

**CODE OF HYGIENIC PRACTICE FOR LOW AND ACIDIFIED LOW ACID CANNED FOODS<sup>1</sup>**  
**(CXC 23-1979)**

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<sup>1</sup> The application of this Code 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.

## CODE OF HYGIENIC PRACTICE FOR LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS

### CXC 23-1979

#### SECTION I - SCOPE

1. This Code of practice is concerned with the canning and heat processing of low-acid and acidified low-acid foods as defined in this Code, 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.

#### SECTION II - DEFINITIONS

2. 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 and a water activity greater than 0.85.

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/cm<sup>2</sup> (10 psig), (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/cm<sup>2</sup> (10 psig), (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.

### **SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA**

#### **3.1 Environmental Hygiene and Areas from which Raw Materials are derived**

##### **3.1.1 Unsuitable growing or harvesting areas**

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

##### **3.1.2 Protection from contamination by wastes**

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

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

##### **3.1.3 Irrigation control**

Food should not be grown or produced in areas where the water used for irrigation might constitute a health

hazard to the consumer through the food.

#### 3.1.4 **Pest and disease control**

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

### 3.2 **Harvesting and Production**

#### 3.2.1 **Techniques**

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

#### 3.2.2 **Equipment and containers**

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

#### 3.2.3 **Removal of obviously unfit raw materials**

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

#### 3.2.4 **Protection against contamination and damage**

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

### 3.3 **Storage at the Place of Production/Harvesting**

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

### 3.4 **Transportation**

#### 3.4.1 **Conveyances**

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

### 3.4.2 Handling procedures

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

## 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 the *General Principles of Food Hygiene* (CXC 1-1969), 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 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.

##### 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.

### **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 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 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 labelled with a warning about their toxicity and use. They should be stored in locked rooms or cabinets used only for that purpose and dispensed and handled only by authorized and properly trained personnel or by persons under strict supervision of trained personnel. Extreme care should be taken to avoid contaminating food.

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

## 5.9 **Personal Effects and Clothing**

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

## **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 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.

## **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 blanchers should be minimized by good design, the use of adequate operating temperatures and by routine cleaning.

7.1.5 All steps in the production process, including filling, closing, heat processing and cooling should be performed as rapidly as possible and under conditions which will prevent contamination, and deterioration, and minimize the growth of 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 Protection of empty product containers during plant cleaning

Empty containers should be removed from the packing room and from the conveyors which lead to the filling machines before production lines are washed down. If not practicable 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 shutdown. 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 0.1 mm (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) Overlap = 0 = (CH + BH + Te) - W
- ii)

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

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:

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

$$\text{Percent Body Hook Butting} = \frac{(BH - 1.1Tb)}{(W - 1.1(2Te + Tb))} \times 100$$

or

$$= b/c \times 100 \text{ (fig. 2)}$$

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

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.

