be removed from the hands. Employees who handle fish with their bare hands shall not wear fingernail polish, because it may flake off and contaminate the product.



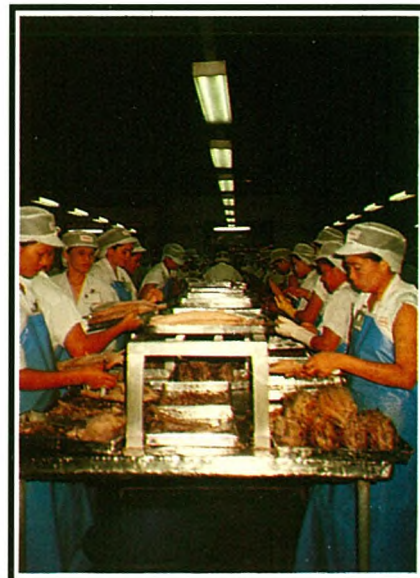
Loin cleaning operation in which time and sanitation should be controlled



Personnel hygiene is vital



Workmanship is considered important to many markets



GMP 6.3 *No person who is known to be suffering from any communicable disease, is a known “carrier” of any disease or has an infected wound or open lesion on any part of the body shall be permitted to handle the fish.*

REASON

Any person suffering from a communicable disease or who has an infected wound or open lesion or is a disease carrier has the potential to infect the food product with bacteria capable of causing food poisoning. The following guidelines are given in FAO/WHO Codex Alimentarius *Recommended International Code of Practice for Low-acid and Acidified Low Acid Canned Foods*:

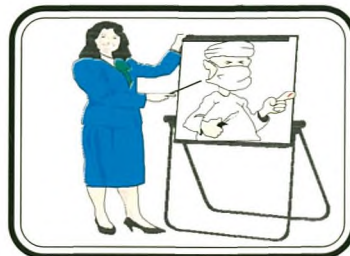
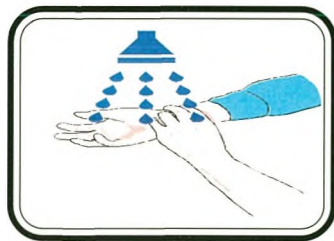
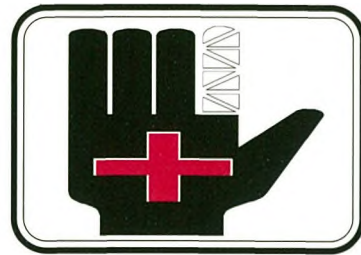
Hygiene Training: Managers of establishments should arrange for adequate and continuing training of every food handler in hygienic handling of food and in personal hygiene so that they understand the precautions necessary to prevent contamination of food. Instruction should include relevant parts of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

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

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 diarrhoea, is permitted to work in any food handling area in any capacity in which there is any likelihood of such a person directly or indirectly contaminating food with pathogenic microorganisms. Any person so affected should immediately report to the management that he is ill.

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

Washing of Hands: Every person engaged in a food handling area, while on duty, should wash his hands after each absence from duty with a suitable hand cleaning preparation under running warm, potable water. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. Notices requiring hand-washing should be prominently displayed. There should be adequate supervision to ensure compliance with this requirement.



GMP 6.4 Off-colour loins (discoloured flesh, either green, orange or red), off-odour fish and fish exhibiting “honeycomb” material detected during cleaning or during loin inspection shall be removed from the tuna pack.

REASON

This is a critical processing step. Off-colour, off-odour and honeycombed flesh are indicative of quality deterioration and such flesh must be removed, since its inclusion in the final pack would render the final product unacceptable.



Defective loin meat

GMP 6.5 Care shall be taken to ensure that cleaned edible product is not contaminated with offal.

REASON

Offal is defined as non-edible parts of the tuna, including viscera, scales, eyes, gills, skin, bones, blood meat and other material not characteristic of the pack, and any rancid or decomposed flesh which would render the product unacceptable.

GMP 6.6 There shall be a complete washdown and cleaning of processing surfaces and the cleaning tables shall be sanitized at the end of each work shift. Containers used to transport finished material shall be washed after each use. The table shall be rinsed down at least once during a 4-hour period.

REASON

Unless there is a complete washdown and sanitizing of processing surfaces, cleaning tables, and containers used to transport the cleaned flesh, there will be an accumulation of pieces of fish and an increase in bacterial growth, thereby contaminating the product coming in contact with these surfaces.

Table should be washed down every 4 hours, and trays washed at every use



GMP 6.7 Cleaned fish loins and flesh shall be stored for as short a period as possible, and not for more than one hour before the material is packed in a can.

NOTE: The storage of cleaned fish shall be deemed to start from the time cleaned product is placed on conveyors or in trays until the product is packed in a can.

REASON

In order to prevent the growth of spoilage bacteria, cleaned loins, chunks and flakes shall be stored for as short a period as possible, and definitely not more than one hour before being packed.

Cleaned loins should be packed within 1 hour



< 1 hour

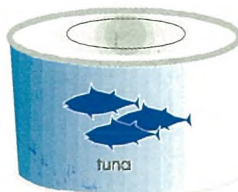
SECTION VII
PACKING

GMP 7.1 INGREDIENTS

GMP 7.1.1 *Ingredients other than tuna shall be of food grade quality. Dry or fresh ingredients shall be inspected upon receipt for cleanliness and other attributes as appropriate.*

REASON

Ingredients are part of the final product and, as such, must be of food grade quality.



GMP 7.1.2 *The water supply for “spring water” tuna packs shall meet the requirements of the competent authority having jurisdiction.*

GMP 7.2 EMPTY CANS AND LIDS

GMP 7.2.1 *All lots of cans and lids brought into the cannery shall be inspected according to pre-determined standards and procedures. Cans shall be inspected for proper type of inside enamel, outside coating, defects and integrity of the side seam and bottom double seams, and general cleanliness. Cans shall be cleaned thoroughly prior to filling. Records shall be kept on the can lots and compiled in such a manner that can lots can be related to finished product can codes.*

REASON

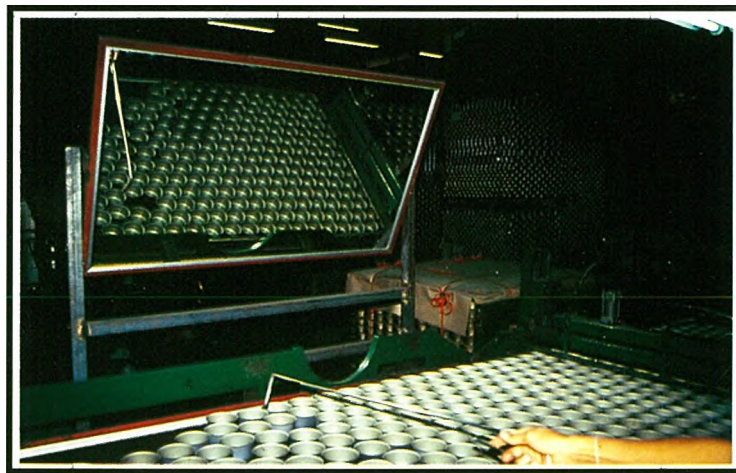
Empty cans and lids must meet specifications and the cans must be cleaned before any final product is put into them.



Every lot of empty cans should be inspected



Inspection of can ends



Inspection of empty cans before use

*Inspection of loin
before packing*



GMP 7.3 FILLING

GMP 7.3.1 Prior to can filling, cleaned fish loins and flesh shall be visually inspected for defects including off-colours, skin, bones, blood meat, foreign matter, etc. and all defective material removed.

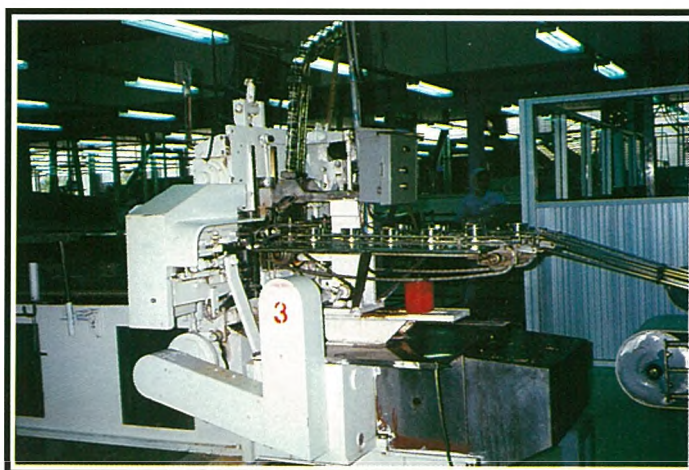
REASON

Can filling is the last point where visual inspection can take place and at which defective material can be removed from the product.

GMP 7.3.2. Filling shall be done by hand or by machine to ensure that cans are filled to the proper level. In preparation for filling, loins shall be cut neatly and uniformly to ensure proper piece size for the intended style of pack. Cans which are improperly filled shall be removed from the processing line and corrected or rejected as required. Balance scales or other suitable weighing devices shall be available at the filling area to ensure that minimum fish fill weight and net weight requirements are met.

REASON

It is essential that can filling operations, mechanical or manual, ensure that the filling requirements specified in the scheduled process for the particular type of tuna pack being produced are met. Improper can filling, overfilling and underfilling can adversely affect the safety and shelf life of a product. Improper filling or overfilling can result in product being deposited on the flanges where it interferes with the double-seam formation during the seaming operation and leads to a high proportion of cans being produced with seam defects or with inadequate vacuum due to insufficient head space.



Packing machine

GMP 7.3.3 The recipe for the particular product involved shall be adhered to fully, to insure that sufficient liquid (oil, water, broth), salt and/or other ingredients are added, to bring can contents up to total fill specifications and net weight requirements.

REASON

It is essential that can contents meet the recipe specifications and net weight requirements so that the intended label correctly describes the product, and that the product will be properly processed.

GMP 7.4 CANSEAMING

GMP 7.4.1. Cans shall be washed after seaming to remove any extraneous materials from the surfaces.

REASON:

Extraneous material adhering to the surfaces of cans is a real source of contamination to the can contents if any leakage into the can occurs in subsequent stages of processing, handling, storage and distribution.

GMP 7.4.2. The can seams shall be inspected for smoothness and tightness and, if any defects such as scuffed ends, rough edges, lipped metal or other evidence of defective seams are found, the seamer shall be stopped immediately for corrective action. The top double seam and can code shall be inspected every 30 minutes during the operation of each seamer. A daily record of inspections shall be maintained for each line.

REASON

Hermetically sealed containers must protect their thermally processed contents from recontamination with microorganisms. Thus, can integrity is critical for the safety and shelf stability of canned foods. An example of a daily record for seam inspection is given in Chapter 2, table 10.



Seaming machine



Inspection of can ends

Visual inspection of seam



GMP 7.4.3 At least once every 4 hours of seamer operations, after a jam, or after a lengthy shut down, one can from each seaming head of each machine shall be removed for top double seam teardown examination. Can vacuums shall be monitored to ensure proper vacuum drawing procedure sufficient to maintain can ends concave at 35°C. The cans shall be opened and the seams disassembled, measured and inspected to ensure that they meet the recommendations of the can and seamer manufacturers. If defective seams are found, the seamer shall be stopped and all production of finished goods that has passed through the seamer since the last approved can seam inspection shall be isolated and held for further testing. The nature of the defective seams shall be determined, corrections shall be made and the seams shall be retested and found acceptable, before this machine will be returned to regular production. Seam measurements shall be recorded.

REASON

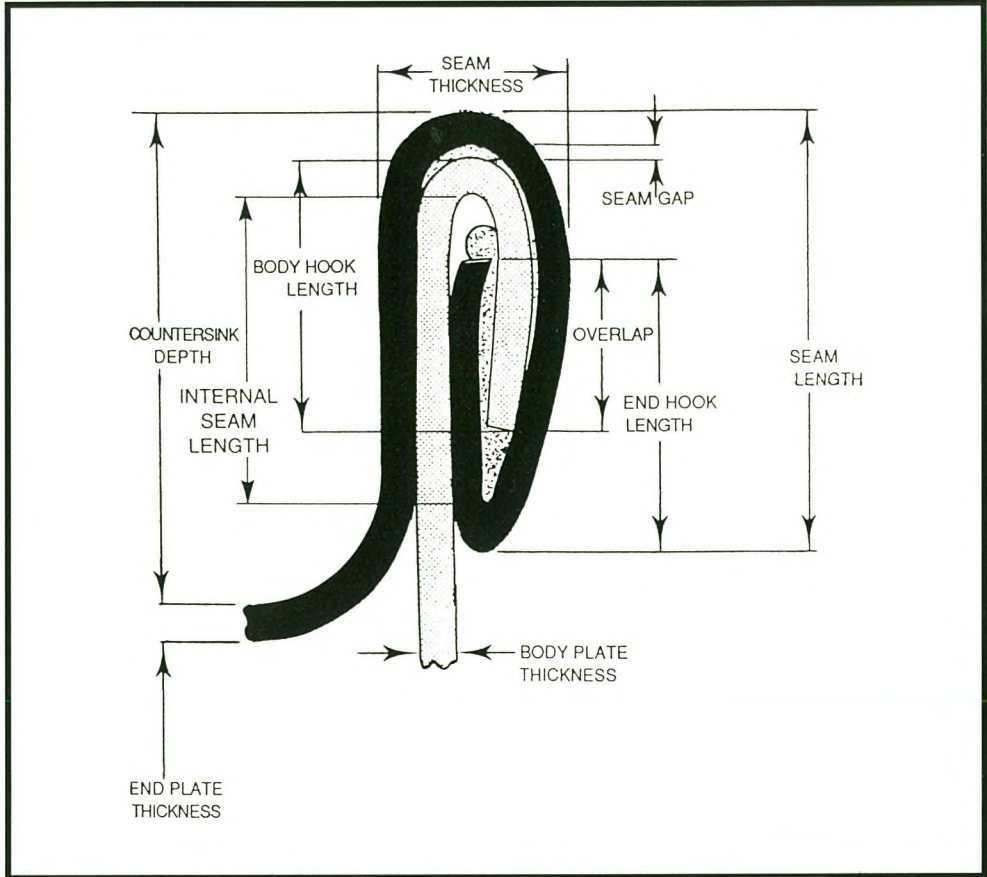
Since the hermetically sealed containers must protect their thermally processed contents from recontamination with microorganisms, can integrity is critical for the safety and shelf stability of canned foods. Producers should be capable of producing lots with can defect levels of 0.01% defective or less. It should be noted that, even under GMP the average number of serious defects may reach up to 0.01% defectives (10 per 100,000) for 3-piece cans and up to 0.004% defectives (4 per 100,000) for 2-piece cans or welded side seam cans. Under GMP, the canning industry must be capable of producing canned products which do not exceed 0.04% defectives (40 per 100,000 cans).

The recommended procedures involved for double seam tear down are given in Appendix I (Recommended International code of Practice Low-Acid and Acidified Low-Acid Canned Foods).

Table 2

VISUAL SEAM EXAMINATION		
EXTERNAL SEAM APPEARANCE		
Inspection Items	Frequency	Sample Size
Check for any externally visible defects or irregularities, for example, cut over, cut seam, vee, droops, false seams, spinner, etc.	1) At the closing machines as frequently as feasible. Minimum - every 30 minutes during operation. Also set up, after adjustments, jam-ups and change overs.	A minimum of cans each seaming head.
	2) Once a day. Cans from each line.	
TEAR DOWN EXAMINATION		
EXTERNAL SEAM MEASUREMENTS		
First Operation		
Inspection Items	Frequency	Sample Size
1. Thickness 2. Width	At set up and at least after every 40 hours of operation.	A minimum of 1 can from seaming head.
Second Operation		
1. Thickness 2. Width 3. Countersink	At set up. After adjustments, jam-up and change overs. Minimum: every 4 hours	A minimum of 1 can from each seaming.
VISUAL INTERNAL SEAM INSPECTION AFTER TEAR DOWN		
Inspection Items	Frequency	Sample Size
1. Tightness 2. Jumped Seam 3. Internal Droop (Juncture Rating) 4. Pressure Ridge 5. Pucker or Pleat	At set up.	A minimum of 1 can from each seaming head.

COMPONENTS OF DOUBLE SEAM



GRAPHIC "Dimensional Terminology of the Double Seam"



Seam tear down

TECHNICAL NOTE: CAN JAM-UPS

Jam-ups, i.e. points where the flow of cans is obstructed, can occur at several points in the line.

Depalletizer and Conveyors: All the affected cans and those in the immediate vicinity must be removed.

Filling Machine: Most jam-ups occur where the cans are ejected from the turret, when the flange of the can becomes jammed in the upper portion of the pocket instead of being released.

Weighing Machine: The area most susceptible to jam-ups on mechanical weighing machines is the underweight eject mechanism where the cans take a sudden change of direction.

Clincher: Devices used to separate the ends of cans and emboss the can code cause jam-ups. Generally, jam-ups occur when the clincher screw-worm is timed improperly, the coder is improperly adjusted, a separator knife is worn or a defective lid is encountered.

Closing Machine: Jam-ups may be caused by defective cans or can ends or improper clinching.

Can Washer: Jam-ups may occasionally occur at the can washer for a variety of reasons.

The following procedure must be followed to clear jam-ups:

1. Remove all sound and damaged cans and fish within the proximity of the jam-up.
2. If all metal can be accounted for,
 - a) It is safe to start the line and re-commence normal operation.
 - b) Inspect the fish and give it to the patching table for separate inspection before use as patching material.
 - c) Wash the empty, undamaged cans and carefully inspect prior to their re-use.
3. If all metal cannot be accounted for,
 - a) Thoroughly wash-out the equipment, paying particular attention to the trouble spots identified above.
 - b) Check the machine for metal fragments; use a waterproof flashlight and mirrored surface steel probe if necessary.
 - c) Start canning again and remove the first six cans; remove the fish and, after inspection, give it to the patching table for inspection and use as patching material.
 - d) Wash out the cans and carefully inspect prior to re-use.
 - e) Resume normal operations.
4. In any event, determine and eliminate the cause of the jam-up.
5. If the jam-up occurred in the seamer, carry out seam tear-downs on the first cans seamed to ensure that the seams are within all established tolerances.
6. Maintain a record of the number and location of every jam-up and the corrective action taken.

GMP 7.5 CAN CODING

GMP 7.5.1 All cans shall be legibly embossed, at the time of can closing, with a can code indicating the establishment and day, month and year of processing.

REASON

Products must be identified by establishment and packing date to facilitate the segregation of lots because of real or potential problems with safety or quality, or to initiate a complete and rapid recall of any lot. It is also standard practice to code batch/retort load and/or shift period/sub-period. In addition, a procedure to permit the complete and rapid recall of any lot of finished food products from the market should be established by the producing company.

SECTION VIII

RETORTING

GMP 8.1 The equipment and procedures used, the process time and temperature and the records maintained shall be approved by the competent authority

REASON

This is necessary to ensure adequate commercial sterilization of canned tuna, and adequate record keeping in case of process deviation or product recalls.

NOTE : In order to comply to minimum standards for processing Low Acid Canned Food :

- 1) The tuna cannery needs to be equipped with:
 - a) retorts properly installed and controls including
 - i) mercury-in-glass thermometers,
 - ii) pressure guages,
 - iii) steam spreaders,
 - iv) venting valves,
 - v) bleeders, and
 - vi) automatic temperature recorders, and
 - b) a steam supply at a sufficient pressure and quantity to ensure uninterrupted sterilization of all products in all retorts. The steam header pressure must maintain a minimum pressure of 90 p.s.i. during maximum utilization, and
 - c) an accurate wall clock positioned in such a manner that it is clearly visible from the retort operator's station, and

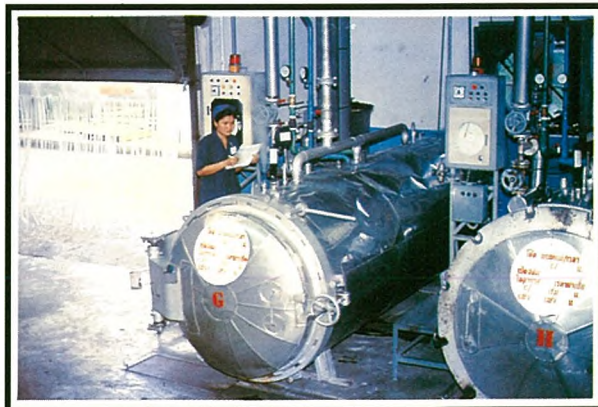
- 2) The tuna cannery is operated in accordance with recognized National and International procedures such as those described in:
 - *Canadian Code of practice for Low-Acid and Acidified Low-Acid Canned Foods,*
 - *The Canadian Food Processing Association: Canned Foods Thermal Processing and Container Evaluation,*
 - *Codex Alimentarius Commission: Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods,*
 - *Codex Alimentarius Commission: Recommended International Code of Practice for Canned Fish,*
 - *National Canners Association: Processes for Low-Acid Canned Foods in Metal Containers Bulletin 26-L, and*
- 3) All retort operators have successfully completed a recognized Retort Operators Course, and have a Certificate/Diploma therefrom, and
- 4) Time and temperature submissions including information listed below, for each product, can size and style of pack have been submitted to verification by the competent authority and
 - a) Scheduled processes shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately considered in establishing the scheduled process. Critical factors that may affect the scheduled process, e.g. minimum headspace, consistency, maximum fill-in weights, ingredients, process times, temperatures, etc., shall be specified in the scheduled process, and
 - b) Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, microbial thermal death time data,



Retort area



Retort equipment



Retort monitoring

Clock



Heat sensitive indicator is used to ensure that cans passed heat processing, and will not mix with un-retorted lot

Retort Operator



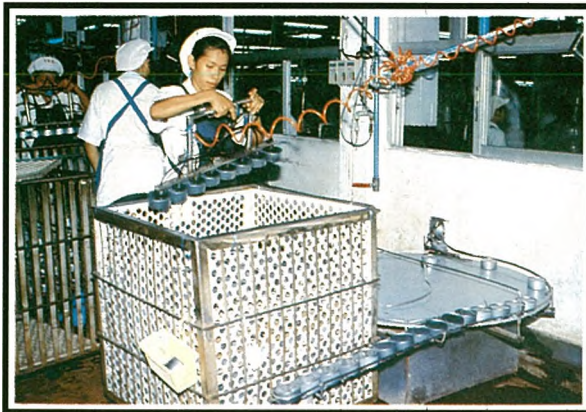
process calculations based on product heat penetration data, and data from inoculated packs. Calculations shall be performed according to procedures recognized by the competent authority. If incubation tests are necessary for process confirmation, they shall include containers from test trials and a number of containers from each of four or more actual commercial production runs during the period of instituting the process, and

- c) Complete records covering all aspects of the establishment of the process and associated incubation tests shall be prepared and shall be permanently retained by the organization making the determination and shall be subject to inspection, and
- 5) Accurate retort records, available for inspection, shall be maintained at all times, and shall include the following information and be kept for a period of not less than 5 years,
- a. Product, including packing medium,
 - b. Date of processing,
 - c. Name of retort operator,
 - d. Retort number,
 - e. Product processed,
 - f. Can size and type
 - g. Code and approximate number of cans,
 - h. Initial temperature,
 - i. Venting schedule, time steam on, time and temperature vent closed,
 - j. Clock time at start of cook, i.e. when processing (sterilization) temperature is reached.
 - k. Temperatures from mercury thermometer and recording thermometer and pressure gauge readings at start of cook,
 - l. Clock time at end of cook,
 - m. Length of time of cook,
 - n. Cooling method and time cooling started and ended and can temperature at end of cooling, and
 - o. Residual chlorine level in cooling water (**GMP 9.3**)

GMP 8.2 The time between seaming the first can of the lot to retorting shall not exceed 2 hours. However, any delay beyond one hour must be treated as a process deviation and the time of cook adjusted to compensate for the increase in microbial load.