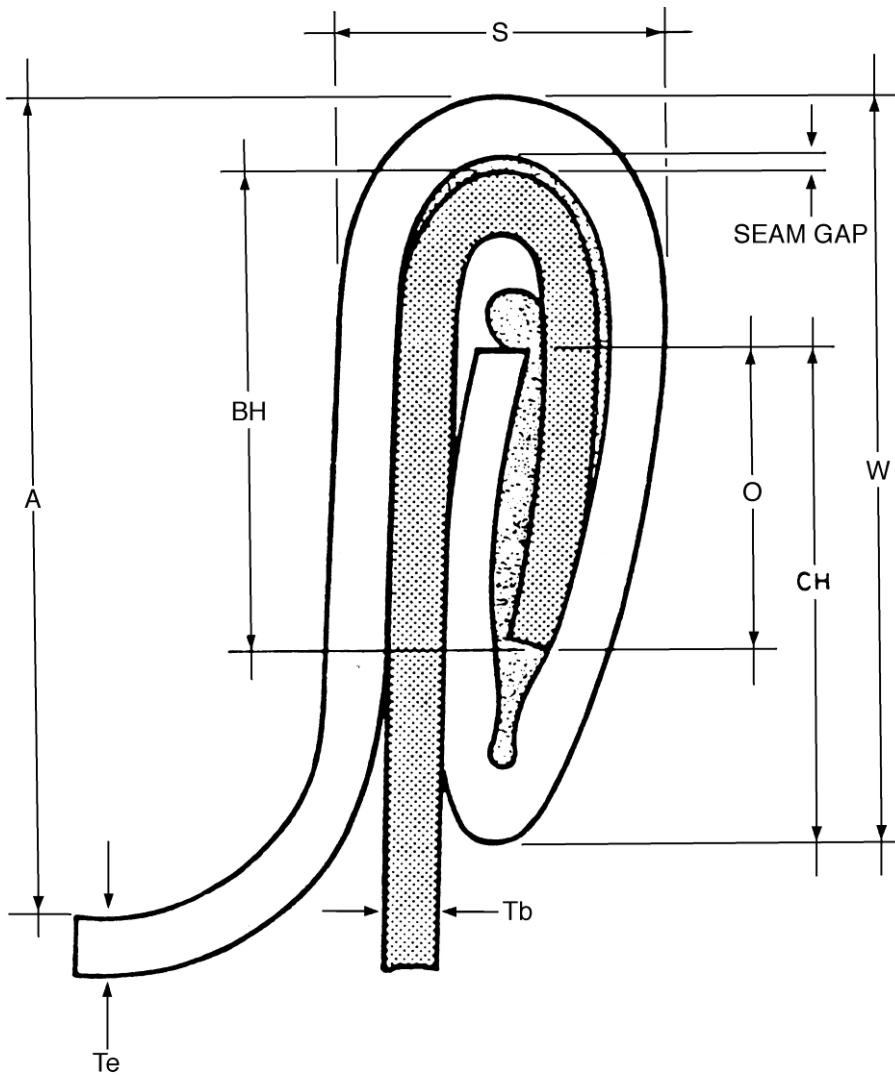


FIGURE 1

DOUBLE SEAM DIMENSIONAL TERMINOLOGY

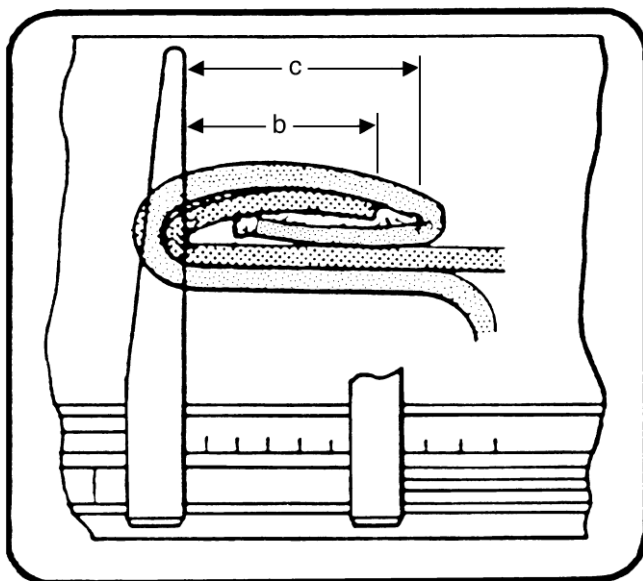


FIGURE 2

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 and container sizes being packed should be posted in a conspicuous place near the processing equipment. Such information should be readily available to the retort or processing system operator and to the agency having jurisdiction. It is essential that all heat processing equipment should be properly designed, correctly installed and carefully maintained. Only properly determined scheduled processes must be used.

7.5.3.2 Heat processing and associated processing operations should be performed and supervised only by properly trained personnel. It is extremely important that the heat processing is carried out by operators under the supervision of personnel who understand the principles of heat processing and who realize the need to follow instructions closely.

7.5.3.3 Heat processing should be commenced as soon as possible after closing to avoid microbial growth or changes in heat transfer characteristics of the products. If during breakdowns the production rate is low, the product should be processed in partly filled retorts. Where necessary, a separate scheduled process should be established for partly filled retorts.

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

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

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

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

### 7.6 Equipment and Procedures for Heat Processing Systems

#### 7.6.1 Instruments and controls common to different heat processing systems

##### 7.6.1.1 Indicating thermometer

Each retort and/or product sterilizer should be equipped with at least one indicating thermometer. The mercury-in-glass thermometer is recognized as the most reliable temperature indicating instrument at the present time. An alternative instrument having equal or better accuracy and reliability may be used subject to the approval of the official agency having jurisdiction. The mercury-in-glass thermometer should have divisions that are easily readable to 0.5°C (1°F) and whose scale contains not more than 4.0°C per cm (17°F per inch) of graduated scale. Thermometers should be tested for accuracy against a known accurate standard thermometer. This should be done in steam or water as appropriate and in a similar position 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/cm<sup>2</sup> (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-subsectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from all retorts venting simultaneously. Other vent piping arrangements and operating procedures which differ from the above specifications may be used, provided that there is evidence that they accomplish adequate venting.

#### 7.6.2.1.11 **Air inlets**

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

#### 7.6.2.1.12 **Critical factors** (see Sub-Section 7.5.4)

### 7.6.2.2 Batch agitating retorts

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

7.6.2.2.2 **Pressure gauges** (see Sub-Section 7.6.1.4)

7.6.2.2.3 **Steam controller** (see Sub-Section 7.6.1.5)

7.6.2.2.4 **Pressure relief valve** (see Sub-Section 7.6.1.6)

7.6.2.2.5 **Steam inlet** (see Sub-Section 7.6.2.1.5)

7.6.2.2.6 **Steam spreaders** (see Sub-Section 7.6.2.1.7)

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

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

7.6.2.2.8 **Stacking equipment** (see Sub-Section 7.6.2.1.9)

7.6.2.2.9 **Vents** (see Sub-Section 7.6.2.1.10)

7.6.2.2.10 **Air inlets** (see Sub-Section 7.6.2.1.11)

7.6.2.2.11 **Retort or reel speed timing**

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

7.6.2.2.12 **Critical factors** (see Sub-Section 7.5.4)

### 7.6.2.3 Continuous agitating retorts

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

7.6.2.3.2 **Pressure gauges** (see Sub-Section 7.6.1.4)

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

7.6.2.3.4 **Pressure relief valve** (see Sub-Section 7.6.1.6)

- 7.6.2.3.5      **Steam inlet** (see Sub-Section 7.6.2.1.5)
- 7.6.2.3.6      **Steam spreaders** (see Sub-Section 7.6.2.1.7)
- 7.6.2.3.7      **Bleeders and condensate removal** (see Sub-Section 7.6.2.2.7)
- 7.6.2.3.8      **Vents** (see Sub-Section 7.6.2.1.10)
- 7.6.2.3.9      **Retort and reel speed timing** (see Sub-Section 7.6.2.2.11)
- 7.6.2.3.10     **Critical factors** (see Sub-Section 7.5.4)

#### 7.6.2.4 Hydrostatic retorts

- 7.6.2.4.1      **Indicating thermometers** (see Sub-Section 7.6.1.1)

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

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

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

- 7.6.2.4.3      **Pressure gauges** (see Sub-Section 7.6.1.4)
- 7.6.2.4.4      **Steam controllers** (see Sub-Section 7.6.1.5)
- 7.6.2.4.5      **Steam inlet** (see Sub-Section 7.6.2.1.5)
- 7.6.2.4.6      **Bleeders**

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

- 7.6.2.4.7      **Venting**

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

- 7.6.2.4.8      **Conveyor speed**

The speed of the container conveyor should be specified in the scheduled process and should be determined

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

7.6.2.4.9 **Critical factors** (see Sub-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 7.6.1.3)

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 7.6.1.4)

7.6.3.2.4 **Pressure relief valve** (see Sub-Section 7.6.1.6)

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 7.6.1.5)

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 cm<sup>2</sup> (2 lbs per square in.) on a working scale of not more than 1.4 kg/cm<sup>2</sup>/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 the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 0.07 kg/cm<sup>2</sup> (1 lb per square in.) greater than the pressure of unsterilized product. Product flow should be directed either to waste or recirculated until the cause of the improper pressure relationship has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

### 7.6.5.2 **Product container sterilization, filling and closing operations**

#### 7.6.5.2.1 **Recording 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, automatic recording devices should be used to record, where applicable, the sterilization media flow rates and/or temperatures. Where a batch system is used for container sterilization, the sterilization conditions should be recorded.

#### 7.6.5.2.2 **Timing method(s)**

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

#### 7.6.5.2.3 **Startup**

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

#### 7.6.5.2.4 **Loss of sterility**

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

#### 7.6.6 Flame sterilizers, equipment and procedures

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

#### 7.6.7 Other systems

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

#### 7.6.8 Cooling

To avoid thermophilic spoilage and/or organoleptic deterioration of the product, the containers should be cooled as rapidly as possible to an internal temperature of 40°C (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, labelling and packaging equipment result in increased can abuse. When such leakage occurs, water on the can provides a source and a transport medium for microbial contamination from conveyor and equipment surfaces to areas on or near the can seams. To control leaker infection it is necessary to ensure that:

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

- 2) conveying systems and equipment are designed to minimize abuse 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°C 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 containers knocking into each other, (for example, on gravity runways), or by pressing against each other, for example, when the backup of containers on cable runways results in the development of excessive pressure 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, labelling and packaging equipment increases the risk of microleakage. Special care should be taken to prevent abuse to glass containers and their closures, as well as to semi-rigid and flexible containers.

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

#### 7.7.4 Post process cleaning and disinfection

Any container conveyor or equipment surface that is wet during production periods will permit rapid growth of infecting microorganisms unless it is effectively cleaned at least once every 24 hours and, in addition, regularly disinfected during production periods. The chlorine in the cooling water deposited on these surfaces from cooled cans is not an adequate disinfectant. Any cleaning and disinfection program that is instituted should be carefully evaluated before being adopted as a routine procedure. For example, properly treated surfaces should have a mesophilic aerobic bacterial level of less than 500 c.f.u. per 25/cm<sup>2</sup> (4/in<sup>2</sup>). 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.

## **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 initialled by the person conducting the review.

#### 8.2.2 Container closure records

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

#### 8.2.3 Water quality records

Records should be kept of tests showing 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.

### 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 tinplate should be avoided as should pastes and adhesives that contain acids or mineral salts.

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

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

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

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

9.6 Any of the above conditions may necessitate reference to the guidelines for the Salvage of Canned Foods Exposed to Adverse Conditions.

## **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.

## **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.

## APPENDIX I

**ACIDIFIED LOW-ACID CANNED FOODS****SECTION I - SCOPE**

This Appendix applies to the manufacture and processing of low-acid canned foods which have been acidified, fermented and/or pickled prior to canning to have an equilibrium pH of 4.6 or less after heat processing. These foods include but are not limited to, artichokes, beans, cabbage, cauliflower, cucumber, fish, olives (other than ripe olives), peppers, puddings and tropical fruits, singly or in combination.

Excluded are acid beverages and foods, jams, jellies, preserves, salad dressings, vinegar, fermented dairy products, acid foods that contain small amounts of low-acid foods but having a resultant pH that does not significantly differ from that of the predominant acid food, and those foods where scientific evidence clearly shows that the product does not support the growth of *Clostridium botulinum*; for example, those tomato or tomato products where the pH does not exceed 4.7.

**SECTION II - DEFINITIONS**

(See definitions, SECTION II of the principal document)

**SECTION III - HYGIENE REQUIREMENTS IN PRODUCTION/HARVESTING AREA**

As stated in SECTION III of the principal document.

**SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES****4.1 Location**

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

**4.2 Roadways and Yards**

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

**4.3 Buildings and Facilities**

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

**4.4 Sanitary Facilities**

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

**4.5 Equipment and Utensils**

As stated in Sub-Section 4.5 in the principal document, except that 4.5.2.4 is modified as follows:

4.5.2.4 Retorts and product sterilizers are pressure vessels and as such must be designed, installed, operated and maintained in accordance with the safety standards for pressure vessels of the agency having jurisdiction. Where open canal cookers, spray cookers and heat exchangers are used to achieve commercial sterility of acidified low-acid foods they must be designed, installed, operated and maintained in accordance with applicable safety standards of the agency having jurisdiction.

**SECTION V - ESTABLISHMENT: HYGIENIC REQUIREMENTS**

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

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

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

**SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS****7.1 Raw Material Requirements and Preparation**

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

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

7.1.3 As stated in Sub-Section 7.1.3 of the principal document.

7.1.4 Blanching by heat, when required in the preparation of food for canning, should be followed by either rapidly cooling the food or subsequent processing without delay.

7.1.5 All steps in the process, including canning, should be performed under conditions which will prevent contamination, deterioration, and/or the growth of microorganisms of public health significance in the food product.

**7.2 Prevention of Cross-Contamination**

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

**7.3 Use of Water**

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

**7.4 Packaging**

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

**7.4.1 Storage of Containers**

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

**7.4.2 Inspection of Empty Product Containers**

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

**7.4.3 Proper Use of Product Containers**

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

**7.4.4 Protection of Empty Product Containers During Plant Cleaning**

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

**7.4.5 Filling of Product Containers**

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

#### 7.4.6 Exhausting of Containers

As stated in Sub-section 7.4.6 of the principal document.

#### 7.4.7 Closing Operations

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

#### 7.4.8 Inspection of Closures

##### 7.4.8.1 Inspection for gross defects.

As stated in Sub-Section 7.4.8.1 of the principal document.

##### 7.4.8.1.1 Inspection of glass container closures.

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

##### 7.4.8.1.2 Inspection of can seams.

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

##### 7.4.8.1.3 Inspection of seams for deep-drawn aluminum containers.

As stated in Sub-Section 7.4.8.1.3 of the principal document.

##### 7.4.8.1.4 Inspection of seals of semi-rigid and flexible containers.

As stated in Sub-Section 7.4.8.1.4 of the principal document.

#### 7.4.9 Handling of Containers After Closure

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

#### 7.4.10 Coding

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

#### 7.4.11 Washing

As stated in Sub-Section 7.4.11 of the principal document.