REASON

Spoilage of canned fish in sealed containers can occur quickly at cannery temperatures, particularly in temperate and warmer weather conditions. Even very slight spoilage becomes quite noticeable because any odorous gases produced will be retained in the container and will consequently result in souring, off-flavour and loss of vacuum. Also, it is necessary to limit and control the conditions which permit the growth of staphylococci and the production of toxins, which are not destroyed by the heat normally applied during heat processing.



First can of first basket is taken for temperature measurement

Loading of cans



SECTION IX

CAN COOLING

GMP 9.1 After finishing a full retort cycle, the canned tuna products shall be water-cooled. The temperature of the cans after cooling shall be between 45° - 50°C.

REASON

If canned fish is not substantially cooled after heat processing, it will continue to cook, and its texture and flavour may be impaired. This condition is known as stackburn. Furthermore, problems with struvite will often be avoided if canned fish is cooled rapidly. Struvite, which is magnesium ammonium phosphate, forms from the natural constituents of some fish products during the heat process; it crystallizes out of solution and lodges in the flesh as the product cools. If cooling is slow, the crystals of struvite are large and consumers may mistake them for glass. If cooling is rapid the crystals formed will be very small and the problem of adverse consumer reaction may be avoided. In addition, if cans are kept at elevated temperatures for too long a period, thermophilic microorganisms not destroyed by the retorting process may grow and cause spoilage.

Water cooling should not reduce the temperature of the container below the point at which its surfaces will be dried quickly by the residual heat in each container. Each can must retain sufficient heat to quickly evaporate any water droplets left on the can after retorting. Failure to do this may cause external corrosion of the can.



45° - 50° C

Can temperature measurement



Restricted area



Don't touch can in basket; only authorized personnel are allowed into restricted areas

GMP 9.2 The cooled cans shall be dried in a clean area free from sources which could dirty the cans with water spots, oil, stains, dirt, dust, etc. Cans must not be touched by hands until they are dry and cooled. Cans shall not be rewashed after retorting.

REASON

Entry to the cooling area must be restricted to those working in the area. This will ensure that people, clothing, aprons, gloves or any other foreign objects do not come into contact with the cans as they are cooling. The cooling area must be clean and free of sources of dust and dirt and there must be no possibility of condensed water, dust and dirt or other debris falling onto the cooling cans.

People must not touch the cooling cans until they are dry and cool. Hand contact, particularly without proper gloves/glove dips, increases the possibility of contamination, particularly since the cans have a vacuum and may draw in minute amounts of air or moisture which could result in post-process contamination.

Protection of the canned food must extend to the post-cooling container handling systems. Studies have indicated that excessive bacterial contamination may develop on wet and soiled post-cooling can handling equipment, even though the cooling water is chlorinated or is naturally of good sanitary quality. Bacterial contamination may be transferred, in varying degrees, to the seam areas of the cans, and may lead to contamination of the product.

Cans should be handled gently. If the cans are roughly handled after processing, the seams may be damaged and the can bodies dented. Dents may fracture the lacquer coating in the can. Leaks caused by dents or by damaged seams can result in the contamination of the product. Cans are also very susceptible to vacuum loss due to rough handling and this may also lead to contamination of the product.

GMP 9.3 All water used for cooling shall be safe and sanitary. Water shall be chlorinated, and a residual chlorine level of at least two parts per million in the cooling water discharged at completion of cooling shall be maintained at all times. Residual chlorine shall be measured at least twice per packing shift and the results recorded on the retort records. Chlorine shall be added to the water at least twenty minutes prior to use of the water for cooling purposes.

REASON

Cooling water may be sucked into the can when the seam is hot, and there is a correlation between the microbial population levels in water used to cool cans after processing and the rates of spoilage which occur in these cans. Increased contamination of cooling water invariably causes a proportional increase in product spoilage in the cans, and may cause a health hazard.

Water of good sanitary quality must be used and chlorination employed to keep the chance of contamination at a minimum. A measurable free chlorine residual of at least 2 ppm is required at the discharge end of the cooler.

In order to ensure adequate contact time, sufficient chlorine to produce a 2 ppm residual must be added at least 20 minutes prior to use of the cooling water. Care must be taken to ensure the levels of chlorine are not so high as to damage the exterior finish of the cans.

GMP 9.4 Retorted and unretorted cans shall not be mixed together.***REASON***

It is essential that a system for product traffic control in the retort room be established to prevent unretorted product bypassing the retort process and being mixed with retorted product. In addition, each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, should, prior to each use, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means to indicate visually those units that have been retorted. A visual check can then be performed to determine whether or not, as a result of retorting, the appropriate change has occurred in the heat sensitive indicator for all retort baskets, trucks, cars, or crates. Records that these checks have been made should be kept.

<p style="text-align: center;">SECTION X</p> <p style="text-align: center;">LABELLING</p>

GMP 10.1 Prior to labelling, the filled and sealed cans shall be examined to remove defective, swollen, rusty, dirty and damaged cans. Filled and labelled cans shall be examined as they leave the labelling area prior to being placed in cartons for shipment, and any defective, or damaged cans removed.

REASON

Every cannery produces some cans with defects. Except for problems which become evident during storage, the final stage of processing at which defective cans can be identified and removed is during labelling and casing. The processor must ensure that all cans are inspected for abnormalities. Some methods of finding defective cans employ single or double dud testing and checkweighing, as well as hand culling. The latter is sometimes the only method of finding some defects such as scrap in die, metal plate flaw or false seams.

All can handling equipment from the labelling area through to the warehouse must be operated in such a manner that container damage is avoided. Dents on can bodies or damage to container ends may result in closure defects and leaker spoilage. Rough handling or improperly adjusted or maintained runways or conveyors may result in punctures, seam defects, or leaking containers. Careful handling of containers must continue through palletizing, casing, and storage or warehousing; in these areas, container damage and leaker spoilage may result from improper equipment operation, careless fork lift operation or improper stacking procedures.

SECTION XI

CASING

GMP 11.1 Clean and sound materials shall be utilized. Codes on cans must be the same as case codes with respect to the plant and day, month and year of processing. Cartons/cases legibly marked with code.

REASON

It is essential that cartons and cases of products be identified by establishment and packing date and other information such as process batch, to facilitate the segregation of lots with potential or real safety or quality defects, or to facilitate recall procedures.



Casing

SECTION XII
PRODUCT STORAGE

GMP 12.1 The properly cased goods shall be kept in a clean, dry storage area to ensure that they are protected from excess heat, cold, water, dust, dirt, debris or any other foreign matter. The storage area shall also be kept insect- and rodent-free to prevent product contamination. Filled cartons are not to be stacked so high that container damage results.

REASON

This section is necessary since proper warehousing of the finished product can greatly influence its safety and shelflife.



Product storage in warehouse



Products after labelling and casing

<p style="text-align: center;">SECTION XIII</p> <p style="text-align: center;">QUALITY CONTROL</p>
--

GMP 13.1 The quality control (QC) program for each canned tuna manufacturing establishment shall be developed by the manufacturer and approved by the competent authority.

GMP 13.2 Staff responsible for QC shall be specifically designated and appropriately trained, with periodic upgrading to ensure that they remain abreast of current knowledge. Retort supervisors shall be trained to meet the standards required by the competent authority. QC staff shall identify and appropriately monitor in accordance with established procedures, the critical control points in the manufacturing process.

GMP 13.3 QC records must be maintained in an appropriate manner and be available for examination by management and appropriate government regulatory authorities.

REASON

The quality and safety of seafood products can be affected by a range of different factors. The most important of these include:

- a) the characteristics expected of the products themselves,
- b) the characteristics of the materials used to make them including ingredients, packaging and additives,
- c) the conditions in which processing takes place, including the construction, equipping, maintenance, operation and sanitation of buildings, facilities and equipment,
- d) the qualifications, reporting relationships and performance of personnel who perform work,

- e) the activities they perform, including work methods and equipment operating procedures, and
- f) steps taken to preserve quality and ensure safety during post-production storage and distribution, including conditions of storage, inventory management, shipping procedures and product recall.

A comprehensive quality management program includes consideration of all of the following elements for each of the factors listed above:

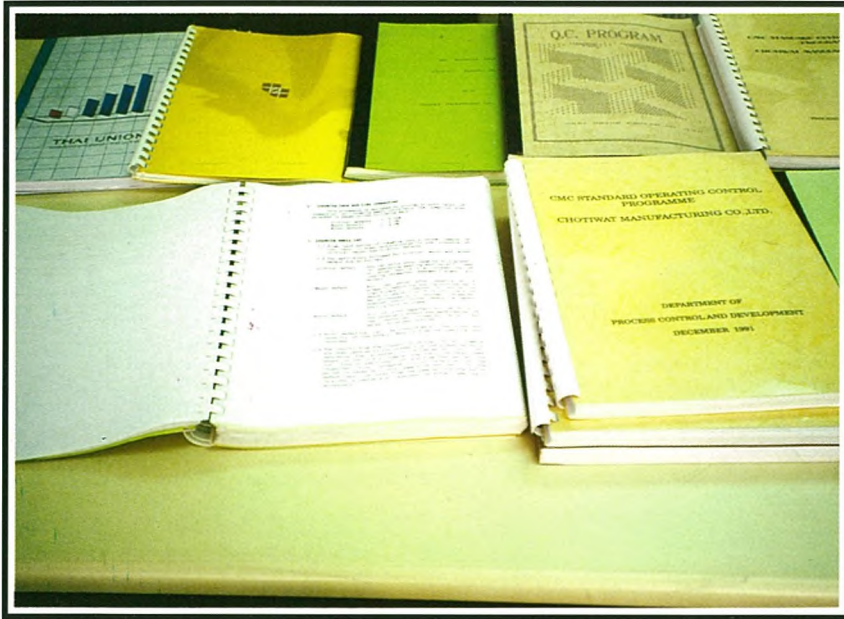
1. Specifying and defining the requirements set by the buyer, company, GMP and regulations,
2. Designation of responsibilities for meeting requirements,
3. Communication of the requirements to people expected to meet them,
4. Definition of systems for measuring compliance with the requirements,
5. Establishment of guidelines and procedures for dealing with situations in which non-compliance is indicated by the measurement system,
6. Implementation of the system for measuring compliance and of the guidelines and procedures for dealing with non-compliance, and
7. Verification through documentation, follow-up, audit and external evidence that specifications have been met and/or that appropriate procedures have been followed.

Of the above elements, the first five have customarily been referred to collectively as “*quality assurance*”, the sixth as “*quality inspection and process control*”, the seventh as “*quality verification*”; and the total as “*quality control*”.



Sensory evaluation of end product

Quality Control, or perhaps more appropriately “*quality management*”, involves planning, organizing and controlling operations to ensure that products consistently meet requirements set for them, whatever those requirements may be. In this context, quality management is not separate from but is an integral part of every management function. With respect to product quality and safety, it emphasizes prevention, rather than detection of problems and it should involve every person whose decisions and activities can affect the consistent meeting of requirements. It also involves the channelling of raw materials into products for which they are most appropriate, considering the manufacturer's own needs to obtain optimum value from the raw material, process them efficiently, and satisfy the customers who will buy the products as well as any minimum requirements for product quality and safety set by regulatory authorities.

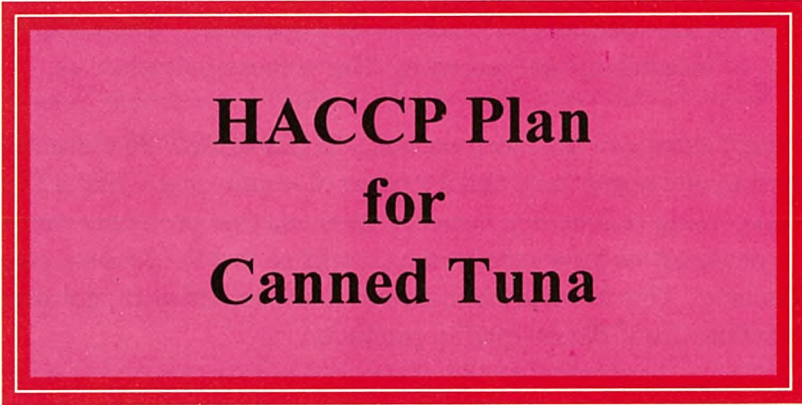


Quality manuals

Quality record verification



CHAPTER 2



**HACCP Plan
for
Canned Tuna**

Good Manufacturing Practices (GMP) refers to all the measures implemented to ensure product quality, safety and fitness for human consumption; from raw material quality, fish plant construction, personnel hygiene and hygienic operating practices. All processors need to process under GMP's using a system of Quality Control. Hazard Analysis Critical Control Point (HACCP) is a technique for reviewing and analysing a specific manufacturing operation's compliance with the GMP, with the objectives of identifying control procedures and implementing preventive measures required to ensure consumer safety and to prevent economic fraud. It is a system of self-regulatory quality control which, if properly implemented, can be used by both manufacturers and regulatory agencies to provide assurance about the safety of the product.

A number of quality control points exist in the processing of the product. However, critical control points (CCP) are those points in a food production process where failure to carry out control measures will introduce unacceptable risks to the consumers. These CCP's need to be identified, and a system of monitoring and recording data at these points set up.

HACCP represents a major change in how seafood safety is guaranteed. In essence, Hazards are Analysed in the processing of canned tuna, and a system of monitoring Critical Control Points is set up to assure the processing is done in a correct manner so that problems can be prevented before they occur. It is necessary to have monitoring records so that the process may be audited for product safety assurance. This is what the regulator is concerned with, not product quality as there are different markets for different quality products.

A HACCP Plan for the product has to be developed and this section provides information for the development of such a plan. Every manufacturer must develop its own plan (or plans). The HACCP concept is based on developing a plan tailored to particular production lines, thus there may be differences in the plans developed by different companies producing the same product; however, the information presented here is generic to the process of canning tuna.

While it is a system of self-inspection rather than government inspection, the government inspection services will periodically conduct audits of manufactures programmes, to assure that the system is working to prevent hazards to food safety. Importers in countries may have to verify that the programme has been followed; this may include on-site inspection, review of records and the quality program.

Regulatory authorities are concerned with safety; however, many authorities are also concerned with aspects of quality and the prevention of economic fraud. While there are different markets for different qualities of product, the differing limits of acceptability for the markets should not be exceeded. Therefore, the HACCP plan may need concern itself not only with safety, but also with quality and marketing requirements.

To ensure that the quality of the product is maintained, consider merging the HACCP plan developed with the overall quality control programme, but maintaining the HACCP documents separately for HACCP program audit purposes.

Two aspects of a good HACCP plan are not covered in this manual, economic fraud and recall.

The first has to do with labelling. Procedures have to be in place to ensure that the product is not mislabelled to content such as species substitution, or weight and that labelling is done in manner required by the intended market. The second aspect delay with sales and shipping records, coding of the product and recall procedures established; to ensure an ability to trace the products to the customers to whom they were sold.

This information is based on the experience of the Thailand Department of Fisheries in the conduct of their activities. It is given as guidance for the manufacturers to develop their own HACCP plans. The information is generic and must be modified to suit each manufacturers conditions. Further, as noted above, it is not complete. A HACCP plan needs to meet the requirements of the competent authority having jurisdiction.

Lot acceptance should be based on a sampling plan and an example is attached as table 3. Samples of forms which can be used to record keeping purpose are given as table 4.

The Recommend International Code of Hygienic Practice for low-acid and acidified low-acid canned foods is attached as Appendix .

Processing Step	GMP No	Hazad Type	Hazard	CCP	Preventive Measures	Monitoring
Receiving	1.1	Quality Safety	<ul style="list-style-type: none"> - Decomposed fish - Damaged fish 	Receiving area	<ul style="list-style-type: none"> - Control supply source - Have supplier provide a product temperature history 	<ul style="list-style-type: none"> - Measure temperature upon receipt - Visual inspection - Sample for histamine testing
Butchering	1.2 1.3	Quality Safety	<ul style="list-style-type: none"> - Decomposed fish - Histamine 	Butchering tables	<ul style="list-style-type: none"> - Control temperature of fish - Control lag time from end of thaw to end of butchering 	<ul style="list-style-type: none"> - Measure backbone temperature - Sensory inspection - Take sample for histamine analysis
Loin Cleaning	6.4	Quality	<ul style="list-style-type: none"> - Decomposed fish - Green meat. orange meat or honeycomb 	Loin cleaning tables	<ul style="list-style-type: none"> - Control lag time from end of cooking to end of cooling - Control time of loin cleaning and hygienic practices - Train workers to detect loin 	<ul style="list-style-type: none"> - Measure temperature and time of cooling - Visual inspection - Sanitation inspection
Packing	7.2 7.3.2	Safety	<ul style="list-style-type: none"> - Defect empty can 	Empty can storage area	<ul style="list-style-type: none"> - Select can suppliers - Set up empty can sampling plan and specification required - Train workers on container integrity 	<ul style="list-style-type: none"> - Visual and seam tear down inspection upon arrival - Visual inspection prior to feeding to line
	7.3.2	Safety	<ul style="list-style-type: none"> - Over fill 	Weighing table	<ul style="list-style-type: none"> - Adjust packing machine - Calibrate balance and weigh used 	<ul style="list-style-type: none"> - On-line weigh check - Calibration of balance
Seaming	7.4.3	Safety	<ul style="list-style-type: none"> - Defect double seam 	Seamer	<ul style="list-style-type: none"> - Adjustment of seamer - Test run before use - Train Q.C./seam mechanic 	<ul style="list-style-type: none"> - Visual seam inspection - Seam tear down
Retorting	8	Safety	<ul style="list-style-type: none"> - Improper processing resulting in outgrowth of microbes and toxins 	Retort area	<ul style="list-style-type: none"> - Train retort operators - Establish schedule process - Retort equipment checked and calibrated - Close surveillance of operations (by Q.C./Q.A.) 	<ul style="list-style-type: none"> - All thermal processes operations
Post Process Handling	9.2	Safety	<ul style="list-style-type: none"> - Post process contamination 	Cooling zone	<ul style="list-style-type: none"> - Restricted area traffic control - Sanitation 	<ul style="list-style-type: none"> - Check admittance to area (visual inspection) - Daily sanitation check

Critical Limits	Corrective Actions	Verification	Records
Frozen fish < -18°C Fresh fish ~0°C Histamine < 50ppm	<ul style="list-style-type: none"> - Inform/change supplier - If histamine >50ppm, increase surveillance at butchering 	<ul style="list-style-type: none"> - Annually, conduct survey of supplier handling system - Conduct histamine/temperature relationships 	<ul style="list-style-type: none"> - Supplier temperature record - Raw materials receiving record - Supplier sources and history
Histamine <50ppm Fish temperature 0 - 5°C Lag time 2 hours	<ul style="list-style-type: none"> - If >10% grade 3 fish, lot should be individually culled - If >10% grade 4 (rejected) fish found, lot should be rejected - If histamine >50ppm, increase surveillance, more culling for sensory test - Inform supplier - Reduce volume on line 	<ul style="list-style-type: none"> - Occasional increased samplings for sensory and histamine analysis - Check graders' competence with histamine and sensory determination 	<ul style="list-style-type: none"> - Raw fish grading form - Chemical analysis form - Lot processing record - Training record
<ul style="list-style-type: none"> - Lag time not >6 hours - Loin cleaning time <1 hour - No defect or decomposed loin - Sanitation: visually accepted 	<ul style="list-style-type: none"> - If lag time exceed limits, adjust production volume, fish should be put in chilled room for any delay anticipated - Increase surveillance at at butchering table - Improve cleaning and sanitation 	<ul style="list-style-type: none"> - Run pre-cooking test - Conduct histamine/temperature relationship - Check samples on workers and graders - Plant sanitation inspection daily 	<ul style="list-style-type: none"> - Cooling time and temperature record - Loin cleaning and quality record - Training record
[Based on sampling plan and can specifications]	<ul style="list-style-type: none"> - Segregate defect cans - If more than acceptance no. reject lot 	<ul style="list-style-type: none"> - Inspection of can manufacturers - Obtain Q.C. program of can manufacturers 	<ul style="list-style-type: none"> - Record of can manufacturers audit - Empty can inspection record - Can storage, depalletization and feeding log - Can specifications - Training record
[Based on value specified in process establishment]	<ul style="list-style-type: none"> - Segregate defect can - If more than acceptance no. adjust packing machine 	<ul style="list-style-type: none"> - Inspection of performance and practice - Record check 	<ul style="list-style-type: none"> - Record of empty can manufacturers audit - Empty can inspection record - Can storage, depalletization and feeding log - Can specification - Training record
[As determined in initial verification according to size of can]	<ul style="list-style-type: none"> - Closing machine maintenance and adjustment - Hold products for further investigation 	<ul style="list-style-type: none"> - Inspection of performance and practice - Record check 	<ul style="list-style-type: none"> - Seamer inspection report - Visual inspection report - Seam tear down report - Investigation report
[As determined in initial verification - calculated for each retort, can size and product type]	<ul style="list-style-type: none"> - Hold lot/reprocess lot 	<ul style="list-style-type: none"> - Periodic checks on heat distribution in retort and temperature recording equipment. Have process verified by competent authorities. Check competence of operation. - Record review daily 	<ul style="list-style-type: none"> - Retort operation record - Temperature recording charts - Investigation report
Entrance to authorized personnel only	<ul style="list-style-type: none"> - Stop unauthorized entrees 	<ul style="list-style-type: none"> - Review of traffic control program by inspection - On site verification 	<ul style="list-style-type: none"> - Product control report - Investigation report

Table 3

Sampling plan and rejection numbers for the inspection of fish

The sample size, (the number of fish to be inspected) is determined by randomly sampling at least 10 fish from the lot to determine the average weight of each fish. Divide the average weight into the estimated or actual weight of the lot to be examined to determine the total number of fish in the lot. Based on the total number of fish the following sampling schedule shall be applied:

No. of Fish in the lot	Sample Size	Rejection Number *
2 - 15	2	1
16 - 25	3	1
26 - 90	5	1
91 - 150	8	2
151 - 500	13	2
501 - 1200	20	3
1201 - 10000	32	4
10001 - 35000	50	6
35001 - 500000	80	8
500000+	125	11

*the minimum number of defective units needed to reject the lot. Once the rejection number has been exceeded, the inspection may be stopped. Please note: this plan does not apply to lots of fish that were hand culled or graded individually.

Example of Incoming Shipment Inspection Form

Date			
Item			
Supplier			
Code Marks			
Quantity			
No. Units			
Sample Size			
Rejection Level			
No. Rejected			
Accept/Reject			
Condition.			
Consigned to:			
Internal Code No.			
Initial			
Corrective Action/ Notes			

Raw Fish Grading Form

Plant _____
 Date _____
 Species _____

Location _____
 Lot Number _____

SAMPLE																			
TOTE																			
GRADE																			
EYES																			
GILLS																			
TEXTURE																			
PHYSICAL DAMAGE Edible portion of fish																			
BELLY CAVITY Internal organs and belly wall																			
ODOUR Belly cavity and cut through nape																			
GRADE ASSIGNED																			

Comments

Signature of Grader : _____

Signature of Grader : _____

Signature of Grader : _____

CANNED TUNA GMP CHECK LIST

THAWING TO STAGING

Plant : _____

Date : _____

Shift : _____

Inspector : _____

Tank No.	Tote No.	Species	Fish Wt. (Kg)	Water Temperature				Thaw Time		Fish Temperature			Comments	Staging Start	Rack No.	Staging End Steam On	Staging Duration	Butcher Duration	Ambient Temp. (Staging)
				Time/Temperature				Start	End	End of Thaw									
				1	2	3	4												

(Developed by DFO Canada)

EXAMPLE NUOCA

No: _____

Company Name

Notice of Unusual Occurrence
(NUOCA)

Line: _____ Time: _____ Date: _____

Control Point: _____


Cited for : _____

Signature (Foreman): _____

Signature (QA/QC): _____

(Developed by National Marine Fisheries Service)

CHAPTER 3



**Inspection/Verification
of a
Tuna Cannery**

This section contains information for use by inspection agencies and manufacturers to assess their operation in relation to their Quality Control Program.

In carrying out the inspection and verification, the inspector or auditor (designated experience personnel to carry out plant inspection audit) should first:

- 1) familiarize themselves with the process,
- 2) be aware of companies QC programme,
- 3) have equipment needed for inspection checked and calibrated,
- 4) have a checklist of items to be inspected.

Equipment needed for inspection included a flashlight, steam vent sizer, chlorine test kit, lightmeter, tape measure, divider (for checking temperature records), stopwatch and a thermometer.

The main activities of a plant inspection and audit is to assure that the requirements of the official agency having jurisdiction and a specified QC program is being followed. This can be accomplished by:

- 1) observation of operation and hygienic practices used in the plant.
- 2) review of records kept, for plants operating under a HACCP program a record of CCP's is essential,
- 3) review of the QC program.

Essential components of cannery inspection are construction, equipment, personnel hygiene, hygienic requirements, processing practices and process controls as given in Appendix - Codex Alimentarius, Recommended International Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods.

The equipment that should be inspected includes, canning equipment, empty can handling, retort, retort controls and instrumentation, steam supply, and warehouse and handling equipment. A checklist includes:

Equipment Checklist

ITEM 1 : Canning Equipment

- a. General
- b. Butchering, Gutting, Cleaning Equipment
- c. Filling Machines
- d. Pre-Cookers

- e. Dispensing Machines
- f. Weighing Machines
- g. Patching Tables
- h. Sealing Equipment
- I Can Washers
- j. Conveyors

ITEM 2 : Empty Can Handling Equipment

ITEM 3 : Retort Controls and Instrumentation

- a. Temperature Measuring Devices
- b. Temperature Recorders and Controllers
- c. Pressure Gauges
- d. Timers, Clocks

ITEM 4 : Retort Equipment

- a. General
- b. Dividers, Separators
- c. Steam Spreaders
- d. Bleeders
- e. Vent Piping
- f. Water Piping
- g. Air Lines
- h. Drains
- I. Safety and Pressure Relief Valves

ITEM 5 : Steam Supply (Including Boilers)

ITEM 6 : Warehousing, Post Process Handling Area and Equipment

- a. General
- b. Restricted Post Process Area
- c. Air Cooling and Interim Storage
- d. Handling Systems

Some specific processing practices and process controls that should be checked are:

Processing Practices and Process controls Checklist

1.0 Manufacturing Controls

1.1 Safety of Product Formulation

- 1.1.1 Food Additives
- 1.1.2 Nutritional Requirements
- 1.1.3 Label Accurately Reflects Products Formulation (Allergen Control)

1.2 Empty Containers

- 1.2.1 Empty Container Defects Inspection
- 1.2.2 Visual Inspection at Depalletizer
- 1.2.3 Empty Container Handling
- 1.2.4 Container Cleaning Prior to Filling
- 1.2.5 Protection of Cleaned Containers

1.3 Container Closure

- 1.3.1 Visual Examination
- 1.3.2 Destructive Examination

1.4 Thermal Process

- 1.4.1 Validated Process
- 1.4.2 Product Formulation (critical factors monitored and controlled)

1.5 Filling

- 1.5.1 Filling of Container
- 1.5.2 Flange and Sealing Area (monitoring and control)

1.6 Retort Operation

- 1.6.1 Lag Time
- 1.6.2 Initial Temperature
- 1.6.3 Basket or Retort Loading
- 1.6.4 Posting of Vent Schedule, Scheduled Processes and Retort Operating Procedures
- 1.6.5 Adherence to Posted Vent Schedule
- 1.6.6 Adherence to Scheduled Process
- 1.6.7 Adherence to Retort Operation Procedures
- 1.6.8 Thermal Status (heat sensitive indicators)
- 1.6.9 Time/Temperature Recording Device
- 1.6.10 Written Process Deviation Procedure

1.7 Post Process

- 1.7.1 Cooling Water
- 1.7.2 Bactericide Check
- 1.7.3 Chlorine/Water Contact Time

- 1.7.4 Container Cooling
- 1.7.5 Container Handling
- 1.7.6 Container Drying

1.8 Verification of Manufacturing Controls

- 1.8.1 Means of Verification Established

2.0 Premises

2.1 Outside Property

- 2.1.1 Roadways
- 2.1.2 Drainage
- 2.1.3 Grounds

2.2 Building

- 2.2.1 Building Exterior
- 2.2.2 Interior Design and Construction
- 2.2.3 Lighting
- 2.2.4 Ventilation
- 2.2.5 Drainage and Sewage Systems
- 2.2.6 Process Flow - Cross Contamination

2.3 Sanitary Facilities

- 2.3.1 Washrooms, Lunchrooms and Change rooms
- 2.3.2 Hand washing and Sanitizing Facilities
- 2.3.3 Process Area Hand/Feet Disinfection
- 2.3.4 Equipment Cleaning and Sanitizing Facilities

2.4 Water Quality

- 2.4.1 Water Supply - Potable
- 2.4.2 Testing/Monitoring
- 2.4.3 Cross-connection
- 2.4.4 Water Treatment Chemicals
- 2.4.5 Recirculated Water
- 2.4.6 Ice Supply
- 2.4.7 Steam

3.0 **Storage/transport**

3.1 Receiving of Raw Materials

- 3.1.1 Specifications
- 3.1.2 Handling

3.2 Storage

- 3.2.1 Temperature and Humidity Control
- 3.2.2 Finished Product
- 3.2.3 Returned Foods
- 3.2.4 Non-Food Chemicals

4.0 **Equipment**

4.1 General Equipment Design and Installation

- 4.1.1 Food Contact Surfaces
- 4.1.2 Chemicals and Lubricants
- 4.1.3 Preventative Maintenance Program
- 4.1.4 Waste Containers

4.2 Retort Equipment

- 4.2.1 Temperature Measuring Devices
- 4.2.2 Timing Devices
- 4.2.3 Recorder Controller
- 4.2.4 Retort Installation
- 4.2.5 Heat Distribution
- 4.2.6 Retort Steam Supply

4.3 Container Closure Equipment

- 4.3.1 Installation, Operation and Maintenance

5.0 **Personnel**

5.1 Training

- 5.1.1 General Food Hygiene
- 5.1.2 Technical Training

5.2 Hygienic Practices

- 5.2.1 Communicable Disease

- 5.2.2 Washing of Hands
- 5.2.3 Personal Cleanliness and Conduct
- 5.2.4 Controlled Access

6.0 Sanitation/Pest Control Program

6.1 Adequacy of Sanitation Program

- 6.1.1 Written Program for all Areas and Equipment

6.2 Adherence to Written Program

- 6.2.1 Firm Monitors Adherence to Written Program
- 6.2.2 Firm Verifies Effectiveness of Program

6.3 Adequacy of Pest Control Program

- 6.3.1 Written Program

6.4 Adherence to Pest Control Program

- 6.4.1 Firm Monitors Adherence to Written Pest Control Program
- 6.4.2 Firm Verifies Effectiveness of Program

7.0 Records

7.1 Safety of Product Formulation

- 7.1.1 Safety of Product Formulation Records

7.2 Empty Container Records

- 7.2.1 Empty Container Defect Inspection Records

7.3 Container Closure Records

- 7.3.1 Visual Examination Records
- 7.3.2 Destructive Examination Records
- 7.3.3 Records Reviewed and Signed

7.4 Thermal Process Records

- 7.4.1 Validated Scheduled Process
- 7.4.2 Critical Product Formulation Factor Records

7.5 Fill Records

7.5.1 Critical Fill Factor Records

7.6 Retort Operation Records

7.6.1 Retort Operator Records

7.6.2 Process Deviation Records

7.6.3 Thermal Status Records

7.7 Post-Process Records

7.7.1 Bactericide Check Records

7.7.2 Verification Records

7.8 Process Record Retention

7.8.1 Retention of Processing Records

7.9 Finished Product Distribution

7.9.1 Finished Product Distribution Records

7.10 Health and Safety Complaints

7.10.1 Health and Safety Complaint Records

7.11 Sanitation

7.11.1 Cleaning and Disinfection Records

7.11.2 Pest Control Records

7.12 Equipment

7.12.1 Equipment Calibration Records

7.12.2 Heat Distribution Test Records

7.12.3 Closing Machine Maintenance Records

8.0 **Recall (Health & Safety)**

8.1 Written Recall System

8.2 Code Identification

8.3 Procedures for Recall Notification

Information on the heat process, retorts and retort control instrumentation, venting and process establishment and heat distribution tests should be kept and reviewed by a competent authority. An example of a survey form for some of the information required is attached.

In assessing compliance with the GMP's, a checklist used by the DOF Thailand is attached.

After completion of inspection/audit a report should be generated, the manufacture should be informed of the results and recommendations and corrective actions if required.

CANNERY RETORT SURVEY FORM

PLANT : _____ LOCATION : _____

DATE : _____ INSPECTOR: _____

1. EQUIPMENT

Retort Shell

Diameter _____ Length _____

Single door? _____ Double door? _____

Steam Supply:

1. Steam header pipe size _____ (in.)
2. Pipe size to retort _____ (in.)
3. Number branch lines off main header _____
4. Size of regulating valve _____ (in.)
5. Steam line pressure _____ (p.s.i.) (regulated pressure)
6. Steam spreader size _____ (in.)
 - number of holes _____
 - size of holes _____ (in.)

Instruments and Controls:

1. Type of controller unit _____
2. Controller probe wells bled? Yes _____ No _____
3. Thermometer - range _____
 - degrees per scale division _____
 - easily read _____
4. Thermometer wells bled? _____
5. Pressure gauges wells - range _____
 - pounds per scale division _____
 - easily read? _____

Retort Loading Equipment

Retort buggies? _____ baskets? _____

Tumble pack? _____ or divider plates? _____ metal? _____ plastic? _____

divider plate holes - size _____ spacing _____

chemnies used? _____

CANNERY RETORT OPERATION

2. Operation

Written instructions provided to retort operator for:

Venting procedure? _____

Cooking time - temperature? _____

Venting Schedule used:

Time _____ (min), and

Temperature _____ (°F, °C) (minimum)

Venting test conducted by _____

Cooking Processes Used:

Product	Can Size	Init. Temp. (°F, °C)	Process	
			Time (min.)	Temp. (°F, °C)
-----	-----	-----	-----	-----
-----	-----	-----	-----	-----
-----	-----	-----	-----	-----
-----	-----	-----	-----	-----

Process Authority: _____

Can Cooling:

In retort? _____

Out of retort? _____

Water spray? _____

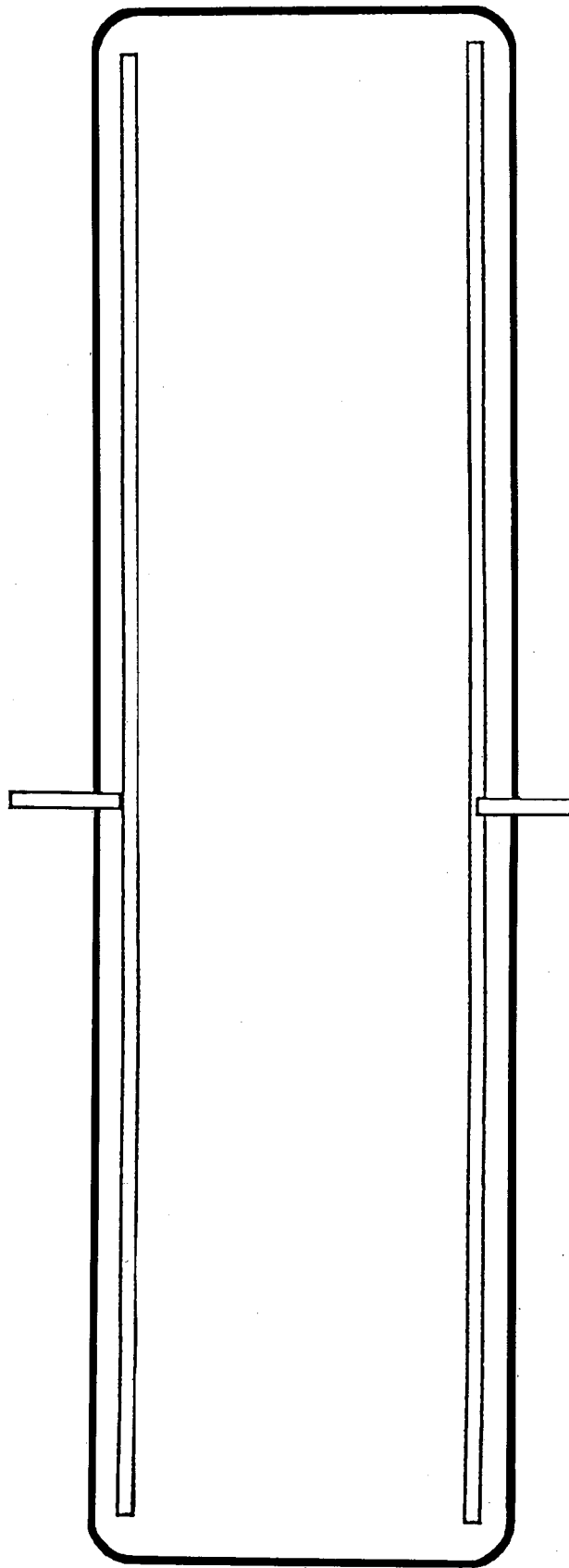
In air? _____

Water flood? _____

Water channel? _____

Air overpressure? _____

Cooling Time _____ (min)



Canned Tuna GMP Compliance

Plant: _____ Inspector: _____ Date: _____

RECEIPT, EXAMINATION, HANDLING & STORAGE OF RAW FISH

Item	GMP	GMP Description	Compliance Category			Comments/Action
			1	2	3	
1	1.1/1.2	Delivered fish inspected & graded				
2	1.1/1.2	Unacceptable fish rejected (lot/individual)				
3	1.1/1.2	Unacceptable fish segregated				
4	1.1/1.2	Records made & maintained				
5	1.3	Chemical analysis conducted				
6	1.3	Unacceptable lots segregated/culled				
7	1.3	Products analysed do not exceed standards				
8	1.3	Chemical analysis records made & maintained				
9	1.3	Laboratory performance satisfactory				
10	1.4	Fish unloaded/in transit - properly protected				
11	1.4	Fish unloaded/in transit - minimum thawing				
12	1.5	Fish stored in sanitary containers				
13	1.5	Timely rotation of stocks & records kept				
14	1.6	Storage temperature no warmer than -18°C (0°F)				
15	1.6	At -18°C (0°F) fish stored no more than 3 months				
16	1.6	Cold storage equipped with temperature measuring device				
17	1.6	Temperature recorded daily				
		RECEIPT, EXAMINATION, HANDLING & STORAGE OF RAW FISH				
		SUBTOTAL				

Canned Tuna GMP Compliance

Plant: _____ Inspector: _____ Date: _____

THAWING, BUTCHERING, STAGING

Item	GMP	GMP Description	Compliance Category			Comments/Action
			1	2	3	
18	2.1	Thawing uniform, matches production capacity				
20	2.1	Recycling not used for more than 1 load in tank				
21	2.1	Thawing water temperature below 20°C (68°F)				
22	2.1	Water tempered before entering thaw tank				
25	2.3	Properly thawed, internal temperature below 5°C (41°F)				
26	2.3	Fish warmer than 5°C (41°F) pre-cooked within 1 hr				
27	3.1	Butchering time limits met				
28	3.2	Fish rinsed prior to butchering				
30	3.3	Fish properly butchered				
31	3.3	Fish washed thoroughly after butchering				
33	3.3	Butchered fish inspected				
34	3.3	Rejected fish segregated				
35	3.3	Rejected fish properly disposed of				
36	3.3	Records made and maintained				
37	3.4	Fish placed cut side down on racks				
39	3.4	Cooking racks clean and sanitary				
40	3.4	No reject quality/improperly eviscerated fish				
41	3.4	Unacceptable fish culled and removed				
42	3.4	Lot reinspected				
43	3.5	Staging time limits met				
44	3.5	Records made and kept				
THAWING, BUTCHERING, STAGING		SUBTOTAL				

Canned Tuna GMP Compliance

Plant: _____ Inspector: _____ Date: _____

PRE-COOKING, COOLING, CLEANING

Item	GMP	GMP Description	Compliance Category			Comments/Action
			1	2	3	
46	4.1	Pre-cook equipment/utensils clean and sanitary				
48	4.1	Pre-cook process adhered to				
49	4.1	Pre-cook records made and maintained				
50	5.1	Cooling to cleaning time limits met (6 hr)				
53	6.2	Outer work clothing functional and cleanable				
54	6.2	Outer work clothing worn when processing				
55	6.2	Aprons and gloves not worn in washrooms or outside				
56	6.2	Waterproof aprons properly cleaned				
57	6.2	Hair restraints used				
58	6.2	Fingernail polish / jewellery not worn				
60	6.3	Open wounds / sores				
61	6.4	Culling / Inspection at end of cleaning line				
62	6.4	Stations staffed with qualified personnel				
63	6.4	Loins properly inspected				
64	6.4	Reject quality flesh / loins removed and disposed of				
65	6.4	Records made and maintained				
66	6.5	Cleaned flesh not contaminated with offal				
67	6.6	Flesh containers washed after each use				
68	6.6	Cleaning tables rinsed once every 4 hrs				
69	6.6	Cleaning surfaces cleaned and sanitized at shift end				
70	6.6	Cleaning and sanitizing records kept				
71	6.6	Cleaned flesh holding time limit met (1 hr maximum)				
72	6.6	Records of cleaned product storage kept				
PRE-COOKING, COOLING, CLEANING		SUBTOTAL				

Canned Tuna GMP Compliance

Plant: _____ Inspector: _____ Date: _____

PACKING, RETORTING, CAN COOLING, LABELLING,
CASING, PRODUCT STORAGE, QUALITY CONTROL PROGRAM

Item	GMP	GMP Description	Compliance Category			Comments/Action
			1	2	3	
73	7.1.1	Ingredients inspected				
74	7.1.1	Non-complying ingredients removed and disposed of				
75	7.1.1	Records made and maintained				
77	7.2.1	Empty cans and lids inspected				
78	7.2.1	Empty cans properly cleaned				
79	7.2.1	Records made and maintained				
80	7.3.1	Loins and flesh inspected at can filling				
81	7.3.1	Defective material removed and reworked				
82	7.3.1	Records made and maintained				
83	7.3.2	Loins cut neatly and uniformly / no product on flange				
84	7.3.2	Filling machine knives checked for nicks				
85	7.3.2	Weighing devices available				
86	7.3.2	Fish fill and net content inspections made				
87	7.3.2	Non-compliant cans removed and corrected or rejected				
88	7.3.2	Records made and maintained				
90	7.3.3	Recipe and fill specifications adhered to				
91	7.3.3	Recipe and fill specifications monitored by QC staff				
92	7.3.3	Non-compliant fill specs, removed and corrected or rejected				
93	7.3.3	Records made and maintained				
94	7.4.1	Cans properly washed after seaming				
95	7.4.2	Can integrity, code legibility and accuracy inspected				
96	7.4.2	Seamer stopped if defects found or specifications not met				
97	7.4.2	Seamer repaired and retested and passes before restart				
98	7.4.2	Responsible agency notified of defects, products isolated				
99	7.4.2	Records made and maintained				
100	7.4.3	Can seam tear-down / measurement every 4 hrs				
101	7.4.3	Seamer stopped if defects found or specifications not met				
102	7.4.3	Seamer repaired and retested and passes before restart				

103	7.4.3	Vacuums measured		
104	7.4.3	Vacuums meet specifications		
105	7.4.3	Integrity or vacuum defects found, responsible agency notified		
106	7.4.3	Integrity or vacuum defects found, products isolated		
107	7.4.3	Integrity of vacuum defects found, products inspected & culled		
108	7.4.3	Integrity of vacuum defects found, serious can destroyed		
109	7.4.3	Integrity or vacuum defects found, cull report to resp. agency		
110	7.4.3	Procedure to clear jam-ups followed		
111	7.4.3	Records made and maintained		
113	7.5.1	Cans coded properly		
116	8.1	Retort operators have approved training		
117	8.1	Retorting procedures adhered to		
118	8.1	Retorting procedures monitored by QC staff		
119	8.1	Records made and maintained		
120	8.2	Cans begin to be heat processed within 2 hrs		
122	9.1	Cans water cooled to 45-50°C (113-122°F)		
123	9.2	Cans dried in clean area of plant		
124	9.2	Cans not touched by hands until cool and dry		
125	9.2	Cans not washed after cooling		
127	9.3	Chlorine added at least 20 min prior to use, ≥2 ppm		
128	9.3	2 ppm residual chlorine maintained at discharge		
129	9.3	Chlorine level measured twice per packing shift		
130	9.3	Records made and maintained		
131	9.4	Unretorted cans not mixed with retorted cans		
132	9.4	Indicators used to check satisfactory retorting		
133	9.4	Records made and maintained		
136	10.1	Product inspection stations before and at labelling		
137	10.1	Cans inspected before and after labelling		
138	10.1	Cans inspected before casing and warehousing		
139	10.1	Defects/swells/rusty/dirty/damaged cans removed		
140	10.1	Defective/swollen cans, lots isolated/identified		
141	10.1	Swollen/serious defects - isolated/destroyed		
142	10.1	Records made and maintained		
143	11.1	Cartons/cases legibly marked with code		
144	11.1	Codes and cartons/cases are same as cans in cases		

145	11.1	Clean, sound material used for cartons and cases			
147	12.1	Can warehouse has proper storage conditions			
151	12.1	Temperature monitored, no excess heat or freezing			
152	12.1	Product storage records made and maintained			
156	13.1	QC control points identified and monitored			
157	13.1	GMP control point deviations identified and corrected			
158	13.1	GMP and QC program records made and maintained			
PACKING, RETORTING, CAN COOLING, LABELLING, CASING, PRODUCT STORAGE, QUALITY CONTROL PROGRAM					
SUBTOTAL					

Canned Tuna GMP Compliance

Plant: _____ Inspector: _____ Date: _____

GENERAL GMP ASSESSMENT ITEMS

Item	GMP	GMP Description	Compliance Category			Comments/ Action
			1	2	3	
19	2.1	Thaw water from a safe and sanitary supply				
23	2.2	Thawing tanks are of a sanitary design				
24	2.2	Thawing tanks constructed of approved materials				
29	3.2	Wash water from a safe and sanitary supply				
32	3.3	Rinse water from a safe and sanitary supply				
38	3.4	Cooking racks of an approved sanitary design				
45	4.1	Cooking equipment and utensils of an approved sanitary design				
47	4.2	Precook time / temperature submitted to the responsible agency				
51	6.1	Cleaning equipment and utensils of an approved sanitary design				
52	6.1	Cleaning area properly designed and constructed				
59	6.3	Communicable diseases / carriers				
76	7.1.2	Spring water meets standards				
89	7.3.3	Recipe / fill specifications provided to responsible agency				
112	7.5.1	Can code key submitted to and approved by responsible agency				
114	8.1	Canning facilities and equipment approved by responsible agency				
115	8.1	Canning process submitted A& approved by responsible agency				
126	9.3	Can cooling water from a safe and sanitary supply				
135	9.4	Traffic control systems utilized				
146	12.1	Warehouse registered and in good repair				
148	12.1	Warehouse sanitation program implemented				
149	12.1	Warehouse insect and rodent control program				
150	12.1	Approved pesticides used				
153	13.1	QC program approved by responsible agency				
154	13.1	QC personnel received approved training				
155	13.1	Training records made and maintained				
GENERAL GMP ASSESSMENT ITEMS		SUBTOTAL				

Sub-total - Receipt, Examination, Handling & Storage of Raw Fish			
Sub-total - thawing, Butchering, Staging			
Sub-total - Precooking, Cooling, Cleaning			
Sub-total - Packing, Retorting, Can Cooling, Labelling, Warehouse			
Sub-total - General GMP Assessment AItems			
Sub-total - GMP Compliance Assessment			
Total			

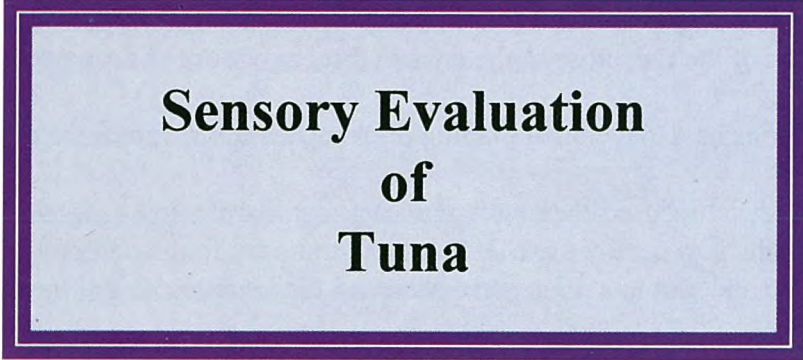
Acknowledged by:

Acknowledged by:

Inspector

Company Representative

CHAPTER 4



**Sensory Evaluation
of
Tuna**

Decomposition of Seafood

Decomposition of seafood is a direct result of temperature and/or handling abuse. This can occur on board the fishing vessel, during transportation and at the packing plant. The manufacturer needs to be vigilant in the purchase, grading and handling of seafood to avoid placing decomposed seafood into commerce.