### 7.5 Acidification and Heat Processing

#### 7.5.1 General Considerations

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

The microbiological safety of acidified low-acid foods depends primarily upon the care and accuracy by which the process has been carried out.

The acidification and heat process required to make acidified low-acid canned foods commercially sterile depends upon the microbial load, type and procedure of acidification, storage temperature, the presence of various preservatives and composition of the products. Acidified low-acid foods with pH values above 4.6 may be able to support the growth of many kinds of microorganisms including the heat resistant spore-forming pathogens such as *Clostridium botulinum*. It should be emphasized that acidification and heat processing of acidified low-acid canned foods are very critical operations involving public health risks and appreciable losses of finished product if inadequately processed.

Instances have been known where improperly processed or sealed acidified canned foods have supported mould and other microbial growth which raised the product pH to above 4.6 and allowed the growth of *Clostridium botulinum*.

## 7.5.2 Establishing Scheduled Processes

7.5.2.1 A scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and heat processing of acidified, fermented and pickled foods.

7.5.2.2 The required acidification and heat process to achieve commercial sterility should be established on the basis of factors such as:

- pH of the product;
- time to reach equilibrium pH;
- product composition or formulation, including dimensional tolerances of solid ingredients;
- levels and types of preservatives;
- water and activity;
- microbial flora including *Clostridium botulinum* and spoilage microorganisms;
- container size and type; and
- organoleptic quality.

7.5.2.3 The heat treatment necessary to achieve commercial sterility of an acidified low-acid canned food is much less than that necessary for low-acid canned foods.

7.5.2.4 Since the acidity of the final product will generally prevent bacterial spore outgrowth, the heat treatment may only be required to kill moulds, yeasts, vegetative cells of bacteria and to inactivate enzymes.

7.5.2.5 The results of these acidification and heat process determination together with established critical factors should be incorporated into the scheduled process. Such a scheduled process should include as the minimum the following data:

- product code or recipe identification;-container size (dimensions) and type;
- pertinent details of the acidification process;
- in-going weight of product(s) including liquor where appropriate;
- minimum initial temperature;
- type and characteristics of heat processing system;
- sterilization temperature;
- sterilization time; and
- cooling method.

7.5.2.6 For aseptically processed foods a similar list should be made which also should include equipment and container sterilization requirements.

7.5.2.7 The product code (identity) should correspond clearly to a complete and accurate product specification containing at least the following where applicable:

- full receipt and preparation procedures;
- pH;
- in-going weight of product(s), including liquor where appropriate;
- headspace;

- drained weight;
- maximum dimensions of product components;
- temperature of product at filling; and
- consistency.

7.5.2.8 Small deviations from the product specification which may seem negligible may seriously affect the adequacy of the process for that product. Any changes in product specifications should be evaluated as to their effect on the adequacy of the process. If the scheduled process is found to be inadequate it must be re-established.

7.5.2.9 Complete records concerning all aspects of the establishment of the scheduled process, including any associated incubation tests, should be permanently retained by the processing plant or by the laboratory establishing the scheduled process.

### 7.5.3 Acidification and Heat Processing Operations

7.5.3.1 Processing operations for control of pH and other critical factors specified in the scheduled process should be performed and supervised only by properly trained personnel.

7.5.3.2 Acidified, fermented and pickled foods shall be so manufactured, processed and packaged that an equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained.

7.5.3.3 To accomplish this the processor should monitor, using pertinent tests, the acidification process at critical control points with sufficient frequency to assure the safety and quality of the product.

7.5.3.4 Commercial sterility must be accomplished using such equipment and instruments as are needed to ensure that the scheduled process is achieved and to provide proper records.

7.5.3.5 Both temperature distribution and rates of heat transfer are important; because of the variety of existing designs in equipment, reference should be made to the equipment manufacturers and to the agency having jurisdiction for details of installation, operation and control.

7.5.3.6 Only properly determined scheduled processes must be used. Scheduled processes to be used for products and container sizes and types being packed should be posted in a conspicuous place near the processing equipment. Such information should be readily available to the retort or processing system operator and to the agency having jurisdiction.

7.5.3.7. It is essential that all processing equipment should be properly designed, correctly installed and carefully maintained.

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

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



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

#### 7.5.4 Critical Factors and the Application of the Scheduled Process

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

- i) maximum fill-in or drained weight;
- ii) headspace of filled product containers;
- iii) product consistency as determined by objective measurement on product taken before processing;
- iv) product style and/or container type which results in layering or stratification of the product in the containers or alteration of the container dimensions (thickness) requiring specific orientation of the containers in the retort;
- v) percent solids;
- vi) net weight;
- vii) minimum closing vacuum (in vacuum packed product);
- viii) pH equilibrium time;
- ix) salt, sugar and/or preservative concentrations; and
- x) dimensional tolerance of solid ingredients.

### 7.6 Equipment and Procedures for Acidification and Heat Processing Systems

#### 7.6.1 Acidification Systems

The manufacturer shall employ appropriate control procedures to ensure that the finished goods do not present a health hazard. Sufficient control, including frequent testing and recording of results, shall be exercised so that the equilibrium pH values for acidified, fermented and pickled foods are not higher than 4.6. Measurements of acidity of foods in-process may be made by potentiometric methods, titratable acidity, or in certain instances colorimetric methods. In-process measurements by titration or colorimetry should be related to the finished equilibrium pH. If the finished equilibrium pH is 4.0 or below, the acidity of the final product may be determined by any suitable method. If the finished equilibrium pH of the food is above 4.0 the measurement of the finished equilibrium pH shall be by a potentiometric method.

##### 7.6.1.1 Direct Acidification

Procedures for acidification to attain acceptable pH levels in the final food include, but are not limited to the following:

- i) blanching of the food ingredients in acidified aqueous solutions;
- ii) immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, care should be taken to assure that the acid concentration is properly maintained;
- iii) direct batch acidification. This can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification;
- iv) direct addition of a predetermined amount of acid to individual containers during production.

Liquid acids are generally more effective than solid or pelleted acids. Care should be taken to ensure that the proper amount of acids is added to each container and distributed uniformly;

- v) addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations; and
- vi) the time for equilibrium and buffering effects should always be taken into account.