Testing for Decomposition

While there are chemical tests for the end products of decomposition (eg histamine) none are as totally encompassing as the sensory approach. This analyst or grader invokes senses (sight, touch, taste, smell) in a subjective testing and rating of the seafood products, for example he/she must bring the flesh of the fish close to the nose to discern odours of decomposition.

A number of countries have developed grading or classification schemes for decomposition.

The USFDA have developed a scheme of sampling raw, frozen and canned tuna, whereby a sample size of 24 units is generally used. If 2 or more units are found defective, a second lot of 24 units are sampled and sent to a reference center, and the lot is rejected if the defect rate is ≥ 1 defect per 12 units.

The Canadian DFO has developed a grading scheme for raw tuna which is outlined in GMP 1.2 (Chapter 2). They have also developed a canned tuna standard (based on the Codex standard) which encompasses sensory evaluation. The part dealing with sensory assessment is given below:

1. Taint

A unit will be considered tainted when any of the following conditions exist:

a) Rancid

Odour characterized by the distinct or readily detectable persistent odour of oxidized oil, (this may be characterized by a pungent sensation in the nasal passage); or

Flavour characterized by distinct flavours present individually or in combination as follows:

bitter, sour, metallic flavours detected at the sides and back of the tongue leaving a lingering aftertaste.

b) Abnormal

Distinct and persistent odours and/or flavour that are burnt or acrid, (e.g as associated with excess scorch).

c) Contaminated

Odours and/or flavours resulting from contamination by solvents, soaps, fuel, oils, grease, etc. that are organoleptically detectable.

2. Decomposition

A unit will be considered decomposed when any of the following conditions exist:

a) Persistent, distinct and uncharacteristic odour characterized by:

- i) fruity (aldehyde odours similar to pineapple or other fruits);
- ii) vegetable odours - (e.g. turnip and cabbage-like but not associated with packing medium);
- iii) sour, yeasty fermented odours;
- iv) ammonia odours, hydrogen sulphide odours; or
- v) other pungent odours such as putrid or faecal.

b) Persistent, distinct and uncharacteristic flavours characterized by:

- i) sweet fruity flavours (e.g. pineapple-like); or
- ii) vegetable flavours (e.g. turnip and cabbage-like but not associated with packing medium); or
- iii) putrid or sour or faecal flavours.

c) Texture

Breakdown of muscle structure characterized by muscle fibres no longer being detectable resulting in the presence of small particles and/or granular, gritty or pasty texture exceeding 20% of the drained content.

d) Appearance

- i) Discolouration characterized by persistent flushed pink, orange or green colours in the flesh exceeding 5% drained contents.
- ii) True Honeycombing exceeding 5% of drained contents.

3. Unwholesome

a) Critical Foreign Material

A lot will be considered defective when any of the following conditions exist:

the presence of any material which has not been derived from tuna (and packing media) and which poses a threat to human health (such as glass, etc); or

distinct and persistent odour or flavour of any material which has not been derived from tuna (and packing media) and which poses a threat to human health (such as solvents, fuel oil, etc.).

b) Foreign Material

A unit will be considered defective when the following condition is found:

the presence of any material which has not been derived from tuna (and packing media) but does not pose a threat to human health (such as insect pieces, sand, etc.).

c) Other Defects

A unit will be considered defective when any of the following conditions exist:

- i) Struvite Crystals (magnesium ammonium phosphate crystals)
Any struvite crystal greater than 5mm in length.
- ii) Sulphide Blackening
Staining of the meat exceeding 5% of the drained contents.

4. Lot Acceptance

A lot will be considered unacceptable if it fails to meet the following final product requirements:

- 1) any single instance of critical foreign matter occurs; or
- 2) the total number of sample units found defective for taint, decomposition or wholesomeness, individually or in combination, exceeds the acceptance number for the sample size designated in the sampling plans; or
- 3) the total number of sample units found defective for decomposition exceeds the acceptance number shown in parentheses for the sample size designated in the sampling plans; or
- 4) the total number of sample units found defective for standards of identify (colour, style of presentation) exceeds the acceptance number for the sample size designated in the sampling plans.

5. Sampling of lots for examination of the product shall be in accordance with the FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (AQL 6.5) (CAC/RM 42-1969) except that acceptance numbers for decomposition shall be reduced in accordance with the sampling plans.

Following the Canadian DFO scheme for canned tuna fish, a guide to organoleptic analysis of canned tuna and a procedure for sensory evaluation of canned tuna is attached. Additionally the Canadian DFO has developed Procedures for the Assessment of Prospective Canned Tuna Inspectors, this is also as attached. Finally, tables of tuna quality indicators are attached with descriptors as developed by the NMFS. This includes quality indicators for raw and pre-cooked product, as well as canned product, which will be helpful in the grading and processing of tuna, particularly as this stage has been deemed a CCP in the HACCP guideline.

Organoleptic Analysis of Canned Tuna Products

Organoleptic Analysis involves the employment of one or more of the physical senses (sight, touch, taste, smell) for subjective testing and rating of food products.

Physical Requirements of Organoleptic Examinations

1. Work in an area that is free of distractions. Don't try to examine a product in a room where other types of analyses are being conducted.
2. Work in an area that is free of foreign odours.
 - a) No smoking at any time.
 - b) Cosmetic odours should be avoided.
 - c) Don't attempt to smell something that is held in another person's hands.
3. A slight positive pressure should be maintained in the testing area so that extraneous odours cannot enter into the testing area. Proper ventilation also removes product odours.
4. Separate participant if possible.
 - a) One person's reaction may affect another's judgement.
5. Lighting should be uniform, as near natural light as possible and not influence the appearance of product being tested.
6. Product to be tested should be a room temperature or slightly above. (This can vary some depending on product).

Other considerations:

1. Be as knowledgeable as possible about the product being examined.
2. Examine only one species or fish product at a time.
3. Take periodic rest breaks during the examinations.
4. Conduct all determinations independently of other examiners and immediately record results.

Procedure for Sensory Evaluation of Canned Tuna
(Developed by NMFS Western Inspection)

General Sensory Guidelines

- a) Use all your senses; sight, smell, touch and taste.
 - b) Rinse with distilled water in between samples.
 - c) Take slow, shallow sniffs.
 - d) When tasting samples, make sure the sample reaches the back and sides of the mouth and keep the sample in the mouth for a few seconds.
1. Open Can
 - a) Only one can per analysis should be open at one time. Do not open cans ahead of time.
 - b) Before you open the can check the exterior of the can for critical defects, i.e., sweller, leakers., major dents, etc. If the can is damaged severely or swollen, it should not be used for sensory analysis.
 2. Observe the liquid
 - a) Check the liquid to see if it is clear, cloudy, etc.
 - b) Smell liquid before draining. This is to see if there are any odours in the head space.
 3. Drain liquid
 - a. Drain the liquid into a container, and smell the liquid.
 - b. You may be able to detect odours of decomposition in the liquid.
 4. Examine the tuna in the can
 - a) Smell the tuna.
 - b) Check the appearance of the tuna, colour, texture, etc.

Developed by NMFS Western Inspection
 5. Empty the tuna on to a tray
 - a) The tray must be large enough that you are able to spread the tuna evenly on the tray.

- b) Smell the can as soon as you empty the can. At this point you may be able to pick up odours of decomposition, fuel, and chemicals from the can.
 - c) Smell the tuna before you spread it out. This will sometimes give you an indication of quality or contamination.
 - d) Place the can face down on the tray. This will trap odours inside the can so that the next analyst will be able to smell the odours.
 - e) Gently spread the tuna evenly on the tray. At this time you are checking for honeycomb, or other foreign material.
6. Gently break up tuna in your fingers, at the same time smell the tuna.
- a) Keep the tuna which you have already examined separate from the unexamined portion of the can.
 - b) Your first opinion is usually the right opinion.
 - c) You should evaluate the can on the odors present, if you are still not able to make a decision, we recommend that you taste the tuna.
 - d) When you taste the tuna, roll the tuna around your mouth, the front, middle, and back.
 - e) Keep the tuna in the mouth for a few seconds.
 - f) After a few seconds spit out the tuna. Rinse your mouth with distilled water. Record your results.
 - g) If you get an off taste or off odour you should clear your senses for the next sample. Rinse your mouth until the taste is gone, to clear your nose you should sniff a glass of distill water.

Department of Fisheries and Oceans

Procedures For the Assessment of Prospective Canned Tuna Inspectors

1. Each Inspector will examine 165 samples of canned tuna. These will be set out in 11 sessions of 15 samples each. The first session will consist of both white and light meat tuna. Two of the remaining 10 sessions will consist of only white tuna (albacore). The other 8 sessions will consist of only light meat tuna (skipjack, yellowfin or tongol).
2. The results of the first session will not be used to determine an Inspector's score. It will only serve as a practise session to refamiliarize Inspectors with the product.
3. A worksheet will be provided for each session on which Inspectors will record whether each of the samples is, in their opinion, of acceptable or reject quality.
4. The samples are only to be assessed on the basis of odour and flavour and should be rejected by Inspectors if they contain indicators of taint and/or decomposition that are distinct and persistent.
5. For those samples that are rejected, Inspectors will indicate the reasons(s) for rejection (taint and/or decomposition) on the worksheet. Also, each Inspector is asked to record the degree of sureness associated with each decision to accept or reject the sample. This designation of sureness will not affect the decision of A or R. Results are recorded as A or A? And R or R?
6. Although it will not be used to determine their score, Inspectors will be asked to record on their worksheets (for sessions consisting of light meat tuna), the species of the fish.
7. In order to determine an Inspector's score, their individual results (whether they accepted or rejected a sample) will be compared with those of an expert panel consisting of three Inspectors of canned tuna who have a proven record of assessing the product in a consistent and correct manner.
8. The prospective canned tuna Inspectors and the expert panel will examine the product at the same time, moving to samples in random sequences as position are available. No information regarding the origin of the individual samples or previous inspection results will be provided to the expert panel or the Inspectors prior to the sessions. However, information regarding the packaging medium will be provided as this is available to Inspectors during routine inspections and is important in the decision making process.
9. There will be no communication among inspectors while they are examining the product. After all 15 samples have been evaluated in a session, the worksheets are to be handed to the workshop coordinator. The prospective canned tuna Inspectors will then leave the room until they are asked to return for the next session.

10. A break of at least 15 minutes will be provided between sessions.
11. To ensure good sanitation assessment sessions:
 - a) Inspectors will wash their hands before examining the product, and
 - b) portions of samples for tasting will be transferred from the coded sample dish to the Inspector's sampling dish by a stainless steel fork. All tasting will be done from the Inspector's dish using his/her own tasting fork.
12. Inspectors must refrain from using perfume or scented lotions while they are attending the assessment.
13. The number of samples to be assessed will be limited to a maximum of 105 per day.
14. Inspectors will only be evaluated against those samples that the expert panel have unanimously accepted or rejected.
15. Inspectors will not be given their score until they have examined all 165 samples.
16. An Inspector's score will be expressed as a percentage of the total number of times their individual results of the expert panel. When they are given their score, Inspectors will be also advised of the number of samples that were used to determine this score as well as the percentage of samples they scored both too easily and too harshly.
17. To qualify as a canned tuna Inspector, Inspectors must attain an overall minimum score of at least 80% with individual scores for the reject and accept samples of no less than 70%. They must also have attained a minimum overall score of at least 75% with individual scores of at least 70% for the reject and accept samples on a previous assessment held at least six months previous to the current reassessment.
18. To retain their status as a canned tuna Inspector, an Inspector must be reassessed every two years and must attain, at that reassessment, a minimum overall score of at least 80% with individual scores for the reject and accept samples of no less than 70%.

Tuna Quality Indicators*

The following are descriptors which can be used to describe quality of raw tuna.

Appearance: Raw

Species	Pass	**B. Pass	B. Fail	Fail
Yellow Fin	translucent pale red colour firm texture	brownish yellow	opaque greenish faded	very opaque green grey soft mushy
Skip Jack	dark red brownish translucent shiny firm	pale pink sl. green iridescent softer sticky	dark brown grey/green dark green opaque cooked app.	iridescent/ green pasty grainy opaque belly burn mushy liquefaction
Albacore	light beige ivory pale pink/ translucent red-brown/ translucent shiny firm	sl. iridescent sl. green pink/brown mushy dry cooked app. opaque soft yellowish	iridescent soft/mushy grey/pink grey opaque blue-purple/ pink grainy	iridescent/heavy opaque belly burn liquefaction green brown

*Developed by NMFS

**B = Border line

Odors: Raw

Product	Pass	B. Pass	B. Fall	Fall
Yellow Fin	sweet fresh neutral	stale sl. brine* sl. fishy oxidized caramel	mod. stale sour musty sl. rancid fruity	v. stale v. sour putrid v. rancid painty ammonia fuel
Skip Jack	gamey meaty seaweed neutral	oxidized stale storage caramelized lt. brine stale meat sl. musty	sl. rancid persistent sour heavy brine fruity	putrid rancid v. stale pungent sour fermented fruity fecal sweet cheesy acid ammonia fuel
Albacore	fresh gamey neutral watermelon	sl. stale/stale oxidized cardboard storage	sl. rancid fruity/nutty musty sour fermented sl. green (urine/sulfur)	v. sour v. rancid putrid cheesy fecal garbage pungent fermented fruity sweet pineapple ammonia fuel

* "Brine" refers to odours of brine in which frozen tuna are being thawed.

The following are descriptors which can be used to describe quality of pre-cooked tuna.

Texture/Appearance: Pre-cooked

Product	Clear Pass	B. Pass	B. Fail	Clear Fail
Yellow Fin	firm texture light-whitish colour	sl. greenish darker mixed colours	honeycomb heavy curd grainy mushy/soft	honeycomb. soft/mushy green red/pink curdy (feverish) grey colour
Skip Jack	light colour yellow/sl. green firm-texture	pink/greenish curds slight greenish meaty mushy	mushy/pasty dry texture	mushy/pasty meaty honeycomb very dark colour feverish (mahogany)
Albacore	light-pale off white colour ivory colour firm turkey like texture-white meat	sl. caramelize lt. greenish dry texture sl. brown grey	tan/orange mod. green tough chewy	brown dark green tough/chewy honey comb heavy orange

Odors: Pre-cooked

Species	Pass	B. Pass	B. Fail	Fail
Yellow Fin	lt. turkey lt. chicken neutral	sl. oxidized sl. stale frozen storage sl. green*	sl. sour stale rancid sl. ammonia	fruity/pineapple sour yeasty rancid painty pungent putrid fuel
Skip Jack	dk. turkey dk. chicken neutral meaty gamey beefy	sl. oxidised oxidized cardboard stale	rancid sour musty urine ammonia yeasty painty	painty rancid urine ammonia musty sour cheesy putrid fecal pungent garbage fruity fuel
Albacore	lt. turkey lt. chicken neutral	sl. sulfide sl. caramel sl. oxidized sl. stale cardboard	sour rancid sulfide/heavy painty shellfish frz. storage	sour putrid green/heavy rancid painty sulfide/heavy fruity fecal sharp peppery pungent fuel

* "Green" odors refers to the phenomena occurring in tuna after PRE-COOKING and retorting. Greening is associated with high levels of TMAO and causes sensory changes characterized by green color, sulphur/urine odors and sulfide flavours.

Flavours: Pre-cooked

Product	Clear Pass	B. Pass	B. Fail	Clear Fail
Yellow Fin	turkey > pre-cooked chicken	sl. oxidized neutral	sour rancid stale	sour bitter fuel
Skip Jack	salty bitter (slight) tangy turkey > dark chicken meat gamey	bitter (sl) salty sl. oxidized stale smoky scorched sl. tang	bitter rancid sour persistent	biting-histamine sour (persistent) bitter rancid/pungent v. salty fuel
Albacore	neutral turkey-light meat chicken	sl. caramelize sl. oxidized sl. stale oxidized sl. green	sour bitter sl. rancid mod. sulfide froz. storage scorched metallic (heavy)	sour bitter sulfide (strong) fuel

The following are descriptors which can be used to describe quality of canned tuna products.

Colours: Canned

Product	Clear Pass	B. Pass	B. Fail	Clear Fail
Yellow Fin	light - white/yellow colour	sl. green	darker green grainy/meaty grey colour	feverish red/pink curdy honeycomb orange heavy green
Skip Jack	light colour - beige firm texture pink/beige	soft/meaty sl. grainy mushy darker beige cloudy free liquid	mushy/pasty med. brown curds iridescent	yellow/brown color feverish pink/red mushy iridescent
Albacore	light colour grainy texture	light/mod green sl. orange sl. caramel	heavy green heavy caramel orange	heavy green honey comb tough texture

Odours: Canned

Product	Clear Pass	B. Pass	B. Fail	Clear Fail
Yellow Fin	Chicken (lt. meat) neutral	sl. oxidized sl. fishy sl. metallic	sl. sour sour rancid sweet/fruity painty	rancid cheesy sweet/fruity very sour heavy green (urine/sulfur) putrid fruity fecal pineapple fuel
Skip Jack	chicken> dark turkey> meat neutral sl. soy meaty gamey	oxidized sl. stale musty/stale stale soy sl. metallic cardboard fleeting sl. scorch	rancid painty sour	rancid putrid, fecal very sour old brine musty fruity sweet/sour cheesy pungent fuel
Albacore	chicken turkey (light meat) neutral sl. sulfide sl. stale sl. metallic sl. caramel	sl. sulfide sl. caramel sulfide stale sl. caramel sl. metallic sl. green sl. crustacean musty mod. green oxidized sl. fishy	musty sour strong sulfide heavier schored rancid heavy green	sour putrid fecal fruity cheesy strong sulfide heavy scorched fuel urea rancid heavy green

Flavours: Canned

Product	Clear Pass	B. Pass	B. Fail	Clear Fail
Yellow Fin	Chicken (lt meat) neutral	oxidized	sl. sour sour bitter	heavy green urine/sulfur bitter sharp (histamine) fuel
Skip Jack	chicken > dark turkey > meat soy capon	sl. bitter oxidized sl. stale dry taste sl. grainy sl. scorched sl. metallic (tangy)	rancid bitter/strong med. sour	rancid strong bitter very sour fuel
Albacore	chicken turkey (light meat) neutral soy vegetable (broth)	sl. sulfide sl. scorched sl. metallic sl. caramel oxidized sl. fishy sl. crustacean	sour rancid heavy green fruity bitter	sour fruity rancid heavy green fuel bitter heavy caramel heavy sulfide pineapple fruity sharp/bite pungent sweet/sour astringent fecal fruity

Vocabulary Definitions

Term	Extend Definitions	Examples
Amine	Aromatic associated with the class of nitrogen-containing compounds, the amines. May be ammoniacal, fishy, or somewhat proteinaceous character like wet wool, wet dog fur.	Anchovies (fishy/amine)
Ammonia	Aromatic characteristic of unscented ammonia.	Old urine, household ammonia
Astringent	The chemical feeling factor on the tongue or other 1% alum in water skin surfaces of the oral cavity describes as puckering/dry and associated with tannins or alum.	Unripe banana, strong tea.
Bitter	Taste on tongue stimulated by solutions of caffeine, quinine, and certain other alkaloids.	Quinine, Allspice, Mace, Thyme, Oregano, Hop Tea
Caramelized	Sweet aromatic, characteristic of browned sugars and some other carbohydrates.	English toffee (Callard & sweetened condensed milk. Bowser) Candy Kitchen
Cardboardy	Aromatic associated with slightly oxidized fats and oils, reminiscent.	Wet cardboard, wet paper filters.
Cheesy	Aromatic associated with ripened cheese, sour aromatic with organic acid notes such as butyric and isovaleric.	Cheddar, Swiss cheese
Chemical	A very general term associated with many different types of compounds, such as solvents, cleaning compounds, and hydrocarbons. Having a distinctly "chemical" nature, perhaps foreign to food products.	Magic Marker (odor only)
Chicken, Dark Meat Cooked	Aromatic associated with freshly cooked chicken meat, dark muscle (thigh or leg)	Baked/boiled chicken thigh or leg
Chicken, White Meat, Cooked	Aromatic associated with cooked chicken white meat breast.	Baked/Broiled chicken breasts
Cold Storage	See: Cardboardy	
Crustacean	The slightly sweet aromatic associated with crabs, lobsters and shrimp.	Fresh cooked crab meat, lobsters

Diesel	A chemical aroma note associated with petroleum products.	
Earthy	Aromatic characteristic of damp soil or slightly undercooked boiled potato	Damp potting soil, undercooked boiled potato, spinach
Estery	Ripe fruit character associated with esters; typically sweet aromatic.	Aged apple cider Fermented, overripe apples
Fecal	An unpleasant aroma associated with complex protein decomposition	
Fermented	Aromatic associated with fermented fruits, vegetables. (Can be yeasty) or grains.	Overripe pineapple, cantaloupe, overripe orange juice
Fish oil	Aroma/flavour associated with slightly rancid fish oil; similar to oil found in mackerel.	Oil of canned sardines
Fishy	Aromatic associated with Triethylamine and old fish	Temperature abused mackerel
Fruity	Aromatic associated with a mixture of non-specific fruits: berries, apples/pears, tropical, melons; usually not citrus fruits	Fruit punch, Juicy Fruit gum
Fuel Oil	A general term to describe the aroma of fuel oils such as diesel oil or kerosene.	
Gamey, Fish	The aromatic associated with heavy, gamey, characteristics of some cooked fish such as Atlantic Mackerel, as opposed to a delicate aroma of fish such as sole. Analogous to the relationship of the heavy, gamey characteristics of fresh venison compared to fresh cooked beef, or duck to chicken.	
Hydrogen Sulfide	Aromatic associated with rotten egg and sewage.	Hard boil egg yolk
Iodine	Typical of the chemical iodine.	
Lactic Acid	A sour aroma note.	Brine from Sauerkraut
Metallic	(1) Aromatic associated with metals, tinny or iron;	Canned tomato juice or plum tomatoes, left open
	(2) A flat chemical feeling factor stimulated on the tongue by metal coins.	Iron tablet

Mouldy	Aromatic characteristic of mould growth or mildew.	Mouldy cheese
Musty, wet	Aromatic characteristic of damp/wet basements or turned soil.	Damp cloth stored in plastic bag, old books
Oxidized	A general non-specific term related to various characteristics of oxidized foods-such as stale, cardboard, rancid, painty, tallow.	Old oil
Painty	Aromatic associated with oxidized oil; similar to the aromatic of linseed oil and oil based paint.	Oil based paints
Pungent	Irritating sharp sensation upon exposure to certain volatiles.	Vinegar, onion, garlic
Putrid	Aromatic associated with anaerobic protein decomposition; decaying vegetation or animal.	Rotten flesh
Rancid	Aromatic associated with oxidized fats and oils.	Old oils, aged potato
Refrigerator/ Freezer	Off/flavour associated with a product that has absorbed odors from refrigerator or freezer.	Dairy products stored uncovered in refrigerator or freezer
Rotten vegetables	Cooked cabbage, cauliflower.	Cooked cabbage
Scorched	Aroma/flavor associated with scorching.	
Sharp	Aromatic characterized by a clean, sour impression	Vinegar
Sour	(1) Basic taste on tongue stimulated by acids.	Unripe fruits, Citrus
	(2) Aromatic caused by lactic acid bacteria.	Sour milk
Sour aroma/ aromatic	A sharp aromatic associated with products that have a sour taste or are fermented.	Vinegar/yogurt
Stale	A general term that describes old product with lower fresh notes and perhaps early stages of oxidation; cardboard is preferred term.	Crackers, cereal or bread year-old beer left open 2-3 days
Sulfide/sulfur	Aromatic associated with hydrogen sulfide, rotten egg.	Rotten eggs, sewer gas, cabbage
Sweet	Taste on the tongue stimulated by sugars and high potency sweeteners.	Dextrose, glucose

Sweet Aromatic	Aromatic associated with materials which also have a sweet taste, such as molasses, caramelized sugar, cotton candy, maple syrup, maltol.	Maple syrup, marshmallows, vanilla beans, molasses
Turkey, Dark Meat, Cured	Aromatic associated with cured dark turkey meat.	
Turkey, white meat cured	Aromatic associated with cooked white turkey meat.	
Watermelon	An aromatic reminiscent of watermelon rind or cucumbers.	Shortening aged in hermetically sealed cans.
Yeasty	Aromatics associated with fresh yeast and yeast fermentation.	Fresh baked yeast bread, fresh yeast cake

CHAPTER 5

Chemical Evaluation Methods for Quality and Safety

This section contains information on the official methods for testing mercury and histamine. It also contains information on analysis of histamine by HPLC and new indicators of freshness, putrescine and cadaverine, using DFO (Canadian) and USFDA methodology and modifications to the methods used by Thailand.

The HPLC method for histamine is experimental, not recognized by the AOAC. Our experience is that it does not give good results with fresh fish. Results with canned tuna are good except when the tuna is canned in oil.

The chemical indices for the product are in somewhat of a flux*:

CANADA methods:

Histamine	<100ppm (average of 5 cans), no one (1) can >300ppm
Putrescine	>0.8ppm early stages of decomposition (Note: not official limits)
Cadaverine	>0.5ppm early stages of decomposition (indices used for comparative tests with sensory)

USFDA methods:

Histamine	<50 ppm (\geq 1 can/12 cans for decomposition, no one (1) can >500 ppm for adulteration)
Putrescine	0.5 - 0.7 ppm decomposed (Note: not official limit - studies in progress)
Cadaverine	0.6 - 0.7 ppm decomposed (Note : not official limit - studies in progress)

This section contains the following information:

1. Determination of mercury in seafood - official method
2. Determination of histamine in seafood - official method - fluorometric method
3. Determination of histamine in canned fish by HPLC
4. Putrescine and cadaverine in canned tuna - DFO (Canada)
5. Putrescine and cadaverine in canned tuna - USFDA
6. Putrescine and cadaverine in canned tuna - Thailand modification
7. Examples of some results for putrescine and cadaverine

* It should be noted that critical limits enforced by countries, may change based on scientific evidence and risk assesment.

LABORATORY QUALITY MANUAL	Issue No. 1
FISH INSPECTION AND QUALITY MANUAL DIVISION, DEPARTMENT OF FISHERIES	Issue date 25/01/95
CHEMICAL METHODS MANUAL	Issued by:
	Approved by:
<p>CHAPTER 1 - CONTAMINANTS SECTION 1 : MERCURY TOTAL</p> <p>1. SCOPE AND APPLICATION</p> <p>1.1 This method is applicable to fish and fish products as well as other biological tissues.</p> <p>2. PRINCIPLE OF THE METHOD</p> <p>2.1 A prepared liquid sample with mercury in the divalent form (Hg ++) enters the system and is mixed with a reducing agent (usually SnCl₂ to form elemental mercury vapor). The mixture flows into a liquid-gas separator where argon or nitrogen is introduced to carry the mercury vapor through a drying tube for water vapor removal.</p> <p>The dry vapor then enters one path of a double path optical cell which has been optimized for fast response time (small diameter) and sensitively (long length). A mercury source, powered by a constant current power supply, delivers a stable source of emission at 254 nm. Absorbance by mercury cold vapor is measured using a solid state detector with a wide dynamic range. The resulting signal is referenced to the simultaneous absorbance of the pure carrier gas flowing through the second optical path under identical conditions.</p> <p>3. SAMPLING PROCEDURE AND STORAGE</p> <p>3.1 Commercial shipment: Take representative sample from the product lot and store as to maintain sample integrity.</p> <p>3.2 Survey samples: Fish may be either pooled or individual. For species normally greater than 30cm in length, and individual fish may be used as a sample. For species less than 30cm length, a pooled sample is required. Store as to maintain sample integrity.</p>	

4. SAMPLE PREPARATION

4.1 Commercial shipment: Sample preparation should take into account the type of product and how it is used and prepared by the consumer.

4.1.1 For fish and fish products that contains no free liquid: comminute the sample until homogeneous.

4.1.2 For products that are packed in water, brine or similar medium that is normally discarded by the consumer: open the package and drain the product on an appropriate size sieve for 1 to 1.5 min. Comminute the part of the sample retained by the screen until a homogeneous blend is obtained.

4.1.3 For products that are packed in a medium that may be or is normally used by the consumer, e.g. fish canned in its own juice or oil: transfer the entire contents of the package into a homogenizer and blend for one minute or until a homogeneous mix is obtained.

4.2 Survey Samples

4.2.1. For individual fish: weigh and measure the fork-length, i.e. from the nose to the fork of the tail, for size correlation.

4.2.2 For a pooled sample: determine the average values for length and weight of the fish.

4.2.3 Pass the skinned fillets through a commercial meat grinder a sufficient number of times to obtain a homogeneous blend (e.g three times).

4.3 Collect the homogenized sample into a thoroughly cleaned, sealable plastic pot or glass bottle. Store the sample in a refrigerator or freezer until required. Ensure that the prepared sample is still homogeneous prior to weighing. If liquid separates from the sample, thoroughly reblend before use.

5. APPARATUS

5.1 Mercury Analyzer, equipped with a mercury vapour lamp, auto-sampler, proportioning pump, and reagent manifold.

5.2 Microwave Digestion Unit: The digestion programs are as follows:

Step 1	250 Watts	5 minutes
Step 2	400 Watt	5 minutes
Step 3	600 Watt	5 minutes
Vent		1 minute

- 5.3 Digestion vessels; TFM vessel (P/N 33802).
- 5.4 Polypropylene bottle (30 ml).

6. REAGENTS

- 6.1 Nitric acid (HNO₃).
- 6.2 Hydrogen peroxide (H₂O₂) 30-40%.
- 6.3 Stannous Chloride SnCl₂ (10%).
- 6.4 Magnesium perchlorate anhydrous. Leeman Labs, Inc. Cat No. 0240-1119.
- 6.5 Hydrochloric acid (10%).
- 6.6 Standard Mercuric(II) Nitrate.

Stock Standard Solution (1.0mg Hg/ml).

High Intermediate Standard Solution (10 μ g Hg/ml). Dil. 1.0ml Stock soln to 100ml with 1N HCl (3).

Low Intermediate Standard Solution (1.0 μ g/ml. Dil. 10.0ml. high intermediate std soln to 100ml with 1N HCl.

Working Standard Solution Dil. 0.5, 1.0, 2.0, 3.0 and 4.0ml low intermediate std soln to 100ml with 1N HCl (0.005, 0.01, 0.02, 0.03 and 0.04 μ g (Hg/ml, resp.).

7. PROCEDURE

- 7.1 Place the TFM vessel (P/N 33802) directly on the balance plate and set to zero. Weigh the sample 0.5g into this vessel.
- 7.2 Add 5ml of HNO₃ conc. and 1ml of H₂O₂ (30%) to the vessel.
- 7.3 Put the vessel into the protection shield, cover and then put the vessels onto the polypropylene rotor body.
- 7.4 Place the polypropylene rotor body to the Microwave Digestion Unit and set the digestion program as follows:

Step 1	250 Watt	5 minutes
Step 2	400 Watt	5 minutes
Step 3	600 Watt	5 minutes
Vent		1 minutes

- 7.5 Place the polypropylene rotor body in the water bath with running water to cool the temperature of the vessel down to room temperature.
- 7.6 Take the vessels out of the polypropylene rotor body, remove the protection shield and the cover.
- 7.7 Transfer the solution to a graduated beaker, washing repeatedly the inside of the vessel with distilled water.
- 7.8 Filter the solution with cotton wool and transfer to 25ml volumetric flask. Adjust the volume to 25ml with distilled water.
- 7.9 Transfer to 30ml polypropylene bottle for mercury determination by mercury Analyzer.
- 7.10 Set up the Mercury Analyzer according to the manufacturer's instructions.
- 7.11 Place the sample, standards and blank, and check samples on the auto-sampler tray. A prepared standard and liquid sample with mercury in the divalent form (Hg^{++}) enters the system and is mixed with a reducing agent (usually SnCl_2 to form elemental mercury vapor. The mixture flows into a liquid-gas separator where argon or nitrogen is introduced to carry the mercury vapor through a drying tube for water vapor removal.

The dry vapor then enters one path of a double path optical cell which has been optimized for fast response time (small diameter) and sensitivity (long length). A mercury source, powered by a constant current power supply, delivers a stable source of emission at 254nm. Absorbance by the mercury cold vapor is measured using a solid state detector with a wide dynamic range. The resulting signal is referenced to the simultaneous absorbance of the pure carrier gas flowing through the second optical path under identical conditions.

8. CALCULATION

- 8.1 Prepare a calibration curve of absorbance versus nanograms Hg in the standards.

8.2 Determine the mercury concentration in the sample by comparing the sample absorbance to the calibration curve, taking into account the sample weight and the dilution factor. Express the result in terms of total mercury on a wet basis (ppm).

9. REFERENCES

9.1 MLS-1200 MEGA Microwave Digestion System with MDR Technology, MILESTONE s.r.l. Sorisole(BG), Italy.

HISTAMINE IN CANNED FISH BY HPLC

1. Reagent

- 1.1 Histamine dihydrochloride
- 1.2 Methanol
- 1.3 Benzoyl chloride
- 1.4 Diethyl ether
- 1.5 6% Trichloric acid
- 1.6 2M Sodium hydroxide
- 1.7 Preparation of standard amine solution

Histamine dihydrochloride was dissolved in 10 ml deionized water. The final concentration was 10 mg/ml solution.

2. Benzoylation Of Standard Amine Solution

The benzoyl derivatives of amines were prepared according to the method of Redmond and Tseng (1979) with minor modification. To the standard amine solution (50 μ l) 2 M sodium hydroxide (1 ml) was added, followed by 10 μ l of benzoyl chloride, mixed on a vortex mixer and allowed to stand 20 min. Saturates sodium chloride solution (2 ml) was added, followed by extraction with 4 ml diethyl ether. After centrifugation, the upper organic layer was transferred into a clean tube and evaporated to dryness in a stream of nitrogen. The residue was dissolved in 500 μ l of methanol and 5 μ l aliquots were injected for HPLC analysis.

3. Sample Preparation and Amine Extraction

After removal of oil, the fish was ground in a Waring Blender 3 min. Twenty grams ground sample was transferred to a 250ml centrifuge tube, and homogenized with 50ml 6% trichloric acid in a Polytron type 10-35 homogenizer 3 min. The homogenate was centrifuged (12000 rpm, 10 min, 4°C) to allow precipitation, and filtered through Whitman No. 1 filter paper. The filtrate was placed in a volumetric flask and made up to 100 ml. Each extract (2ml) was derivatized with benzoyl chloride as described. Recoveries of amines in augmented samples were determined by adding 25-50ppm amines in canned fish.

4. Chromatographic Conditions

Isocratic and gradient elution systems were used. For isocratic systems the mobile phase was methanol - water 55:45 v/v) at 1.5ml/min. at room temperature. The gradient elution program was set at 1.1ml/min, starting with a methanol-water mixture (55:45, v/v) for 2.5 min. The program proceeded linearly to methanol-water 88:22 (v/v), with flow rate increasing from 1.1 ml/min to 1.3 ml/min over 3.5 min. This was followed by the same composition and flow-rate for 2 min, then decreased over 7 min to methanol-water (55:45 v/v) at 1.1ml/min.

Ref: **Gow-Chin Yen and Chiu-Luan Hsieh (1990) Simultaneous Analysis of Biogenic Amines in Canned Fish by HPLC, Journal of Food Science, Vol. 56**

HISTAMINE DETERMINATION BY HPLC

Sample 20G + 60ml 6% TCA.

Homogenize for 3 mins.

Centrifuge for 10 mins and filter.

Adjust the volume to 100ml.

Take 2ml extract to test tube.

Add 1ml 2M NaOH, 10 μ l Benzoyl Chloride. Mix on vortex mixer and stand for 20 mins.

Add 2ml Sat. NaCl and 4ml Diethyl Ether, centrifuge.

Transfer upper organic layer to test tube and evaporate to dryness by N₂ gas.

Dissolve residue in 1ml MeOH and inject 20 μ l for HPLC analysis.

DETERMINATION OF HISTAMINE IN SEAFOOD FLUOROMETRIC METHOD

1. SCOPE APPLICATION

- 1.1 Histamine-like substances” are the principle compounds implicated as causing scombroid poisoning, an allergy-like condition caused predominantly by consumption of toxic fish of the sub-order Scombroidea which includes the tuna, bonito, kingfish, and mackerel. This method is suitable for the analysis of “histamine-like substances” in the above species, fish products utilizing these species, and mahi mahi (dolphin fish). The level of “histamine-like substances” can be used as both an indicator of spoilage and as an indicator of substances of public health significance.

2. PRINCIPLE OF THE METHOD

- 2.1 The “histamine-like substances” are extracted from the sample with methanol, interfering compounds are removed by anion exchange chromatography, and the purified histamine is then derivatized with orthophthalaldehyde (OPT) to form a fluorophore. Its intensity is measure by fluorometry. The results are reported as equivalent histamine levels.

3. INTERFERENCES

- 3.1 In fish flesh, large amounts of the amino acid, histidine, may be present and this compound interferes with the determination of histamine as it also forms a fluorophore with OPT. Several other homologues of histidine and other polyamides may also react with OPT; however, they are normally present at low levels and are not a major problem. The anion exchange procedure should minimize these problems.

4. SAMPLING PROCEDURE AND STORAGE

- 4.1 Take a representative sample from the product lot and store so as to maintain sample integrity.

5. SAMPLING PREPARATION

- 5.1 Upon receipt of the sample by the laboratory, the sample information should be checked and recorded in the laboratory records. The condition of the sample should be checked to ensure that fresh samples have been properly refrigerated and that frozen samples are still frozen. It is essential that a sample has been handled and stored in a manner that ensured its original quality has been maintained.
- 5.2 Fresh raw samples should be prepared immediately upon receipt but in no instance should a delay longer than 3 hours under refrigeration be permitted, otherwise the sample should be quick frozen upon receipt. Store other samples to maintain their integrity taking into account the type of product and how it is stored commercially.

- 5.3 Sample preparation should take into account the type of product and how it is used and prepared by the consumer. Samples that are too large or have a texture that is too tough for homogenization should be treated in a food processor or passed through a food grinder a sufficient number of times to ensure a uniform mix.
- 5.3.1 Fresh raw samples should be analysed immediately after grinding but if this is impossible, they should be quick frozen to ensure that decomposition does not proceed.
- 5.3.2 Products packed in a medium that may be or is normally used by the consumer, e.g. fish canned in its own juice or oil: transfer the entire contents of the package into a homogenizer and blend for one minute or until a homogeneous mix is obtained.
- 5.3.3 Products packed in water, brine or similar medium that is normally discarded by the consumer: open the package and drain the product on an appropriate size sieve for 1 to 1.5 minutes. Comminute the part of the sample retained by the sieve until homogeneous blend is obtained.
- 5.3.4 Processed products containing no separable liquid: thaw in the package (if frozen) and pass the sample through a food grinder a sufficient number of times to obtain a uniform mix. Thorough grinding and mixing is extremely important if the product is made up of several distinct components such as fish dinners.
- 5.4 Collect the homogenized sample into a thoroughly cleaned, sealable plastic cup or glass bottle. Store the sample in a refrigerator or freezer until required. Ensure that the prepared sample is still homogeneous prior to weighing. If liquid separates from the sample, thoroughly reblend before analysis.

A. Apparatus

- (a) Chromatographic tube - 200 x 7 (id) mm polypropylene tube (Chromaflex, Kontes Glass Co. No. K-420160 or equiv.) fitted with Kontes No. K-422372 Kel-F Hubs and ca 45cm Teflon tubing. Control flow rate at >3ml/min by *adjusting ht of column* relative to tubing outlet. Alternative, use 2-way valve in place of tubing.
- (b) Photofluorometer - Perkin-Elmer Model 203 or 204 with medium pressure Hg lamp, or equiv. instrument with excitation at 350 nm and measuring emission at 444nm.
- © Repipets - 1 and 5ml (Labindustries Inc., 620 Hearst Ave, Berkely, CA 94710, or equiv.).

B. Reagents

- (a) Ion exchange resin - Bio-Rad AG 1-X8, 50-100 mesh (Bio-Rad

Laboratories, 1414 Harbour, South, Richmond, CA 94804) or Dowex 1-X8, 50-100 mesh. Convert to -OH form by adding ca 15ml 2N NaOH/g resin to beaker. Swirl mixture and let stand <30 min. Decant liq. and repeat with additional base. Thoroughly wash resin with H₂O, slurry into fluted paper (S&S No. 588, or equiv.), and wash again with H₂O. Prep. Resin fresh weekly and store under H₂O.

Place glass wool plug in base of tube, (a), and slurry in enough resin to form 8cm bed. Maintain H₂O level above top of resin bed at all times. Do not regenerate resin in packed column; rather, use batch regeneration in beaker when necessary. Wash column with ca 10ml H₂O before applying each ext.

- (b) Phosphoric acid - 3.57N. Dil 121.8ml 85% H₃PO₄ to 1 liter. For other concn H₃PO₄, vol. required for 1 L 3.57N acid = 17493/(density H₃PO₄). Standardize 5.00ml by titrn with 1.00N NaOH to phthln end point, and adjust concn if necessary.
- (c) o-Phthalicdicarboxaldehyde (OPT) solution - 0.1%. Dissolve 100mg OPT (Adrich Chemical Co., Inc., No. P3,9400, or equiv.) in 100ml distd-in-glass MeOH (Burdick & Jackson Laboratories, Inc., or equiv.). Store in amber bottle in refrigerator. Prep. fresh weekly.
- (d) Histamine std solution - Store in refrigerator. (1) Stock solution. - 1mg/ml as free base. Accurately ca 169.1mg histamine dihydrochloride (98%, Aldrich Chemical Co., Inc., No. 11,2607, or equiv.) into 100ml vol. flask, and dissolve and dil. to vol with 0.1N HCl. Prep fresh weekly. (2) Intermediate solution - 10 μ g/ml. Pipet 1ml stock solution into 100ml vol. flask and dil. to vol. with 0.1N HCl. Prep fresh weekly. (3) Working solutions - 0.5, 1.0, and 1.5 μ g/5ml. Pipet 1, 2 and 3ml intermediate solution into sep 100ml vol. flasks, and dil. each to vol. with 0.1N HCl. Prep fresh daily.

C. Preparation of Standard Curve

Pipet duplicate 5ml aliquots of each working std solution into sep. 50ml glass or polypropylene erlenmeyers. Pipet in 10ml 0.1N HCl to each flask and mix. Pipet in 3ml 1N NaOH and mix. Within 5 min, pipet in 1ml OPT solution and mix immediately. After exactly 4 min, pipet in 3ml 3.57N H₃PO₄ and mix immediately. It is important to mix thoroughly after each addition and at least once during OPT reaction. (Run 6-10 OPT reactions simultaneously by adding reagents to erlenmeyers in set order) Prep. blank by substituting 5ml 0.1N HCl for histamine solution. Within 1.5 hr, record fluorescence intensity (I) of working std solutions with H₂O in ref. cells, using excitation wavelength of 350nm and emission wavelength of 444nm. Plot I (corrected for blank) against μ g histamine/5ml aliquot.

D. Determination

Weigh 10g sample, add approx. 50ml MeOH, blend in polytron homogenizer and transfer to 100ml vol. flask, rinsing with MeOH and adding rinsing to flask. Heat in water bath to 60°C and let stand 15 min at this temperature. Cool to 25°C, dilute to volume with MeOH, and filter thru folded paper. Alcohol filtrate may be stored in refrigerator several weeks. Pass 4-5ml H₂O thru column, (a), and discard eluate. Pipet 1ml ext onto column and add 4-5ml H₂O. Immediately initiate column flow into 50ml vol. flask contg 5.00ml 1.00N HCl. When liquid level is ca 2 mm above resin, add ca 5ml H₂O and let elute. Follow with H₂O in larger portions until ca 35ml has eluted. Stop column flow, dil. to vol. with H₂O, stopper, and mix. Regenerate eluate.

Pipet 5ml eluate into 50ml erlenmeyer, and pipet in 10ml 0.1N HCl. Proceed as in preparation of calibration curve beginning "Pipet in 3ml 1N NaOH..."

If sample contains >15mg histamine/100g fish, pipet 1ml sample - OPT mixture into 10ml beaker contg exactly 2ml blank-OPT mixt, and mix thoroughly. Read fluorescence of new solution. Dilute and mix aliquots with blank-OPT mixture as needed to obtain measurable reading. This approximation indicates proper dilution of eluate required prior to second OPT reaction needed for reliable quantitation of sample. Alternatively, use sensitivity range control of fluorometer (if instrument has one of aliquot of eluate with 0.1N HCl, and proceed as in preparation of calibration curve beginning "Pipet in 3ml 1N NaOH..."

E. Calculation

Plot of I (measured by meter deflection or recorder response and corrected for blank) against μg histamine/5ml solution should be straight line passing thru origin with slope = $m = [(I_a/1.5) + I_b + 2I_c]/3$.

$$\text{mg Histamine/100g fish} = (10)(F)(1/m)(I_s)$$

Where I_s , I_a , I_b , and I_c = fluorescence from sample, 1.5, 1.0, and 0.5 μg histamine stds resp., and F = dilution factor = (ml eluate + ml 0.1N HCl)/ml eluate. $F = 1$ for undild eluate.

If calibration plot is not linear, use std curve directly for quantitation. Each subdivision on abscissa should be 0.1 μg histamine/5ml solution. Read all values from curve to nearest 0.05 μg histamine/5ml solution.

$$\text{mg Histamine/100g fish} = (10) (F)(W)$$

Where W = μg histamine/5ml solution as detd std curve.

Ref : JAOAC 60, 1125, 1131 (1977)

PUTRESCINE AND CADAVERINE IN CANNED TUNA DFO (CANADA)

1. SCOPE AND APPLICATION

The diamines putrescine and cadaverine, which are formed from the amino acids ornithine and lysine, are the products of bacterial decomposition of fish tissue. These diamines can be used as indices of decomposition in fish and shellfish.

2. PRINCIPLE OF THE METHOD

Putrescine and cadaverine are extracted with methanol, and internal standard hexane diamine is added, and a dry residue of their hydrochloride salts is prepared. The salts are derivatized with pentafluoropropionic anhydride, and then separated from excess reagent on an alumina column. The derivatives are then injected into a gas chromatograph with an electron capture detector to determine the levels of putrescine and cadaverine.

3. SAMPLING PROCEDURE AND STORAGE

Take a representative sample from the product lot and store so as to maintain sample integrity.