#### 7.6.1.2 Acidification by Fermentation and Salt Curing

Temperature, salt concentration and acidity are important factors in controlling the fermentation and salt-curing in foods. The process and control of the fermentation should be monitored by appropriate tests. The concentration of salt in the brine should be determined by a chemical or physical test, at sufficient intervals to assure the control of the fermentation. The process of the fermentation should be monitored by pH measurements or acid/base titrations or both according to the methods set forth in Sub-Section 7.6.2 or by equivalent methods, at sufficient intervals to assure the control of the fermentation. The concentration of salt or acid in the brine in bulk tanks containing salt stock may become significantly diluted. Therefore it should be routinely checked and adjusted as necessary.

#### 7.6.2 Instruments and Control Procedures for Acidification Processes (see Appendix II)

#### 7.6.3 Instruments and Controls Common to Different Heat Processing Systems

##### 7.6.3.1 Indicating Thermometer

Each sterilizer or cooker 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 1C° (2F°) and whose scale contains not more than 4C°/cm (17F° per in.) of graduated scale.

Thermometers should be tested for accuracy, in steam or water as appropriate, in the operational aspect against a known accurate standard thermometer. This should be done upon installation, and at least once a year thereafter or more frequently as may be necessary to ensure their accuracy. A thermometer that deviates more than 0.5C° (1F°) from the standard should be replaced. A daily inspection of mercury-in-glass thermometers should be made to detect, and if found, replace thermometers with divided mercury columns or other defects.

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

##### 7.6.3.3 Temperature/Time Recording Devices

Each sterilizer or cooker should be equipped with at least one temperature/time recording device. This recorder may be combined with the steam controller and may be a controlling recording instrument. It is important that the correct chart is used for each device. The recording accuracy should be equal to or better than  $\pm 1\text{C}^\circ$  ( $\pm 2\text{F}^\circ$ ) at the process temperature. The recorder should agree within 1C° (2F°) of the indicating thermometer at the process temperature. A means of preventing unauthorized changes in the adjustment should be provided. It is important that the chart should also be used to provide a permanent record of the sterilization time. The chart timing device should also be accurate.

##### 7.6.3.4 Pressure Gauges

As stated in sub-Section 7.6.1.3 of the principal document with the addition of the following sentence:

If a retort is only used at atmospheric pressure, a pressure gauge may not be necessary.

#### 7.6.3.5 Steam Controller

When appropriate each sterilizer or cooker should be equipped with a steam controller to maintain temperature. This may be a recording-controlling instrument when combined with a recording thermometer.

#### 7.6.3.6 Pressure Relief Valves

As stated in Sub-Section 7.6.1.5 of the principal document with the addition of the following sentence:

If a retort is only at atmospheric pressure, a pressure relief valve may not be necessary.

### 7.6.4 Commonly Used Heat Processing Systems

#### 7.6.4.1 Processing at Atmospheric Pressure or by Hot-fill and Hold

Commercial sterility should be accomplished using suitable equipment and the necessary instrumentations as in Sub-Section 7.6.3 of this Appendix to ensure that the scheduled process is achieved and to provide proper records. Both temperature distribution and rates of heat transfer are important. Because of the variety of equipment available, reference should be made to the manufacturer and the agency having jurisdiction for details of installation, operation and control. Where a hot-fill and hold technique is used it is important that all inner surfaces of the container reach the scheduled container sterilization temperature.

#### 7.6.4.2 Processing Under Pressure in Retorts

As stated in Sub-Sections 7.6.2, 7.6.3 and 7.6.4 in their entirety in the principal document.

#### 7.6.5 Aseptic Processing and Packaging Systems

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

#### 7.6.6 Flame Sterilizers, Equipment and Procedures

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

#### 7.6.7 Other Systems

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

#### 7.6.8 Cooling

As stated in Sub-Section 7.6.8 of the principal document.

##### 7.6.8.1 Cooling Water Quality

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

### 7.7 **Post-Processing Contamination**

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

### 7.8 **Evaluation of Deviations in the Scheduled Process**

Whenever any process operation deviates from the scheduled pressures for any acidified, fermented or pickled food, or whenever the equilibrium pH value of the finished product is higher than 4.6 as determined by appropriate analysis (see Appendix II of this Code as disclosed from records, or otherwise, the commercial processor) should either:

- a) fully reprocess that code lot of the food by a process established by a competent processing authority as adequate to assure a safe product; or
- b) set aside that portion of the food involved for further evaluation as to any potential public health significance. Such evaluation should be made by competent processing experts in accordance with procedures recognized as being adequate to detect any potential hazard to public health and should be acceptable to the agency having jurisdiction unless such evaluation demonstrates that the food code lot has undergone a process that has rendered it safe, the food set aside shall either be fully reprocessed to render it safe or destroyed. A record should be made of the procedures used in the evaluation, the results obtained, and the actions taken on the product involved. Either upon completion of full reworking and the attainment of a safe food or after the determination that no potential for public health hazard exists, that portion of the food involved may be shipped in normal distribution. Otherwise, the portion of the food involved shall be suitably disposed of under adequate and proper supervision to assure the protection of the public health.

## **SECTION VIII - QUALITY ASSURANCE**

As stated in Section 8 of the principal document.

### 8.1 **Processing and Production Records**

Records should be maintained of examination of raw materials, packaging materials and finished products, and of suppliers' guarantees or certifications that verify compliance with the requirements of this Code.

### 8.2 **Record Review and Maintenance**

Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, should be maintained and should contain sufficient additional information such as product code, date, container size and product, to permit a public health hazard evaluation of the processes applied to each code lot, batch or other portion of production.

### 8.3 **Deviations from Scheduled Processes**

All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified. Such departures should be recorded and made the subject of a separate file, or a log identifying the appropriate data and delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.

### 8.4 **Distribution of Product**

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

#### **8.5 Retention of Records**

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

### **SECTION IX - STORAGE AND TRANSPORT OF THE FINISHED PRODUCT**

As stated in SECTION IX of the principal document.

### **SECTION X - LABORATORY CONTROL PROCEDURES**

As stated in SECTION X of the principal document.