4. SAMPLE PREPARATION

- 4.1 Upon receipt of the sample by the laboratory, the sample information should be checked and recorded in the laboratory records. The condition of the sample should be checked to ensure that fresh samples have been properly refrigerated and that frozen samples are still frozen, it is essential that a sample has been handled and stored in a manner that ensures its original quality has been maintained.
- 4.2 Fresh raw samples should be prepared immediately upon receipt but in no instance should a delay longer than 3 hours under refrigeration be permitted, otherwise the sample should be quick frozen upon receipt. Store other samples to maintain their integrity taking into account the type of product and how it is stored commercially.
- 4.3 Sample preparation should take into account the type of product and how it is used and prepared by the consumer. Samples that are too large or have a texture that is too tough for homogenization should be comminuted in a food processor or passed through a food grinder a sufficient number of times to ensure a uniform mix.
 - 4.3.1 Fresh raw samples should be analysed immediately after grinding; but if this is impossible, they should be quick frozen to halt decomposition.
 - 4.3.2 Products packed in a medium that may be or is normally used by the consumer, e.g. fish canned in its own juice or oil: transfer the entire contents of the package into a homogenizer and blend for one minute or until a homogeneous mix is obtained.

- 4.3.3 Products packed in water, brine or similar medium that is normally discarded by the consumer: open the package and drain the product on an appropriate sieve for 1 to 1.5 minutes. Comminute the part of the sample retained by the sieve until a homogeneous blend is obtained.
- 4.3.4 Processed products containing no separate liquid: thaw in the package (if frozen) and pass the sample through a food grinder a sufficient number of times to obtain a uniform mix. In the case of products that are made up of several separate distinct components such as fish dinners, only the fish component would be analysed.
- 4.4 Collect the homogenized sample into a thoroughly cleaned, sealable plastic cup or glass bottle. Store the sample in a refrigerator or freezer until required. Ensure that the prepared sample is still homogeneous prior to weighing. If liquid separated from the sample, thoroughly reblend before analysis.

5. REAGENTS

- 5.1 Pentafluoropropionic (PFP) anhydride : Refrigerate and protect from moisture
- 5.2 Ethyl acetate : Distilled in glass
- 5.3 Toluene : Distilled in glass
- 5.4 Methanol : Distilled in glass
- 5.5 **Stock solution** (1mg/ml Putrescine, 1mg/ml Cadaverine)
Dissolve 100mg each of putrescine and cadaverine in 0.1N HCL and dilute to 100ml in volumetric flask.
- Intermediate solution** (10 μ g/ml)
Dilute 1ml stock solution into 100ml volumetric flask.
- Working solution** (1 μ g/ml)
Dilute 10ml intermediate solution into 100ml volumetric flask.
- 5.6 **Hexane Diamine stock solution** (1mg/ml)
- Dissolve 100mg hexane diamine in 0.1N HCL and dilute to 100ml in a volumetric flask.
- Working Solution** (10 μ g/ml)
Dilute 1ml stock solution to 100ml in a volumetric flask.

6. PROCEDURE

6.1 Extraction

Weigh 10g sample, add approx. 45ml MeOH, blend in polytron homogenizer and transfer to 100ml volumetric flask. Adjust to volume with MeOH, shake and let settle.

6.2 Derivatization

6.2.1 For standards, pipet the following into 100ml round bottom flask:

Working solution.	ml used	diamine in sample (μg)
B	1	1
B	5	5
A	1	10
A	2	20

For sample, pipet 10ml extract into flask.

6.2.2 Pipet 1ml hexane diamine working solution (internal std) into each flask.

6.2.3 Add 0.5ml 1N HCL and evaporate to dryness on a rotary evaporator at 50°C.

6.2.4 To residue, add 1ml ethyl acetate 250 μl pentafluoropropionic acid anhydride (PFPA).

6.2.5 Stopper flask loosely, swirl contents to mix thoroughly and place in a 50°C water bath for 30 mins, swirling occasionally (If the reaction has not cleared within 15 min add an additional 250 μl PFPA, if reaction mixture remains cloudy then no reaction took place).

6.2.6 After reaction, evaporate at 50°C the solvent/reaction mixture to a glass with nitrogen.

6.2.7 Dissolve the resulting glass in 2ml of 30:70 ethyl acetate:toluene.

6.2.8 Prepare alumina column (80 x 9mm bed volume) with 3% moisture deactivated alumina, with 1 cm anhydrous sodium sulphate.

6.2.9 Condition column with 10ml hexane, collect effluent, and total derivatized extract to column bed.

6.2.10 Rinse flask with further 3ml 30:70 and add to column when initial extract absorbed onto bed surface.

6.2.11 Repeat with 18ml 30:70, and add to column. Collect entire column effluent, mix by swirling.

6.3 Clean Up

Prepare alumina column

ALUMINA : Heat alumina 2 hours at 125°C, stopper and let cool to room temperature. Adjust activity by adding 3g water to 97g alumina. Equilibrate for a minimum of 4 hrs with shaking.

For each sample, pack a 24 x 10.5mm column to a height of 8cm. Cover with 1cm of anhydrous sodium sulphate.

6.4 Chromatography Condition

Set up chromatography as follows:

Megabore Capillary Column DB-225 (30m x 0.53mm ID)

- Oven Temperature -iso-	180°C
- Injector Temperature	200°C
- ECD Detector Temperature	280°C
- Carrier Gas N ₂ /He	10ml/min
- Make-up Gas N ₂	50ml/min
- Run-End Time	15ml/min

7. CALCULATIONS

If an integrator - data handling system, is not used, calculate the ratio of the standard peak height (putrescine or cadaverine) to the peak height of the hexane diamine. From the standard ratios, plot a calibration curve (this should be linear from 1µg/g to 20µg/g). The concentration of putrescine and cadaverine can then be calculated.

$$\text{Concpu} = \frac{\text{Concps} \times \text{Hiss} \times \text{Hpu}}{\text{Hps} \times \text{Hisu}}$$

where : pu = putrescine in unknown
 ps = putrescine in standard
 iss = internal standard in standard
 isu = internal standard in unknown

8. REFERENCE

- 8.1 STARUSZKIEWITCZ W.F. AND BOND, J.F., Gas Chromatography Determination of Cadaverine, Putrescine, and Histamine in Foods. JAOAC (V.64 No. 3 1981).
- 8.2 FARN, G AND SIMS, G., Chemical Indices of Decomposition in Tuna, Proceedings of an International Symposium on Seafood Quality Determination. Elsevier Science Publishers, B.V. Amsterdam 175-183 (1986).

Putrescine and Cadaverine - Fish Quality Indices

Sample Extraction

Weigh 10.0g of sample into a 150ml beaker.

Add 60ml MeOH and homogenize with a polytron homogenizer.

Transfer homogenate (rinsing with MeOH) to 100ml volumetric flask, make up to volume.

Mix volumetric flask contents thoroughly, allow sample residues to settle, producing a clear extract.

Pipet 10ml of the clear extract into a 125ml round bottom flask.

Add 1.00ml of 5ppm hexane diamine working solution and 0.50ml 1N HCl to the 10ml of extract.

Evaporate to complete dryness on a vacuum rotary evaporator at 50°C.

Derivatization Process and Sample Clean-Up

To the dried sample add 1ml ethyl acetate & 250 μ l pentafluoropionic acid anhydride (PFPA).

Stopper flask loosely, swirl contents to mix thoroughly, and place in a 50°C water bath for 30 minutes, swirling occasionally. (If the reaction has not cleared within 15 min add an additional 250 μ l PFPA, if reaction mixture remains cloudy then no reaction took place).

After reaction, evaporate at 50°C the solvent/reaction mixture to a glass with nitrogen.

Dissolve the resulting glass in 2ml of 30:70 - ethyl acetate:toluene.

Prepare alumina column (80x9mm bed volume) with 3% deactivated alumina, with 1cm anhydrous sodium sulphate.

Condition column with 10ml hexane, collect effluent, add total derivatized extract to column bed.

Rinse flask with further 3ml 30:70 and add to column when initial extract absorbed into bed surface.

Repeat with 18ml 30:70, and add to column.

Collect entire column effluent, mix by swirling.

Chromatographic Conditions

Packed Column OV-225 (6ft x 0.25"OD x 4mm ID)	
- Oven Temperature - iso-	180°C
- Injector Temperature	200°C
- ECD Detector Temperature	280°C
- Carrier Gas N ₂ /He	60 ml/min
- Make-up Gas N ₂	----
- Run-End Time	20 minutes

Megabore Capillary Column DB-225 (30m x 0.53mm ID)	
- Oven Temperature -iso-	180°C
- Injector temperature	200°C
- ECD Detector Temperature	280°C
- Carrier Gas N ₂ /He	10 ml/min
- Make-up Gas N ₂	50 ml/min
- Run-End Time	15 minutes

PUTRESCINE AND CADAVERINE IN CANNED TUNA USFDA

Modifications have been made to the GLC method for the determination of putrescine and cadaverine developed by Staruskiewicz and Bond to reduce the number of steps and shorten the time it takes to analyse a sample. The original method involved four steps - extraction of the sample, making a fluorinated derivative, putrifaction of the reaction by column chromatography, and detection of the diamines by GLC. Modifications have been made in the extraction procedure (using 75% methanol in water instead of 100% methanol) and by replacing the column chromatography with solid phase extraction (SPE).

Materials and Methods

Apparatus

1. Gas Chromatograph (electron capture detector) : Varian Model 3700 or equivalent, with model 20-21 Ni 63 pulsed capture detector. Representative operating conditions: temperature (°C) : injection port 210, detector 320, column 165; gas flow (ml/min): Nitrogen 25; electrometer range 10 - 10amp full scale. Detector makeup purge gas as needed (e.g. 40ml/min).
2. GLC column (for putrescine and cadaverine derivatives): Glass column 1.8m (6ft) x 2 mm id, packed with 3% OV -225 on 100 - 120 mesh Gas Chrom Q. Condition with gas flow at room temperature for 2 hrs., increase temperature gradually (ca 6°C/min) to 240°C, and hold for 16 hrs.

Retention times of PFP derivatives were 6, 10, 12 min, respectively, for putrescine, cadaverine, and hexane diamine.

Reagent

1. Pentafluoropropionic (PFP) anhydride. : Refrigerate and protect from moisture.
2. Methanol: Distilled in glass.
75% methanol : To 750ml MeOH in a 1 litre flask, add distilled water with swirling to volume.
3. SPE Tubes : SUPELCLEAN LC - Alumina-N SPE tubes, 3ml size Cat # 5-7086, Supelco Inc., Bellefonte, PA 16823-0048 USA.
4. Hexane diamine standard solution:

Stock Solution : Dissolve 163mg hexane diamine dihydrochloride in 0.1N HCl and dilute to 100ml in vol. flask with 0.1N HCl.

Intermediate Solution : 20µg/ml. Dilute 2ml stock solution to 100ml in vol. flask with 0.1N HCl.

Working Solution : $5\mu\text{g}/\text{ml}$. Dilute 25 ml Intermediate solution to 100ml in vol. flask with 0.1N HCl.

5. Standard solution of diamines. :

Stock Solution: Dissolve 91.4mg of putrescine dihydrochloride and 171.3mg of cadaverine dihydrochlorine in 0.1N NCl and dilute to 100ml in vol. flask with 0.1N HCl.

Intermediate Standard Solution : ($10\mu\text{g}/\text{ml}$ cadaverine and $5\mu\text{g}/\text{ml}$ putrescine as free base): Dilute 1 ml stock solution to 100ml in vol. flask with 0.1N HCl.

Working Standard Solution : ($1\mu\text{g}/\text{ml}$ cadaverine and $0.5\mu\text{g}/\text{ml}$ putrescine as free base) Dilute 10ml Intermediate solution to 100ml in vol. flask with 0.1N HCl.

Calibration

Pipet 1ml of internal standard solution plus indicated volume (Table 1) of diamine standard solution into 100ml round-bottom 24/40 flask. Add ca. 0.5ml 1N HCl and evaporate to dryness on rotary evaporator at ca. 50°C (or steam bath under nitrogen). To residue add 1ml ethyl acetate and $300\mu\text{l}$ PFP anhydride, stopper, mix and heat at 50°C for 30 min. Swirl solution at least once during reaction.

Add 2ml toluene to the reaction mixture. Add 2ml of hexane to each SPE tube (3ml from Supelco) and let flow through by gravity. Discard the hexane. Add $150\mu\text{l}$ of the diluted reaction mixture to the top of each tube. Start collecting effluent when the sample is added. Add 3 or 4 drops of 30% ethyl acetate in toluene to the tube. After the sample passes into the frit, add 2ml of 30% ethyl acetate in toluene. Add an additional 6ml for a total of 8ml of 30% ethyl acetate in toluene and collect all the effluent. Inject $102\mu\text{l}$ into the GLC system. Calculate ratio $r_c = \text{peak height PFP cadaverine}/\text{peak height PFP hexane diamine}$ vs. cadaverine derivated (w). Repeat calculation for r_p values for putrescine.

Determination

Fishery products : Extract product with 75% methanol as follows:

Transfer 10g prepared sample to blender bowl and add approx 60ml 75% methanol. Blend for ca 2 min at high speed. Transfer to 100ml vol. flask, rinsing lid and blender jar with 75% methanol and adding rinsing to flask. Heat in water bath to 60°C and let stand at this temperature for 15 min. Cool to room temperature and dilute to volume with 75% methanol. Filter thru folded filter paper.

Pipet 10ml extract into round bottom flask, add 1ml internal standard solution and ca 0.5ml 1N HCl, and evaporate to dryness on rotary evaporator at ca 50°C . Continue as in Calibration, sentence 3, beginning "to residue....".

If values obtained for putrescine and cadaverine are above the most concentrated calibration standards then a smaller volume will be injected in order to quantify the sample content. However, no injection will be acceptable if the internal standard is less than 5% of full scale. If the sample is so concentrated that this approach is unacceptable then the sample may be qualified through adjustment of the instrument attenuation.

Table 1. Diamine Calibration Standard

Calibration Solution	Std Solution	ml used	Equivalent μg cadaverine/g sample	Equivalent μg putrescine/g sample
I	B	0.5	0.5	0.25
II	B	1	1	0.5
III	B	5	5	2.5
IV	A	1	10	5
<i>If required for Higher Levels</i>				
V	A	2	20	10
VI	A	3	30	15
VII	A	5	50	30
VII	A	10	100	30

A = Intermediate solution

B = Working solution

Notes

1. Adjust GC to give full scale recorder response for injection of $2\mu\text{l}$ of calibration solution IV.
2. Full calibration of GC using duplicate injections of each of the calibration solution is required only at the beginning of study unless the instrument is shut down during analyses. On succeeding days when samples are analysed, rechromatograph Calibration Solution II to insure that calibration of instrument is stable.
3. A calibration solution beyond IV is required if amine levels the calibration range. For example, if $85\mu\text{g}$ cadaverine/g is found in a sample, run a calibration solution at a level of ca $100\mu\text{g/g}$ to extend the calibration line, employing the same analytical technique used for the sample extract analysis, e.g., attenuation factors or a reduction in the volume injected into the GC.

In each case in which the sample values are higher than the most concentrated calibration standard a new calibration standard higher than the determined values will be prepared and analysed in similar fashion.

Alternatively, carry a smaller aliquot of the 75% methanol extract (eg. 1 ml) through the procedure and multiply by the appropriate factor to calculate $\mu\text{g/g}$ values.

Calculation

For each sample calculate r_c and r_p from the chromatogram. Determine W_c and W_p from the calibration graph.

$$\mu\text{g diamine/g sample} = (W) (F)$$

Where F = attenuation (or dilution) factor, if required.
All calculations will be carried out to 0.1 $\mu\text{g/g}$.

Results and Discussion

Elution profiles of cadavarine and putrescine from 3ml SPE tubes were determined using standard solutions as shown in figure 1 and 2. A putrescine recovery of 98% was obtained with 8ml of eluent using concentrations of 1 μg to 30 μg . A cadaverine recovery of 100% was obtained with 8 ml of eluent using concentrations of 2 μg to 60 μg . Satisfactory results were obtained with the SPE columns with varying samples sizes up to 200 μl and varying concentrations of eluent from 25% to 35%.

Table 2 shows a comparison of several brands of SPE columns and the effect on the recovery of the diamines from the column. The larger column containing 1.7g alumina (Waters) and 1.6g alumina (Supelco) has a larger sample capacity but also required a larger elution volume. A quantitative recovery was obtained on all the columns containing 1g of alumina by adjusting the concentration of the eluent. The column containing 0.5g of alumina did not have a large enough capacity to separate the diamines from the excess reagent.

The Fisher PrepSep was eliminated because the mixture from PFP reaction would have to be diluted with 5 times the volume of toluene for an effective clean-up which would cause problems in detection in the GLC system. The Baker column was eliminated because of the extra peak that was present in the final chromatogram. The Supelco column was selected due to the smallest elution volume without a large increase in the dilution factor.

The use of SPE columns reduced the sample clean-up time prior to GLC analysis from 1 hr. to 10 mins. The modified method requires less space, is more convenient, eliminates the washing of glass columns, and reduces the amount of solvent used by 2/3.

Table 2 *Comparison of SPE Column*

Brand names	Sample size (μl)	wt. of alumina (g)	conc. of eluent	% recovery
Waters SepPak	250	1.7	12ml 100% EtOAC	100
Fisher PrepSep	100	1.0	4ml 20% EtOAC	100
Benton & Jackson	100	0.5	2ml 15% EtOAC	no separation
Supelco 6ml tube	200	1.6	16ml 30% EtOAC	100
Baker 6ml tube	100	1.0	8ml 30% EtOAC	100 w/extra peak
Supelco 3ml tube	100	1.0	8ml 30% EtOAC	100

DETERMINATION OF PUTRESCINE AND CADAVERINE

Sample Extraction

Weigh 10g of sample into a 150ml beaker.

Add 60ml of 75% MeOH and homogenate with a polytron homogenizer.

Transfer homogenate (rinsing with 75% MeOH) to a 100ml vol. flask, heat in water bath at 60°C for 15 min.

Cool and dilute to column with 75% MeOH.
Filter thru Whatman No. 1.

Pipet 10ml of the clear extract into a 125ml RBF.

Add 1ml of 5 ppm hexane diamine working solution and 0.5ml 1N HCl to the 10ml of extract.

Evaporate to complete dryness on a vacuum rotary evaporator at 50°C.

Derivatization Process and Sample Clean-Up

To the dried sample add 1ml ethyl acetate & 300 μ l PFPAA.

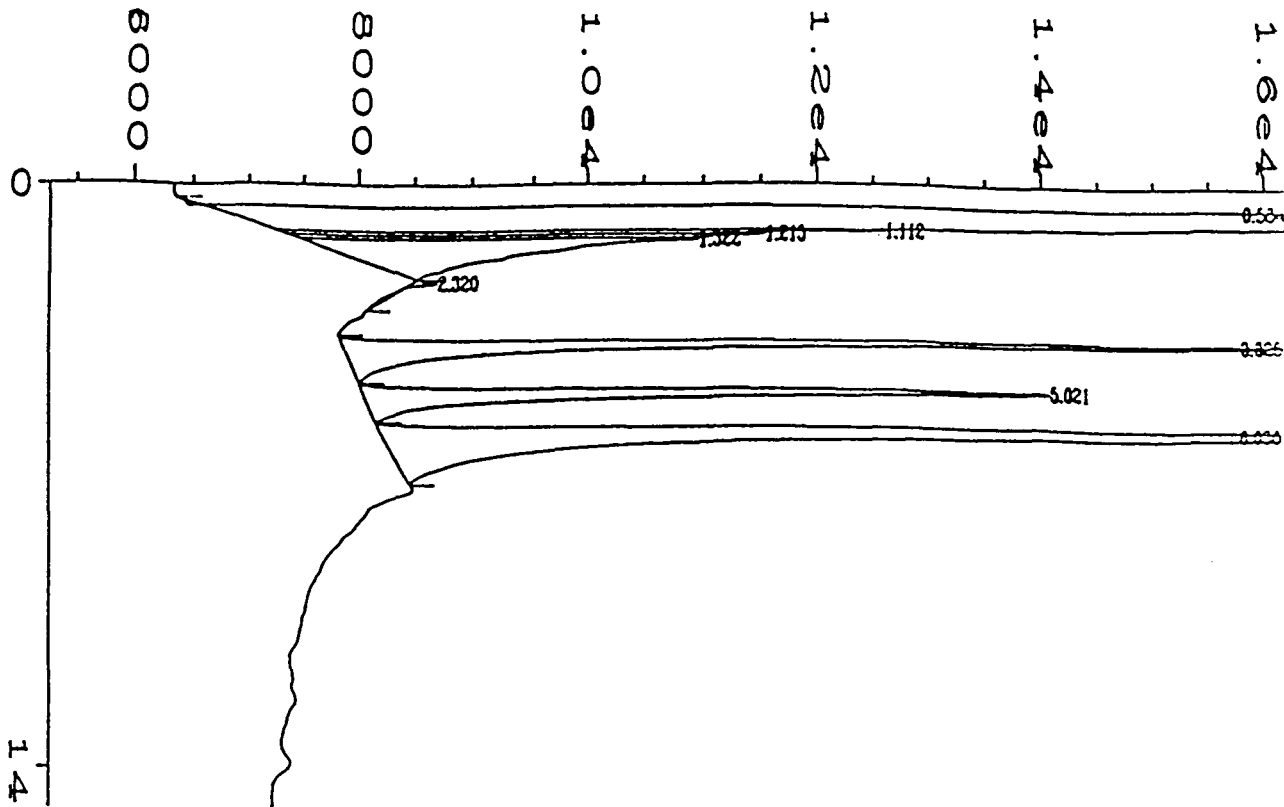
Stopper flask loosely, swirl contents to mix thoroughly, and place in a 50°C water bath for 30 min, swirling occasionally.

Add 2ml of toluene to the reaction mixture.

Add 2ml of hexane to SPE tube and let flow through by gravity. Discard the hexane.

Add 150 μ l of the diluted reaction mixture to SPE tube, following with 3 or 4 drops of 30% ethyl acetate in toluene. Start collecting effluent when the sample is added.

Add 2ml of 30% EtOAC, then additional 6ml for a total of 8ml and collect all the effluent.



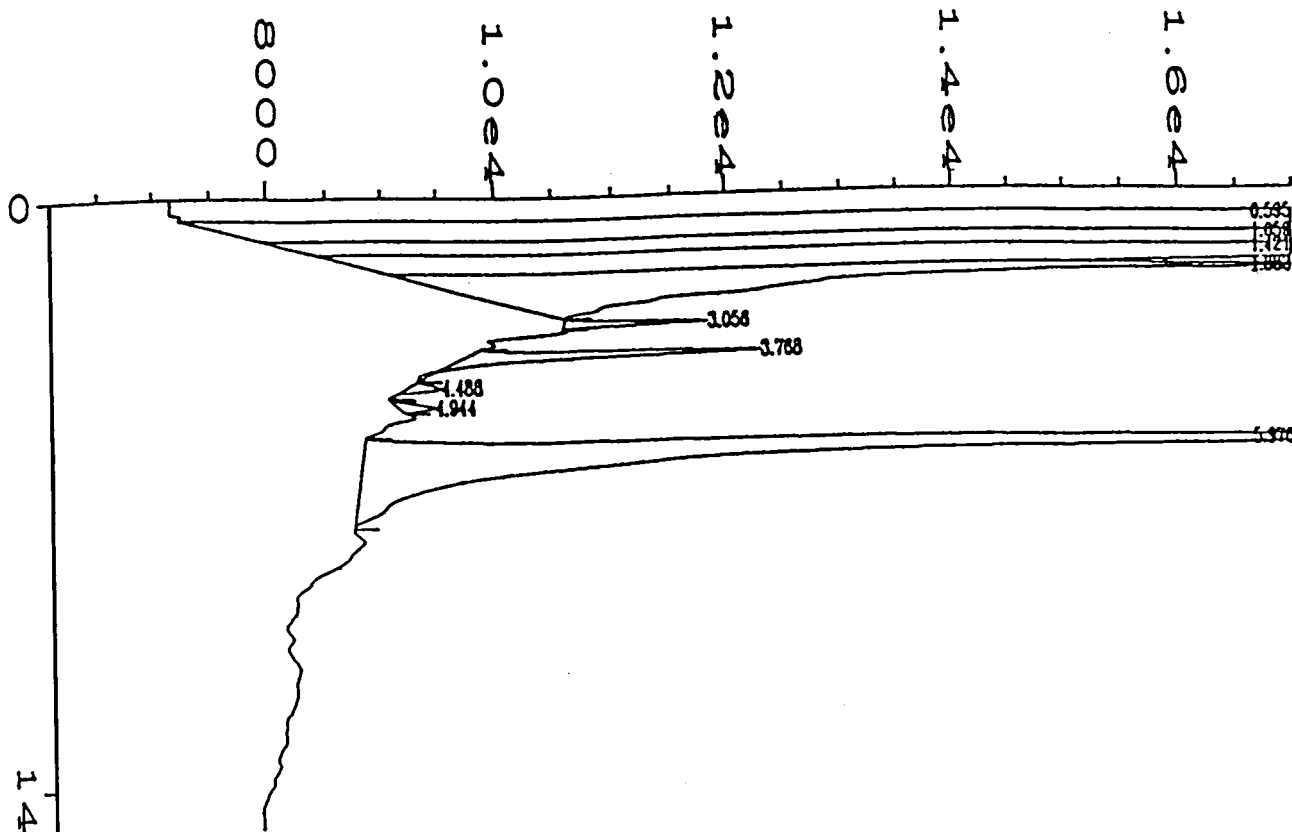
Internal Standard Report

Data File Name	: C:\HPCHEM\1\DATA\PC\001F0139.D	Page Number	: 1
Operator	: supapun	Vial Number	: 1
Instrument	: INSTRUMEN	Injection Number	:
Sample Name	: pstd	Sequence Line	: ECD.MTH
Run Time Bar Code	:	Instrument Method	: ECD/MTH
Acquired on	: 15 Jul 95 10:15 AM	Analysis Method	: 1
Report Created on	: 15 Jul 95 10:31 AM	Sample amount	: 1
Last Recalib on	: 15 Jul 95 10:05 AM	ISTD Amount	:
Multiplier	: 1		

Sig. 1 in C:\HPCHEM\1\DATA\PC\001F0139.D

Ret Time	Area	Type	Width	Ref #	Amount %	Name
3.825	112482	BB	0.177	1	223.626	putrescine
5.021	86359	BB	0.214	1	221.776	cadaverine
6.036	230896	BB	0.287	1-IR	100.000	hexane diamine

Time Reference Peak	Expected RT	Actual RT	Difference
3	6.085	6.036	-0.8%



Internal Standard Report

Data File Name	: C:\HPCHEM\1\DATA\PC\009F0145.D	Page Number	: 1
Operator	: supapun	Vial Number	: 9
Instrument	: INSTRUMEN	Injection Number	:
Sample Name	: PFI 15	Sequence Line	:
Run Time Bar Code	:	Instrument Method	: ECD.MTH
Acquired on	: 15 Jul 95 12:49 PM	Analysis Method	: ECD/MTH
Report Created on	: 15 Jul 95 01:06 PM	Sample amount	: 1
Last Recalib on	: 15 Jul 95 10:05 AM	ISTD Amount	: 1
Multiplier	: 1		

Sig. 1 in C:\HPCHEM\1\DATA\PC\009F0145.D

Ret Time	Area	Type	Width	Ref #	Amount %	Name
3.768	23855	BB	0.143	1	41.731	putrescine
4.944	3063	BB	0.141	1	6.922	cadaverine
5.976	262408	BB	0.331	1-IR	100.000	hexane diamine
Time Reference Peak						
		Expected RT		Actual RT		Difference
3		6.085		5.976		-1.8%

**Determination of Putrescine and Cadavarine
Modified from USFDA and DFO (Canada)**

Sample Extraction

Weigh 10g of sample into a 150ml beaker.

Add 60ml of 75% MeOH and homogenize with a polytron homogenizer.

Transfer homogenate (rinsing with 75% MeOH) to a 100ml vol. flask, make up to volume.

Mix volumetric flask contents thoroughly, allow sample residues to settle, producing a clear extract.

Pipet 10ml of the clear extract into a 125ml round bottom flask.

Add 1ml of 5ppm hexane diamine working solution and 0.5ml 1N HCl to the 10ml of extract.

Evaporate to complete dryness on a vacuum rotary evaporator at 50°C.

Derivatization Process and Sample Clean-Up

To the dried sample add 1ml ethyl acetate and 300 μ l PFPAA.

Stopper flask loosely, swirl contents to mix thoroughly, and place in a 50ml water bath for 30 min, swirling occasionally.

Add 2ml of toluene to the reaction mixture.

Add 2ml of hexane to SPE tube and let flow through by gravity, discard the hexane.

Add 150 μ l of the diluted reaction mixture to SPE tube, following with 3 or 4 drops of 30% ethyl acetate in toluene. Start collecting effluent when the sample is added.

Add 2ml of 30% EtOAC, then additional 6ml for a total of 8ml and collect all the effluent.

Inject 1 μ l to GC.

INTRODUCTION

The Code of Practice for Low-Acid and Acidified Low-Acid Canned Food was adopted by the Codex Alimentarius Commission at its 13th Session in 1979 and subsequently revised in 1989 by the 18th Session. Additional information contained in Appendices IV and V was adopted by the 19th Session of the Commission in 1991. The Code has been sent to all Member Nations and Associate Members of FAO and WHO as an advisory text, and it is for individual governments to decide what use they wish to make of it. The Commission has expressed the view that codes of practice might provide useful checklists of requirements for national food control or enforcement authorities.

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

**RECOMMENDED INTERNATIONAL CODE OF HYGIENIC
PRACTICE FOR LOW AND ACIDIFIED LOW ACID CANNED FOODS
CAC/RCP 23-1979, Rev. 1 (1989)**

CONTENTS

SECTION I:	SCOPE	147
SECTION II:	DEFINITIONS	147
SECTION III:	HYGIENE REQUIREMENTS IN PRODUCTION/ HARVESTING AREA	150
SECTION IV:	ESTABLISHMENT: DESIGN AND FACILITIES	152
SECTION V:	ESTABLISHMENT: HYGIENE REQUIREMENTS	157
SECTION VI:	PERSONNEL HYGIENE AND HEALTH REQUIREMENTS	159
SECTION VII:	ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS	161
SECTION VIII:	QUALITY ASSURANCE	196
SECTION IX:	STORAGE AND TRANSPORTATION OF FINISHED PRODUCT	200
SECTION X:	LABORATORY CONTROL PROCEDURES	200
SECTION XI:	END-PRODUCT SPECIFICATIONS	201
REFERENCE FOR TEAR-DOWN EVALUATION OF A DOUBLE SEAM		202

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

CAC/RCP 23-1979, Rev. 1 (1989)

1. SECTION I - SCOPE

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

2. SECTION II - DEFINITIONS

For the purposes of this Code:

- 2.1 "Acid food" means a food that has a natural pH of 4.6 or below.
- 2.2 "Acidified low-acid food" means a food which has been treated so as to attain an equilibrium pH of 4.6 or lower after heat processing.
- 2.3 "Aseptic Processing and packaging" means the filling of a commercially sterile product into sterilized containers followed by hermetical sealing with a sterilized closure in an atmosphere free from microorganisms.
- 2.4 "Bleeders" (Bleeds) means small orifices through which steam and other gases escape from the retort throughout the entire heat process.
- 2.5 "Canned food" means commercially sterile food in hermetically sealed containers.
- 2.6 "Cleaning" means the removal of food residues, dirt, grease or other objectionable material.
- 2.7 "Code lot" means all product produced during a period of time identified by a specific container code mark.
- 2.8 "Coming-up-time" means the time, including venting time, which elapses between the introduction of the heating medium into the closed retort and the time when the temperature in the retort reaches the required sterilization temperatures.
- 2.9 "Commercial sterility of thermally processed food" means the condition achieved by application of heat, sufficient, alone or in combination with other appropriate treatments, to render the food free from microorganisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during distribution and storage.

- 2.10 "Commercial sterility of equipment and containers used for aseptic processing and packaging of food" means the condition achieved and maintained by application of heat, or other appropriate treatment, which renders such equipment and containers free from microorganisms capable of growing in the food at temperatures at which the food is likely to be held during distribution and storage.
- 2.11 "Disinfection" means the reduction, without adversely affecting the food, by means of hygienically satisfactory chemical agents and/or physical methods, of the number of microorganisms to a level that will not lead to harmful contamination of food.
- 2.12 "Equilibrium pH" is the pH of the macerated heat processed food product.
- 2.13 "Flame sterilizer" means an apparatus in which hermetically sealed containers of foods are agitated at atmospheric pressure, by either continuous, discontinuous or reciprocating movement, over gas flames to achieve commercial sterility of foods.
- 2.14 "Heating curve" means a graphical representation of the rate of temperature change in the food throughout the heat process; this is usually plotted on semi-log graph paper so that the temperature on an inverted log scale is plotted against time on a linear scale.
- 2.14.1 "Broken heating curve" means a heating curve which shows a distinct change in the rate of heat transfer such that the curve may be represented by two or more distinct straight lines.
- 2.14.2 "Simple heating curve" means a heating curve which approximates a straight line.
- 2.15 "Headspace" means the volume in a container not occupied by the food.
- 2.16 "Holding time", see sterilization time.
- 2.17 "Incubation tests" means tests in which the heat processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs under these conditions.
- 2.18 "Initial temperature" means the temperature of the contents of the coldest container to be processed at the time the sterilizing cycle begins, as specified in the scheduled process.
- 2.19 "Low-acid food" means any food, other than alcoholic beverages, where any component has a pH value greater than 4.6 after heat processing.
- 2.20 "Potable water" means water fit for human consumption. Standards of potability should be no less strict than those contained in the latest edition of the "International Standards for Drinking Water", World Health Organization.

- 2.21 "Product container" means a container designed to be filled with food and hermetically sealed.
- 2.21.1 "Hermetically sealed containers" are containers which are sealed to protect the contents against the entry of microorganisms during and after heat processing.
- 2.21.2 "Rigid container" means that the shape or contours of the filled and sealed container are neither affected by the enclosed product nor deformed by an external mechanical pressure of up to 0.7 kg/cm² (10 psi"), (i.e., normal firm finger pressure).
- 2.21.3 "Semi-rigid container" means that the shape or contours of the filled, sealed container are not affected by the enclosed product under normal atmospheric temperature and pressure but can be deformed by an external mechanical pressure of less than 0.7 kg/cm² (10 psi"), (i.e., normal firm finger pressure).
- 2.21.4 "Flexible container" means that the shape or contours of the filled, sealed container are affected by the enclosed product.
- 2.22 "Retort" means a pressure vessel designed for thermal processing of food packed in hermetically sealed containers.
- 2.23 "Scheduled process" means the thermal process chosen by the processor for a given product and container size to achieve at least commercial sterility.
- 2.24 "Seals" of a semi-rigid container and lid or flexible container, means those parts which are fused together in order to close the container.
- 2.25 "Sterilization temperature" means the temperature maintained throughout the thermal process as specified in the scheduled process.
- 2.26 "Sterilization time" means the time between the moment sterilization temperature is achieved and the moment cooling started.
- 2.27 "Thermal process" means the heat treatment to achieve commercial sterility and is quantified in terms of time and temperature.
- 2.28 "Venting" means thorough removal of the air from steam retorts by steam prior to a scheduled process.
- 2.29 "Water Activity (a_w)" is the ratio of the water vapour pressure of the product to the vapour pressure of pure water at the same temperature.

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

3.1 Environmental Hygiene and Areas from which Raw Materials are derived

3.1.1 Unsuitable growing or harvesting areas

Food should not be grown or harvested where the presence of potentially harmful substances would lead to an unacceptable level of such substances in the food.

3.1.2 Protection from contamination by wastes

3.1.2.1 Raw food materials should be protected from contamination by human, animal, domestic, industrial and agricultural wastes which may be present at levels likely to be a hazard to health. Adequate precautions should be taken to ensure that these wastes are not used and are not disposed of in a manner which may constitute a health hazard through the food.

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

3.1.3 Irrigation control

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

3.1.4 Pest and disease control

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

3.2 Harvesting and Production

3.2.1 Techniques

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

3.2.2 Equipment and containers

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

3.2.3 Removal of obviously unfit raw materials

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

3.2.4 Protection against contamination and damage

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

Storage at the Place of Production/Harvesting

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

Transportation

3.4.1 Conveyances

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

3.4.2 Handling procedures

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

4. SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

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

4.2 Roadways and Areas used by Wheeled Traffic

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

4.3 Buildings and Facilities

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

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

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

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

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

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

4.3.7 In food handling areas:

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

Walls, where appropriate, should be of water-proof, non-absorbent, washable materials, sealed and free of insects, and should be light coloured. Up to a height appropriate for the operation they should be

smooth and without crevices, and should be easy to clean and disinfect. Where appropriate, angles between walls, between walls and floors and between walls and ceilings should be sealed and coved to facilitate cleaning.

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

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

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

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

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

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

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

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

4.4 Sanitary Facilities

4.4.1 Water supply

4.4.1.1 An ample supply of water, in compliance with Sub-Section 7.3 of the Recommended International Code of Practice - General

Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 2(1985)), under adequate pressure and of suitable temperature should be available with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination.

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

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

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

4.4.2 Effluent and waste disposal

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

4.4.3 Changing facilities and toilets

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

4.4.4 Hand washing facilities in processing areas

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

4.4.5 Disinfection facilities

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

4.4.6 Lighting

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

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

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

4.4.7 Ventilation

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

4.4.8 Facilities for storage of waste and inedible material

Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should

be designed to prevent access to waste or inedible material by pests and to avoid contamination of food, potable water, equipment, buildings or roadways on the premises.

4.5 Equipment and Utensils

4.5.1 Materials

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

4.5.2 Sanitary design, construction and installation

4.5.2.1 All equipment and utensils should be so designed and constructed as to prevent hygienic hazards and permit easy and thorough cleaning and disinfection and, where practicable, be visible for inspection. Stationary equipment should be installed in such a manner as to permit easy access and thorough cleaning. Canneries should have suitable conveyor systems to transport empty product containers to the filling stations. Their design, structure and installation should ensure that such containers do not become contaminated or unacceptable because of damage.

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

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

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

4.5.3 Equipment identification

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

4.6 Steam Supply

Steam supply to the thermal processing system should be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands for steam by the plant.

5. SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS

5.1 Maintenance

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

5.2 Cleaning and Disinfection

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

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

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

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

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

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

5.3 Hygiene Control Programme

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

5.4 By-Products

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

5.5 Storage and Disposal of Waste

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

5.6 Exclusion of Domestic Animals

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

5.7 Pest Control

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

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

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

5.8 Storage of Hazardous Substances

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

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

5.9 Personal Effects and Clothing

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

6. SECTION VI - PERSONAL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene Training

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

6.2 Medical Examination

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

6.3 Communicable Diseases

The management should take care to ensure that no person, while known or suspected to be suffering from, or to be a carrier of a disease likely to be transmitted through food or while afflicted with infected wounds, skin infections, sores or with diarrhoea, is permitted to work in any food handling area in any

capacity in which there is any likelihood of such a person directly or indirectly contaminating food with pathogenic microorganisms. Any person so affected should immediately report to the management that he is ill.

6.4 Injuries

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

6.5 Washing of Hands

Every person, while on duty in a food handling area should wash his hands frequently and thoroughly with a suitable hand cleaning preparation under running warm water in compliance with Sub-Section 7.3 of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1 of this Code. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 Personal Cleanliness

Every person, while on duty in a food handling area should maintain a high degree of personal cleanliness, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor. During periods where food is manipulated by hand, any jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in food handling.

6.7 Personal Behaviour

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

6.8 Gloves

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

6.9 Visitors

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

6.10 Supervision

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

7. SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 Raw Material Requirements

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

7.1.2 Raw materials or ingredients should be inspected and sorted prior to being moved in to the processing line and where necessary laboratory tests should be made. Only clean sound raw materials or ingredients should be used in further processing.

7.1.3 Raw materials and ingredients stored on the premises of the establishment should be maintained under conditions that will prevent spoilage, protect against contamination and minimize damage. Stocks of raw materials and ingredients should be properly rotated.

7.1.4 Blanching by heat, when required in the preparation of food for canning, should be followed by either rapidly cooling the food or subsequent processing without delay. Thermophilic growth and contamination in blenchers should be minimized by good design, the use of adequate operating temperatures and by routine cleaning.

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

7.2 Prevention of Cross-Contamination

7.2.1 Effective measures should be taken to prevent contamination of food

material by direct or indirect contact with material at an earlier stage of the process.

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

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

7.2.4 All equipment which has been in contact with raw materials or contaminated material should be thoroughly cleaned and disinfected prior to being used for contact with end-products.

7.3 Use of Water

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

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

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

7.4 Packaging

7.4.1 Storage and characteristics of containers

All packaging material should be stored in a clean and sanitary manner. The material should be appropriate for the product to be packed and for

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

7.4.2 Inspection of empty product containers

7.4.2.1 Appropriate sampling and inspection schemes should be used by both container manufacturer and canner to ensure that containers and closures are in compliance with jointly agreed specifications and any requirements of the agency having jurisdiction that may apply. As a minimum these should include those inspections and measurements given in Sub-Section 7.4.8 of this Code. Empty containers are particularly subject to damage by fault operation of depalletizers and by badly designed or controlled conveyors to filling and seaming machines.

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

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

jamming a filling or sealing machine and necessitating a shutdown. Faulty containers may leak during or after thermal processing and storage.

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

7.4.3 Proper use of product containers

Product containers must never be used within the cannery for any purpose other than packing food. They should never be used as ash trays, small waste containers, receptacles for small machine parts or for other purposes. This should be avoided because there is a considerable risk that such containers may accidentally find their way back onto the production line and result in the packing of food in the same container with very objectionable or possible dangerous material.

7.4.4 Empty containers should be removed from the packing room and from the conveyors which lead to the filling machines before production lines are washed down. If not practicable the containers may be shielded or located so they will not become contaminated or obstruct clean-up operations.

7.4.5 Filling of product containers

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

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

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

7.4.6 Exhausting of containers

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

7.4.7 Closing operations

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

The equipment manufacturer's or supplier's instructions should be followed meticulously.

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

7.4.8 Inspection of closures

7.4.8.1 Inspection for external defects

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

after starting up of machines following a prolonged shut down. Side seams should be visually examined for defects or product leakage.

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

7.4.8.1.1 Inspection of glass container closures

Glass containers consist of two pieces, viz., a glass container and lid (closure) usually metal, which can be twisted or pried off according to the closure design. Appropriate detailed inspections and tests should be conducted by competent personnel at intervals of sufficient frequency to ensure consistently reliable hermetic sealing. Many different designs of closures exist for glass jars, so that it is impossible to give definitive recommendations for such closures. The recommendations of the manufacturer should be carefully followed. Records of such tests and corrective actions should be maintained

7.4.8.1.2 Inspection and tear-down of double seams

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

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

Micrometer measurement:

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

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

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

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

- a) body hook length (BH)
- b) cover hook length (CH)
- c) end plate thickness (Te)
- d) body plate thickness (Tb)
- e) overlap (OL)
- f) tightness rating
- g) juncture rating
- h) pressure ridge (chuck impression)

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

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

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

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

$$\begin{aligned} \text{Free Space} &= S - (2Tb + 3Te) \\ \text{Percent Body Hook Butting} &= \frac{(BH - 1.1 Tb) \times 100}{[W - 1.1 (2 Te + Tb)]} \quad \text{or} \\ &= b/c \times 100 \quad (\text{fig. 2}) \end{aligned}$$

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

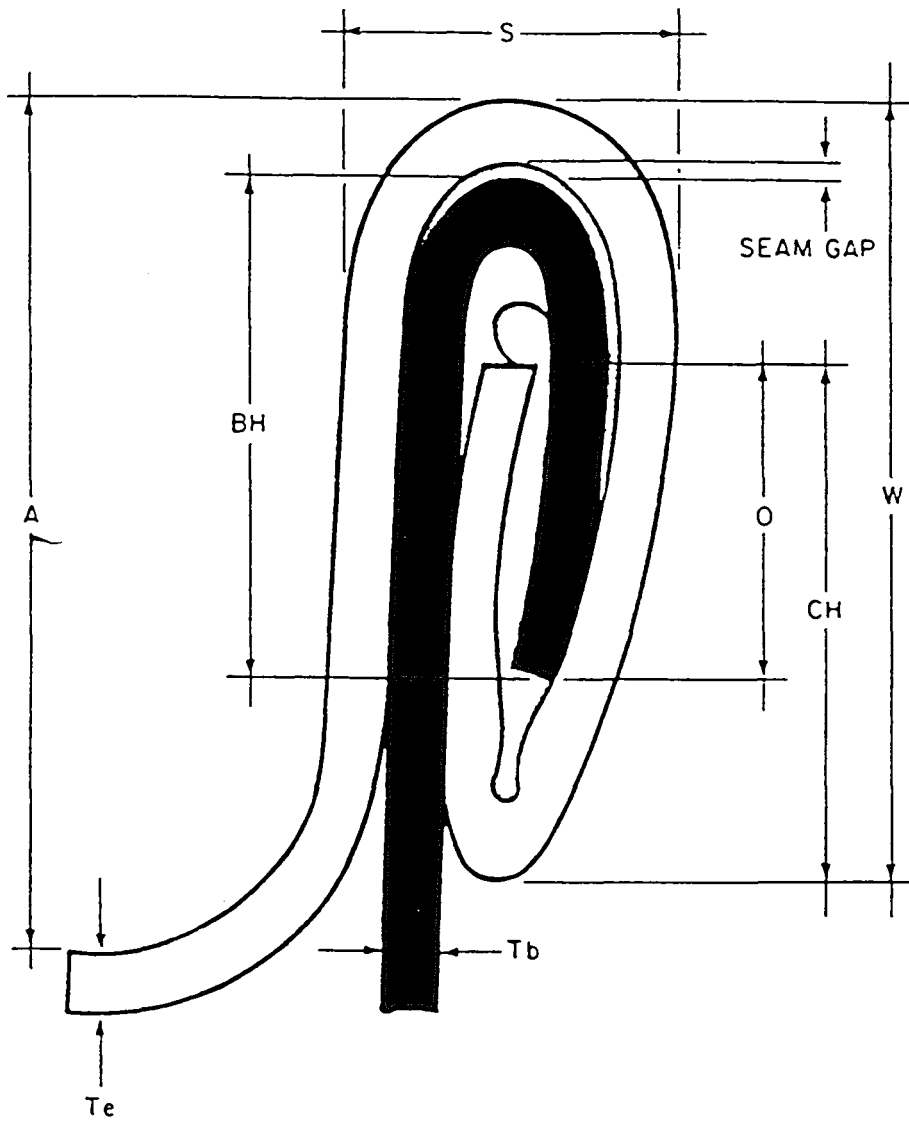


FIGURE 1

DOUBLE SEAM DIMENSIONAL TERMINOLOGY

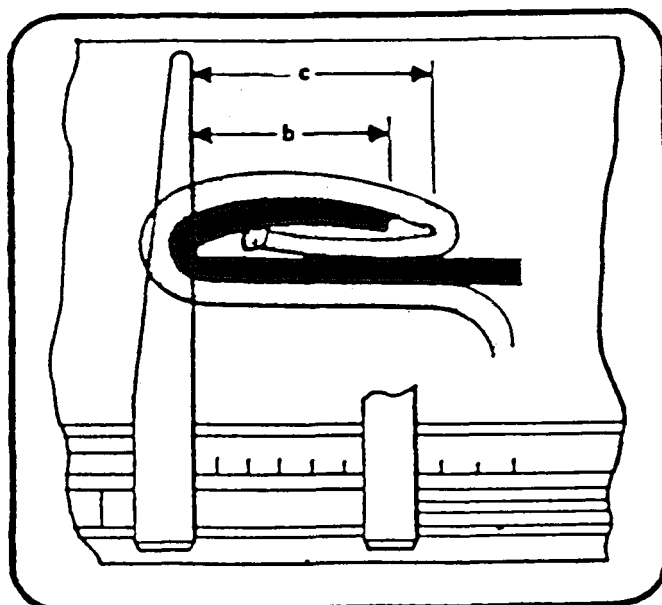


FIGURE 2

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

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

7.4.8.1.3 Inspection of heat seals

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

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

7.4.8.1.4 Closure defects

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

7.4.9 Handling of containers after closure

7.4.9.1 At all times containers should be handled in a manner that protects container and closures from damage which may cause defects and subsequent microbial contamination. Design, operation and maintenance or container handling methods should

be appropriate for the types of containers used. Poorly designed or incorrectly operated container conveying and loading systems are known to cause damage. For example, cans which are scramble packed may suffer damage, even when water cushioned, when the level of the cans in a crate or the crateless retort reduces the effectiveness of the cushion. Additionally, damage which may adversely affect integrity may be caused by poor alignment of the can feed mechanism, or by the presence of floaters.