### **SECTION XI - END-PRODUCT SPECIFICATIONS**

As stated in SECTION XI in its entirety in the principal document, except that Sub-Section 11.3 will be altered to read, "Acidified low-acid foods should have received a processing treatment sufficient to provide commercial sterility".

**APPENDIX II****ANALYTICAL METHODOLOGY FOR pH MEASUREMENT<sup>2</sup>**

Methods that may be used to determine pH or acidity for acidified, fermented and pickled food include, but are not limited to the following:

**1.1 Potentiometric Method for the Determination of pH****1.1.1 Principles**

The term "pH" is used to designate the intensity or degree of acidity. The value of pH, the logarithm of the reciprocal of the hydrogen ion concentration in solution, is determined by measuring the difference in potential between two electrodes immersed in a sample solution. A suitable system consists of a potentiometer, a glass electrode, and a reference electrode. A precise pH determination can be made by making an electromotive force (emf) measurement of a standard buffer solution whose pH is known, and then by comparing that measurement to an emf measurement of a sample of the solution to be tested.

**1.1.2 Instruments**

The primary instrument for use of pH determination is the pH meter or potentiometer. For most work, an instrument with a direct-reading pH scale is necessary. Battery and line-operated instruments are available commercially. If the line voltage may be unstable, line-operated instruments should be fitted with voltage regulators to eliminate drifting of meter-scale readings. Batteries should be checked frequently to assure proper operation of battery operated instruments. An instrument using an expanded unit scale or a digital readout system is preferred since it allows more precise measurements.

**1.1.3 Electrodes**

The typical pH meter is equipped with a glass membrane electrode. The most commonly used reference electrode is the calomel electrode, which incorporates a salt bridge filled with saturated potassium chloride solution.

- i) Care and use of electrodes. Calomel electrodes should be kept filled with saturated potassium chloride solution, or other solution specified by the manufacturer because they may become damaged if they are allowed to dry out. For best results, electrodes should be soaked in buffer solution, distilled or deionized water or other liquid specified by the manufacturer for several hours before using and kept ready by storing with tips immersed in distilled water or in buffer solution used for standardization. Electrodes should be rinsed with water before immersing in the standard buffers and rinsed with water or the solution to be measured next between sample determinations. A lag in meter response may indicate aging effects or fouling of the electrodes, and cleaning and rejuvenation of the electrodes may be necessary. This may be accomplished by placing the electrodes in 0.1 molar sodium hydroxide solution for 1 minute and then transferring them to 0.1 molar hydrochloric acid solution for 1 minute. The cycle should be repeated twice, ending with the electrodes in the acid solution. The electrodes should then be thoroughly rinsed with water and blotted with soft tissue before proceeding with the standardization.
- ii) Temperature. To obtain accurate results, the same temperature should be used for the

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<sup>2</sup> (If and when a suitable I.S.O. text becomes available it will be considered as a replacement for this Appendix)

electrodes, the standard buffer solutions, the samples, for the standardization of the meter, and pH determinations. Tests should be made at a temperature between 20°C to 30°C (68°F to 86°F). When tests have to be made outside this temperature range appropriate correction factors should be established and applied. While thermal compensators are available, they should not be relied upon to give accurate results.

- iii) Accuracy. The accuracy of most pH meters is stated to be approximately 0.1 pH unit, and reproducibility is usually  $\pm 0.05$  pH unit or less. Some meters permit the expansion of any pH unit range to cover the entire scale and have an accuracy of approximately  $\pm 0.01$  pH unit and reproducibility of  $\pm 0.005$  pH units.

#### 1.1.4 General Procedure for Determining pH

When operating an instrument, the manufacturer's instructions should be used and the following techniques for pH determination observed:

- i) switch the instrument on and allow the electronic components to warm up and stabilize before proceeding;
- ii) standardize the instrument and electrodes with commercially-prepared standard 4.0 pH buffer or with freshly prepared 0.05 molar potassium acid phthalate buffer solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th ed., 1984, section 50.007(c). Note the temperature of the buffer solution and set the temperature compensator control at the observed temperature;
- iii) rinse the electrodes with water and blot but do not wipe with soft tissue;
- iv) immerse the tips in the buffer solution and take the pH reading, allowing about 1 minute for the meter to stabilize. Adjust the standardization control so that the meter reading corresponds to the pH of the known buffer (for example, 4.0) for the temperature observed. Rinse the electrodes with water and blot with soft tissue. Repeat procedure with fresh portions of buffer solution until the instrument remains in balance on two successive trials. To check the operation of the pH meter, check the pH reading using another standard buffer such as one having a pH of 7.0 or check it with freshly prepared 0.025 molar phosphate solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th ed., 1984, section 50.007(e). Expanded scale pH meters may be checked with pH 3.0 or pH 5.0 standard buffers. Buffers and instruments can be further checked by comparison with values obtained with a second properly standardized instrument;
- v) indicating electrodes may be checked for proper operation by first using an acid buffer then a base buffer. First standardize the electrodes using a pH 4.0 buffer at or near 25°C. Standardization control should be adjusted so that the meter reads exactly 4.0. Electrodes should be rinsed with water, then blotted and immersed in a pH 9.18 borax buffer prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th ed., 1984, section 50.007(f). The pH reading should be within  $\pm 0.3$  units of the 9.18 value; and
- vi) the pH meter can be tested for proper operation by shorting the glass and reference electrode inputs, thereby reducing the voltage to zero. In some meters this is done by switching the instrument to standby, and in other instruments by use of a shorting strap. With the instrument shorted out, standardization control should be turned from one extreme to another. This operation should produce a deflection greater than  $\pm 1.5$  pH unit from centre scale.

#### 1.1.5 Determining pH on Samples

- i) adjust the temperature of the sample to room temperature (25°C), and set the temperature compensator control to the observed temperature. With some expanded scale instruments, the sample temperature must be the same as the temperature of the buffer solution used for the standardization;
- ii) rinse and blot the electrodes. Immerse the electrodes in the sample and take the pH reading, allowing 1 minute for the meter to stabilize. Rinse and blot the electrodes and repeat on a fresh portion of sample. Oil and grease from the samples may coat the electrodes, therefore, it is advisable to clean and standardize the instrument frequently. When oily samples cause fouling problems, it may become necessary to rinse the electrode with ethyl ether; and
- iii) determine two pH values on the well-mixed sampled. These readings should be in agreement with one another to indicated that the sample is homogeneous. Report values to the nearest 0.05 pH unit.