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

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

7.4.10 Coding

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

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

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

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

7.4.11 Washing

7.4.11.1 Where necessary, filled and sealed containers should be thoroughly washed before sterilization to remove grease, dirt

and product from the outside of the container.

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

7.5 Thermal Processing

7.5.1 General considerations

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

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

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

7.5.2 Establishing scheduled processes

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

Microbial flora including *Clostridium botulinum* and spoilage microorganisms;

Container size and type;
pH of the product;

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

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

- 7.5.2.2 The second step is to determine the scheduled process taking into account the sterilizing facilities available and the desired product quality by carrying out heat penetration tests. The heat penetration into the product must be determined under the most adverse conditions that are likely to be met in production. For this purpose the temperature in the slowest heating point in the container contents should be monitored during a heat process. It is essential to carry out an adequate number of heat penetration tests to determine the variations which should be taken into account in the scheduled process. The scheduled process can be determined from the time temperature graph obtained.
- 7.5.2.3 Because of the nature of the packaging materials used in flexible and semi-rigid containers, the container alone cannot generally be used to fix the heat sensing element at the "cold point" in the container contents, which is vital to the proper interpretation of the results. Therefore, other means may be required to ensure that the temperature sensing device is maintained at the pre-determined point in the container contents without altering the heat penetration characteristics. During such testing the container dimensions, specially the thickness, must be controlled.
- 7.5.2.4 If the heat penetration tests have been made using laboratory simulators, the results should be verified in the production retort under conditions of commercial operation because there may be unexpected deviations in product heating and cooling characteristics.
- 7.5.2.5 If accurate heat penetration data cannot be obtained, alternative methods acceptable to the agency having jurisdiction should be used.
- 7.5.2.6 For products showing a simple heating curve only, where size of the container, sterilization temperature, initial temperature or process time are changed from an existing scheduled process the original heat penetration tests can be used to calculate the

scheduled process for the new conditions. The results should be verified by further heat penetration tests when the size of the container is substantially changed.

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

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

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

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

Product and filling specifications should contain at least the following where applicable: full recipe and preparation procedures, filling weights, headspace, drained weight, temperature of product at filling, consistency. Small deviations from the product and filling specifications which may seem negligible can cause serious deviations in the heat penetration properties of the product. For rotational sterilization, viscosity (rather than consistency) can be an important factor, and this should be specified.

- 7.5.2.9 Air content of filled flexible and semi-rigid containers should be kept to a minimum to prevent excessive stressing of the seals during thermal processing.
- 7.5.2.10 For aseptically processed packs a similar list should be made which also should include equipment and container sterilization requirements.
- 7.5.2.11 Complete records concerning all aspects of the establishment of the scheduled process, including any associated incubation tests, should be permanently retained and available.

7.5.3 Heat processing room operations

- 7.5.3.1 Scheduled processes and venting procedures to be used for products container sizes being packed should be posted in a conspicuous place near processing equipment. Such information should be readily available to the retort processing system operator and to the agency having jurisdiction. It is essential that all heat processing equipment should be properly designed, correctly installed and carefully maintained. Only properly determined scheduled process must be used.
- 7.5.3.2 Heat processing and associated processing operations should be performed and supervised only by properly trained personnel. It is extremely important that the heat processing is carried out by operators under the supervision of personnel who understand the principles of heat processing and who realize the need to follow instructions closely.
- 7.5.3.3 Heat processing should be commenced as soon as possible after closing to avoid microbial growth or changes in heat transfer characteristics of the products. If during breakdowns the production rate is low, the product should be processed in partly filled retorts. Where necessary, a separate scheduled process should be established for partly filled retorts.
- 7.5.3.4 In batch operations the sterilization status of the containers should

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

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

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

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

7.5.4 Critical factors and the application of the scheduled process

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

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

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

7.6 Equipment and Procedures for Heat Processing Systems

7.6.1 Instruments and controls common to different heat processing systems

7.6.1.1 Indicating thermometer

Each retort and/or product sterilizer should be equipped with at least one indicating thermometer. The mercury-in-glass thermometer is recognized as the most reliable temperature indicating instrument at the present time. An alternative instrument having equal or better accuracy and reliability may be used subject to the approval of the official agency having jurisdiction. The mercury-in-glass thermometer should have divisions that are easily readable to 0.5°C (1°F) and whose scale contains not more than 4.0°C per cm (17°F per inch) of graduated scale. Thermometers should be tested for accuracy against a known accurate standard thermometer. This should be done in steam or water as appropriate and in a similar position of aspect to that which it is installed in the retort. Such tests should be performed just prior to installation, and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. A dated record of such tests should be kept. A thermometer that deviates more than 0.5°C (1°F) from the standard should be replaced. A daily inspection of mercury-in-glass thermometers should be made to detect and replace, if found, thermometers with divided mercury column or other defects

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

7.6.1.3 Temperature/time recording devices

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

(preferably within 0.5°C (1°F)) and should not be higher than the indicating thermometer at the sterilizing temperature. A means of preventing unauthorized changes in the adjustment should be provided. It is important that the chart should also be used to provide a permanent record of the sterilization temperature in relation to time. The chart timing device should be accurate and checked as often as necessary to maintain accuracy.

7.6.1.4 Pressure gauges

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

7.6.1.5 Steam controller

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

7.6.1.6 Pressure relief valve

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

7.6.1.7 Timing devices

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

7.6.2 Pressure processing in steam

7.6.2.1 Batch (Still retorts)

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

Bulb sheaths of indicating thermometers and probes of temperature recording devices should be installed either within the retort shell or in external wells attached to the retort. External wells should be equipped with an adequate bleeder opening so

located as to provide a constant flow of steam past the length of the thermometer bulb or probe. The bleeder for external wells should emit steam continuously during the entire heat processing period. Thermometers should be installed where they can be accurately and easily read.

7.6.2.1.2 Pressure gauges (see Sub-Section 7.6.1.4)

7.6.2.1.3 Steam controllers (see Sub-Section 7.6.1.5)

7.6.2.1.4 Pressure relief valve (see Sub-Section 7.6.1.6)

7.6.2.1.5 Steam inlet

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

7.6.2.1.6 Crate supports

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

7.6.2.1.7 Steam spreaders

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

7.6.2.1.8 Bleeders and condensate removal

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

7.6.2.1.9 Stacking equipment

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

7.6.2.1.10 Vents

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

procedures which differ from the above specifications may be used, provided that there is evidence that they accomplish adequate venting.

7.6.2.1.11 Air inlets

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

7.6.2.1.12 Critical factors (see Sub-Section 7.5.4)

7.6.2.2 Batch agitating retorts

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

7.6.2.2.2 Pressure gauges (see Sub-Section 7.6.1.4)

7.6.2.2.3 Steam controller (see Sub-Section 7.6.1.5)

7.6.2.2.4 Pressure relief valve (see Sub-Section 7.6.1.6)

7.6.2.2.5 Steam inlet (see Sub-Section 7.6.2.1.5)

7.6.2.2.6 Steam spreaders (see Sub-Section 7.6.2.1.7)

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

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

7.6.2.2.8 Stacking equipment (see Sub-Section 7.6.2.1.9)

7.6.2.2.9 Vents (see Sub-Section 7.6.2.1.10)

7.6.2.2.10 Air inlets (see Sub-Section 7.6.2.1.11)

7.6.2.2.11 Retort or reel speed timing

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

7.6.2.2.12 Critical factors (see Sub-Section 7.5.4)

7.6.2.3 Continuous agitating retorts

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

7.6.2.3.2 Pressure gauges (see Sub-Section 7.6.1.4)

7.6.2.3.3 Steam controllers (see Sub-Section 7.6.1.5)

7.6.2.3.4 Pressure relief valve (see Sub-Section 7.6.1.6)

7.6.2.3.5 Steam inlet (see Sub-Section 7.6.2.1.5)

7.6.2.3.6 Steam spreaders (see Sub-Section 7.6.2.1.7)

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

7.6.2.3.8 Vents (see Sub-Section 7.6.2.1.10)

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

7.6.2.3.10 Critical factors (see Sub-Section 7.5.4)

7.6.2.4 Hydrostatic retorts

7.6.2.4.1 Indicating thermometers (see Sub-Section 7.6.1.1)

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

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

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

7.6.2.4.3 Pressure gauges (see Sub-Section 7.6.1.4)

7.6.2.4.4 Steam controllers (see Sub-Section 7.6.1.5)

7.6.2.4.5 Steam inlet (see Sub-Section 7.6.2.1.5)

7.6.2.4.6 Bleeders

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

7.6.2.4.7 Venting

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

7.6.2.4.8 Conveyor speed

The speed of the container conveyor should be specified in the scheduled process and should be determined with an accurate stop watch, and recorded at the start of processing and at intervals

of sufficient frequency to insure that the conveyor speed is maintained as specified. An automatic device should be used to stop the conveyor and provide warning when the temperature drops below that specified in the scheduled process. A means of preventing unauthorized speed changes should be provided. Additionally a recording device may be used to provide a continuous record of the speed.

7.6.2.4.9 Critical factors (see Sub-Section 7.5.4)

7.6.3 Pressure processing in water

7.6.3.1 Batch (Still retorts)

7.6.3.1.1 Indicating thermometer (see Sub-Section 7.6.1.1)

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

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

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

7.6.3.1.3 Pressure gauge (see Sub-Section 7.6.1.4)

7.6.3.1.4 Pressure relief valve (see Sub-Section 7.6.1.6)

7.6.3.1.5 Pressure control valve

In addition to the pressure relief valve an adjustable pressure control valve of a capacity sufficient to prevent undesired increases in retort

pressure even when the water valve is wide open, should be installed in the overflow line. This valve also controls the maximum water level in the retort. The valve should be suitable screened to prevent blockage by floating containers or debris.

7.6.3.1.6 Pressure recorder

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

7.6.3.1.7 Steam controller (see Sub-Section 7.6.1.5)

7.6.3.1.8 Steam inlet

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

7.6.3.1.9 Steam distribution (see Sub-Section 7.6.2.1.7)

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

7.6.3.1.10 Crate supports (see Sub-Section 7.6.2.1.6)

7.6.3.1.11 Stacking equipment

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

7.6.3.1.12 Drain valve

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

7.6.3.1.13 Water level

There should be a means of determining the water level in the retort during operation (e.g. by using

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

7.6.3.1.14 Air supply and controls

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

7.6.3.1.15 Cooling water entry

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

7.6.3.1.16 Retort headspace

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

7.6.3.1.17 Water circulation

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

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

7.6.3.2 Batch agitating retorts

7.6.3.2.1 Indicating thermometer (see Sub-Section 7.6.3.1.1)

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

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

7.6.3.2.3 Pressure gauges (see Sub-Section 7.6.1.3)

7.6.3.2.4 Pressure relief valve (see Sub-Section 7.6.1.5)

7.6.3.2.5 Pressure control valve (see Sub-Section 7.6.3.1.5)

7.6.3.2.6 Pressure recorder (see Sub-Section 7.6.3.1.6)

7.6.3.2.7 Steam controller (see Sub-Section 7.6.1.4)

7.6.3.2.8 Steam inlet (see Sub-Section 7.6.2.1.5)

7.6.3.2.9 Steam spreader (see Sub-Section 7.6.2.1.7)

7.6.3.2.10 Drain valve (see Sub-Section 7.6.3.1.12)

7.6.3.2.11 Water level indicator (see Sub-Section 7.6.3.1.13)

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

7.6.3.2.13 Cooling water entry (see Sub-Section 7.6.3.1.15)

7.6.3.2.14 Water circulation (see Sub-Section 7.6.3.1.17)

7.6.3.2.15 Retort speed timing (see Sub-Section 7.6.2.2.11)

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

7.6.4 Pressure processing in steam-air mixtures

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

7.6.5 Aseptic processing and packaging systems

7.6.5.1 Product sterilization equipment and operation

7.6.5.1.1 Temperature indicating device (see Sub-Section 7.6.1.3)

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

7.6.5.1.2 Temperature recording device (see Sub-Section 7.6.1.3)

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

7.6.5.1.3 Temperature recorder-controller

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

7.6.5.1.4 Product-to-product regenerators

Where a product-to-product regenerator is used to heat the cold unsterilized product entering the sterilizer by means of a heat exchange system, it

should be designed, operated and controlled so that the pressure of the sterilized product in the regenerator is greater than the pressure of any unsterilized product.

This ensures that any leakage in the regenerator will be from the sterilized product into the unsterilized product.

7.6.5.1.5 Differential pressure recorder-controller

Where a product-to-product regenerator is used, there should be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions should be easily readable and should not exceed 0.14 kg per cm² (2 lbs per square in.) on a working scale of not more than 1.4 kg/cm²/cm (20 lbs per square inch per inch). The controller should be tested for accuracy against a known accurate standard pressure indicator, upon installation and at least once every three months of operation thereafter or more frequently as may be necessary to ensure its accuracy. One pressure sensor should be installed at the sterilized product regenerator outlet, and the other pressure sensor should be installed at the unsterilized product regenerator inlet.

7.6.5.1.6 Metering pump

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

7.6.5.1.7 Product-holding section

The product sterilizer holding section should be designed to give continuous holding of the product, including particulates, for at least the minimum holding time specified in the scheduled process. It should be sloped upward at least 2.0 cm/m (0.25 in. per foot). The holding section

should be designed so that no portion between the product inlet and the product outlet can be heated.

7.6.5.1.8 Startup

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

7.6.5.1.9 Temperature drop in product holding section

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

7.6.5.1.10 Loss of proper pressures in the regenerator

Where a regenerator is used lose sterility whenever the pressure of sterilized product in the regenerator is less than 0.07 kg/cm² (1lb per square in.) greater than the pressure of unsterilized product. Product flow should be directed either to waste or recirculated until the cause of the improper pressure relationship has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

7.6.5.2 Product container sterilization. filling and closing operations

7.6.5.2.1 Recording device

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

7.6.5.2.2 Timing method(s)

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

7.6.5.2.3 Startup

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

7.6.5.2.4 Loss of sterility

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

7.6.6 Flame sterilizers. equipment and procedures

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

7.6.7 Other systems

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

7.6.8 Cooling

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

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

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

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

7.6.8.1 Cooling water quality

Cooling water should consistently be of low microbial content, for example, with an aerobic mesophile count of less than 100 c.f.u./ml. Records should be kept of cooling water treatment and of its microbiological quality. Although containers may normally be considered hermetically sealed, a small number of containers may allow intake of water during the cooling period mainly due to mechanical stress and pressure differential.

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

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

- a) the presence of a measurable residual free chlorine

in the water at the end of the contact time; and

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

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

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

It is essential that cooling water storage tanks be constructed of impervious materials and protected by close-fitting covers thus preventing contamination of the water by seepage, entry of surface waters or other sources of contamination. These tanks should also be fitted with baffles or other means of ensuring thorough mixing of water

and chlorine or other disinfectant. They should be of sufficient capacity to ensure that the minimum residence time is achieved under maximum throughput conditions. Particular attention should be paid to positioning of inlet and outlet pipes to ensure all water follows a pre-determined flow pattern within the tank. Cooling tanks and systems should be drained, cleaned and refilled periodically to prevent excessive organic and microbial buildup. Records should be kept of such procedures.

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

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

7.7 Post Process Container Handling

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

- 1) cans are dried as soon as possible after processing;
- 2) conveying systems and equipment are designed to minimize abuse of the containers; and
- 3) conveyor and equipment surfaces are effectively cleaned and disinfected.

Glass jars may be similarly affected.

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

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

7.7.1 Retort crate unloading

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

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

7.7.2 Container drying precautions

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

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

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

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

7.7.3 Container abuse

Mechanical shock or abuse is mainly caused by either container knocking into each other, (for example, on gravity runways), or by pressing against each other, for example, when the backup of containers on cable runways results in the development of excessive pressure and possible seam

damage due to cable burn. Abuse may also be caused by containers hitting protruding sections on conveying systems. Such mechanical shocks may cause temporary or permanent leaks and result in infection if the containers are wet.

Careful attention to the design, layout, operation and maintenance of conveying systems is necessary if abuse is to be reduced to a minimum. One of the commonest design faults is unnecessary changes in the height of different sections of the conveying system. For lines speeds above 300 cpm, (containers per minute), multi-lane conveying systems coupled with container accumulation tables are recommended. Sensors should be installed to allow the conveyor to be stopped if excessive buildup of containers occur. Poor seam quality in combination with inadequately designed, adjusted or maintained unscrambling, labeling 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 25/cm² (4/in²). The assessment of the continuing effectiveness of post process cleaning and disinfection programs can only be made by bacteriological monitoring.

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

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

Post-cooling areas of continuous cookers, including hydrostatic cookers,

may constitute continuing sources of high bacterial concentrations unless stringent measures are taken to clean and disinfect them regularly to avoid microbial buildup.

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

7.8 Evaluation of Deviation in Heat Processing

7.8.1 Whenever the in-process monitoring records, processor check or other means disclose that a low-acid food or container system has received a thermal or sterilization treatment less than that stipulated in the scheduled process, the processor should:

- a) identify, isolate and then reprocess to commercial sterility that part of the code lot or lots involved. Complete reprocessing records should be retained; or
- b) isolate and retain that part of the code lot or lots involved to permit further detailed evaluation of the heat processing records. Such evaluation should be made by competent processing experts in accordance with procedures recognized as being adequate to detect any hazard to public health. If this evaluation of the processing records demonstrates that the product has not been given a safe thermal treatment, the product isolated and retained shall be either fully reprocessed to render it commercially sterile or suitably disposed of under adequate and proper supervision to assure the protection of the public health. A record should be made of the evaluation procedures used, the results obtained and the actions taken on the product involved.

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

8. SECTION VIII - QUALITY ASSURANCE

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

8.1 Processing and Production Records

Permanent and legible dated records of time, temperature, code mark and other

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

8.1.1 Processing in steam

8.1.1.1 Batch still retorts

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

8.1.1.2 Batch agitating retorts

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

8.1.1.3 Continuous agitating retorts (see Sub-Section 8.1.1.2)

8.1.1.4 Hydrostatic retorts

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

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

8.1.2 Processing in water

8.1.2.1 Batch still retorts

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

8.1.2.2 Batch agitating retorts

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

8.1.3 Processing in steam/air mixtures

8.1.3.1 Batch still retorts

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

8.1.4 Aseptic processing and packaging

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

8.1.4.1 Product container sterilization conditions

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

8.1.4.2 Product line conditions

Pre-sterilization of the product line, "stand-by" and/or "change-to-product", as well as running conditions. Running condition records should include product temperature at the final heater outlet, product temperature at holding section outlet, differential pressures if a product-to-product regenerator is used, and the product flow rate.

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

8.1.5 Flame sterilizers

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

8.2 Record Review and Maintenance

8.2.1 Process Records

Recorder charts should be identified by date, code lot and other data as necessary, so they can be correlated with the written record of lot processed. Each entry of the record should be made by the retort or processing system operator, or other designated person, at the time the specific retort or processing system condition or operation occurs, and the retort 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 products received the scheduled process. The records, including the recorder thermometer chart, should be signed or initialed by the person conducting the review.

8.2.2 Container closure records

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

8.2.3 Water quality records

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

8.2.4 Distribution of product

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

8.3 Retention of records

The records specified in Sub-Section 7.6.1.1, 8.1 and 8.2, should be retained for not less than three years. They should be held in a manner which will permit ready reference.

9. SECTION IX - STORAGE AND TRANSPORT OF FINISHED PRODUCT

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

9.1 Warm containers should not be stacked so as to form incubatory conditions for the growth of thermophilic organisms.

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

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

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

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

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

9.5 The storage conditions, including temperature, should be such as to prevent deterioration or contamination of the product. Rapid temperature changes during storage should be avoided as this may cause the condensation of moist air on the containers and thus lead to container corrosion.

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

10. SECTION X - LABORATORY CONTROL PROCEDURES

10.1 It is desirable that each establishment should have access to laboratory control of

the processes used as well as the products packed. The amount and type of such control will vary with the food product as well as the needs of management. Such control should reject all food that is unfit for human consumption.

- 10.2 Where appropriate, representative samples of the production should be taken to assess the safety and quality of the product.
- 10.3 Laboratory procedures used should preferably follow recognized or standard methods in order that the results may be readily interpreted.
- 10.4 Laboratories checking for pathogenic microorganisms should be well separated from food processing areas.

11. SECTION XI - END-PRODUCT SPECIFICATIONS

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

- 11.1 To the extent possible in good manufacturing practice the products should be free from objectionable matter.
- 11.2 The products should be commercially sterile, and not contain any substances originating from microorganisms in amounts which may represent a hazard to health.
- 11.3 The products should be free from chemical pollutants in amounts which may represent a hazard to health.
- 11.4 The products should comply with the requirements set forth by the Codex Alimentarius Commission on pesticide residues and food additives as contained in permitted lists or Codex Commodity Standards, and should comply with the requirements on pesticide residues and food additives of the country in which the product will be sold.

REFERENCES FOR THE TEAR-DOWN EVALUATION OF A DOUBLE SEAM

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

A Spanish version may be obtained from Jose R. Cruz, University of Puerto Rico, Mayaguez Campus, College of Agricultural Sciences, Venezuela Contact Station, Rico Piedras, Puerto Rico.
2. Can Seam Formation and Evaluation, Item #FA 0003 (English) audio/visual presentation 16 mm film, 20 minutes. The Food Processors Institute 1401 New York Ave., N.W., Washington, D.C. 20005, U.S.A.
3. Evaluation of Double Seams, Parts 1 and 2 (English), audio/visual presentation, 138 slides and audio cassette with illustrated script/employees handbook. The Food Processors Institute, 1401 New York Ave., N.W., Washington, D.C. 20005. U.S.A.
4. Draft Recommended Hold for Investigation Guidelines for Double Seam Measurements, Round Metal Containers for Low-Acid Foods, 1984 (English). NFPA/CMI Container Integrity Task Force, National Food Processors Association, 1401 New York Ave., N.W., Washington, D.C. 20005, U.S.A.
5. Evaluating a Double Seam, 1971 (English, French and Spanish). Dewey and Almy Chemical Division of W.R. Grace & Co., Cambridge, Massachusetts, U.S.A.
6. Double Seam Manual, (English) 1978, Metal Box Ltd., England.
7. Top Double Seam Manual (English), Continental Can Company, Inc., 633 Third Avenue, New York, N.Y., 10017, U.S.A.
8. Examination of Metal Container Integrity, Chapter XXII, U.S.F.D.A. Bacteriological Analytical Manual (BAM) 6th edition 1984 (English), Association of Official Analytical Chemists.
9. Method for the Tear-Down Examination of Double Seams of Metal cans, MFHPB-25(f) (English & French), Bureau of Microbial Hazards, Health Protection Branch, Health and Welfare Canada, Ottawa. Ontario. K1A 0L2. Canada
10. Double Seams for Steel-Based Cans for Foods (English), 1984, Australian Standard 2730-1984, Standards Association of Australia, Standards House, 80 Arthur St., North Sydney, N.S.W., Australia.

11. Défauts et Altérations des Conserves - Nature et Origine (French), 1982, 1ère édition, Edité par AFNOR Tour Europe, Cedex 7, 92080, Paris, la Défense.
12. Le Sertissage - bôites rondes (French) 1977, Carnaud s.a., 65 av. Edouard Vaillant, B.P. 405, 92103 Boulogne s/Seine, Cedex.