#### 1.1.6 Preparation of Samples

Some food products may consist of a mixture of liquid and solid components that differ in acidity. Other food products may be semi-solid in character. The following are examples of preparation procedures for pH testing for each of these categories.

- i) **Liquid and solid component mixtures.** Drain the contents of the container for 2 minutes on a U.S. standard No. 8 sieve (preferably stainless steel) or equivalent inclined at a 17 to 20° angle. Record weights of the liquid and solid portions and retain each portion separately.
  - a) if the liquid contains sufficient oil to cause electrode fouling, separate the layer with a separatory funnel and retain the aqueous layer. The oil layer may be discarded. Adjust the temperature of the aqueous layer to 25°C and determine its pH;
  - b) remove the drained solids from the sieve. Blend to a uniform paste, adjust the temperature of the paste to 25°C and determine its pH; and
  - c) mix aliquots of solid and liquid fractions in the same ratio as found in the original container and blend to a uniform consistency. Adjust the temperature of the blend to 25°C and determine the equilibrated pH. Alternately, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25°C and determine the equilibrated pH.
- ii) **Marinated oil products.** Separate the oil from the solid product. Blend the solid in a blender to a paste consistency; it may become necessary to add a small amount of distilled water to some samples to facilitate the blending. A small amount of added water will not alter the pH of most food products, but caution must be exercised concerning poorly buffered foods. No more than 20 milliliters of distilled water should be added to each 100 grams of product. Determine the pH by immersing electrodes in the prepared paste after adjusting the temperature to 25°C.
- iii) **Semi-solid products.** Food products of semi-solid consistency such as puddings, potato salad, etc., may be blended to a paste consistency, and the pH may be determined on the prepared paste. Where more fluidity is required, 10 to 20 milliliters of distilled water may be added to 100 grams of product. Adjust the temperature of the prepared paste to 25°C and determine its pH.
- iv) pour off the oil, blend the remaining product to a paste and determine the pH of the blended paste. Where more fluidity is required, add 10 to 20 milliliters of distilled water to each 100 grams of product and blend. Adjust the temperature of the prepared paste to 25°C and



determine its pH.

- v) **Large solid components.** The internal pH should be checked with spear electrodes as near as possible to the geometric centre.

### 1.1.7 Process pH Determination

Standardize the meter against standard buffer solution having a pH as close as possible to that of the product. This should be done at the beginning and end of each series of product determination or not less than twice daily.

- i) for process liquids, adjust the temperature of the liquid to 25°C and determine the pH by immersing the electrodes in the liquid;
- ii) drain solid materials on a sieve and blend to a workable paste. Adjust the temperature of the prepared paste to 25°C and determine its pH; and
- iii) where enough solid materials are available to make a paste, blend representative aliquots of liquid and solid materials to a workable paste. Adjust the temperature of the prepared paste to 25°C and determine the equilibrated pH. Alternately, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25°C and determine the equilibrated pH.

## 1.2 Colorimetric Method for the Determination of pH

This method may be used in lieu of potentiometric method if the pH is 4.0 or lower.

### 1.2.1 Principle

The colorimetric method for pH involves the use of indicator dyes in solution that gradually change colour over limited pH ranges. An indicator that has the greatest colour change at approximately the pH of the sample being tested is selected. The pH is determined by the colour of the indicator when exposed to the sample under tests.

### 1.2.2 Indicator Solutions

Most indicator solutions are prepared as a 0.04 percent solution of the indicator dye in alcohol. In testing, a few drops of indicator solution are added to 10 millilitre portions of the sample solution. Colours should be compared using a bright background. Approximate determinations can be made on white porcelain spot plates, the test colours being compared thereon with a set of colour standards. More accurate colorimetric tests can be made using a comparator block fitted with sets of tubes of standard indicator solutions of known pH. Indicators should be verified regularly, at least once per day before use, against the standard buffer solution.

### 1.2.3 Indicator Paper

A paper tape treated with indicator dye is dipped into the sample solution. Depending upon the pH of the solution, the tape will change colour and an approximate pH can be determined by comparison with a standard colour chart.

## 1.3 Titratable Acidity

Acceptable methods for determining titratable acidity are described in "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th ed., 1984, sections 22.060-22.061. The procedure for preparing of standardizing the sodium hydroxide solution is described in *ibid*, sections 50.032-50.035.

## APPENDIX III

## 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 - boîtes rondes (French) 1977, Carnaud s.a., 65 av. Edouard Vaillant, B.P. 405, 92103 Boulogne s/Seine, Cedex.

## APPENDIX IV

**GUIDELINES FOR THE SALVAGE OF CANNED FOODS  
EXPOSED TO ADVERSE CONDITIONS****EXPLANATORY PREFACE**

The purpose of this document is to provide guidelines for the salvage of canned foods manufactured in compliance with the *Code of Hygienic Practice for Low-acid and Acidified Low-Acid Canned Foods* (CXC 23-1979) which are suspected of having become contaminated or otherwise rendered unsuitable for human consumption as a result of being subjected to adverse conditions, for example, flood, fire or other accidents, during their storage, transportation and/or distribution. The guidelines are designed to permit the salvage of canned food unaffected by such conditions and thus reduce the loss of wholesome food whilst preventing the sale or distribution of canned foods which may have been rendered unfit for human consumption.

The salvage operations should only be carried out by trained personnel under the direct supervision of person(s) having expert knowledge of canning and container technology.

The Hazard Analysis Critical Control Point (HACCP) concept should be applied when salvaging canned foods and should include:

1. An assessment of the hazards associated with the adverse conditions which led to the food being suspect and the various salvage operations to which it may be subjected.
2. Identification of the critical control points for the salvage operations and the type or frequency of the control measures deemed necessary.
3. Guidance for the monitoring of the critical control points including maintenance of adequate records.

**1. SCOPE**

These guidelines concern the salvage of lots of canned foods which are suspected of having been contaminated as a result of exposure to adverse conditions, (fire, flood, freezing or other accident), during storage, transportation and distribution. It is not intended to cover canned foods which are suspect as a result of errors or omissions on the part of the processor (canner); however, it may be applied to product subjected to adverse conditions while under the direct control of the processor (canner). A flow chart showing the sequence of events in the salvage of canned foods exposed to adverse conditions is shown in Appendix 1.

**2. DEFINITIONS**

- 2.1 **Adverse conditions** are those conditions which may result in physical damage to and/or contamination of a container or its contents rendering the food unsuitable for human consumption.
- 2.2 **Canned food** means commercially sterile food in hermetically sealed containers.
- 2.3 **Cleaning** means the removal of soil, food residues, dirt, grease or other objectionable matter from the external surface of the container and for the purposes of this code may be extended to the removal of rust and

other products of corrosion.

2.4 **Code lot** means all products produced during a period of time identified by a specific container code mark.

2.5 **Commercial sterility of a 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 under normal non-refrigerated conditions at which the food is likely to be held during distribution and storage.

2.6 **Contamination** means the presence of any objectionable material on the surface of a container, or in a food.

2.7 **Disinfection** of a container means the reduction, without adversely affecting the container or contents, of the number of microorganisms on the container surface to a level that will not lead to harmful contamination of the food.

2.8 **Disposal** means an action (e.g. incineration, burial, conversion to animal feed, etc.) which will prevent a contaminated product from being sold or distributed for human consumption.

2.9 **Hermetically sealed container** means containers which are designed and intended to protect the contents against the entry of microorganisms during and after processing.

2.10 **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.

2.11 **Recanning** means the transfer and sealing of a product into a new hermetically sealable container followed by a scheduled process.

2.12 **Reconditioning** means the cleaning of sound containers and may include disinfection.

2.13 **Reprocessing** means the treatment of a canned food in its original container recovered in a salvage operation followed by a scheduled process.

2.14 **Salvage** means any appropriate process or procedure by which food is recovered from a suspect lot of canned food and by which its safety and fitness for consumption is ensured.

2.15 **Salvor** means the person responsible for carrying out the salvage operations including any or all of the on-site operations.

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

2.17 **Suspect Lot of Canned Food** means a group of containers which is suspected of being contaminated as a result of exposure to adverse conditions and may include a part of, the whole of, or a number of code lots.

### 3. ON-SITE OPERATIONS

#### 3.1 Assessment of Adverse Conditions

The nature and circumstances of the adverse conditions which gave rise to the canned foods being suspect should be assessed and recorded. Special attention should be given to the cause and likely consequences in terms of contamination of the container and/or its contents.

### **3.2 Notification**

The salvor should, as soon as possible, supply the appropriate agency having jurisdiction with the results of the assessment of the adverse conditions as well as the types and quantities of food products involved.

### **3.3 Product Inventory and Identification of Product Location**

Whenever possible prior to removal of any containers of canned food, (including the taking of samples, product segregation, disposal, etc.), a complete inventory of all product involved should be made. The inventory should record the location of all product exposed to the adverse conditions, the quantity of each product type identifying by trade name, container type and size, can and/or carton codes, etc. Before commencing with any salvage operations, the salvor should notify the owner or legal agency of all affected product and provide an inventory of the affected product to the appropriate agency having jurisdiction.

### **3.4 Feasibility of Salvage**

All canned foods subjected to the adverse conditions should be assessed as to whether any salvage is feasible. If salvage operations are not feasible then all product should be disposed of as soon as possible in a manner described in Section 4.2.

### **3.5 Preliminary Sorting**

When salvage is feasible, the product should, whenever possible, be segregated into the following categories: potentially salvageable, not salvageable and unaffected product. This is a general sorting, that is by cartons, cases, pallets, etc., and not by individual containers. Sorting by individual containers is dealt with in Section 4.1. A complete inventory of the not salvageable product should be recorded and the product disposed of in a manner described in Section 4.2. Product not subjected to the adverse conditions and hence unaffected should be separated from that which was involved and can be released for distribution and sale. Such unaffected product would not be subject to the coding requirement of Section 4.7.

### **3.6 Removal from Site and Storage**

In situations when adverse conditions may continue to prevail, all product should be removed from the site as soon as possible.

The official agency having jurisdiction and the owner of the product should be informed as soon as possible by the salvor of the movement of a suspect lot of canned food.

All product involved in the salvage operation should be stored under conditions which protect against their unauthorized removal. Potentially salvageable product should also be stored under conditions which minimize damage, deterioration and contamination and prevent mixing with other products.

A complete record of any product removed from the site in which the quantities, manner of removal and place of subsequent storage are detailed should be made and retained.

## **4. TREATMENT OF POTENTIALLY SALVAGEABLE CANNED FOODS**

### **4.1 Evaluation and Sorting**

Each container of canned food deemed as potentially salvageable from the preliminary sorting (Section 3.5) should be thoroughly inspected. Containers showing visible evidence that their integrity has been lost and/or the contents have become contaminated should be set aside as not salvageable and disposed of in the manner given in Section 4.2.

The remaining salvageable canned food should, by visual inspection, be segregated into the following categories: (a) visually unaffected (appearing normal) containers which do not require reconditioning (4.4), and (b) those that require reconditioning (4.5). Where possible, labels should be removed to permit visual inspection of the entire container surface. The containers which require reconditioning should be further segregated into two groups, those which can be reconditioned (4.5.2) and those which are not reconditionable (4.5.1). The nature and extent of the adverse conditions will dictate which categories may be present in the suspect lot(s).

The inspection, sorting, sampling and evaluation should be conducted by persons trained and experienced in carrying out such procedures.

An inventory of the product in each of the above categories should be recorded. Records of the inventory, inspection, sorting, sampling and subsequent evaluation shall be made and kept for a period acceptable to the agency having jurisdiction.

#### **4.2 Product Not Salvageable**

Canned food which is not salvageable should be carefully disposed of under adequate supervision of the agency having jurisdiction to assure the protection of the public health. Records should be kept detailing the manner and location of disposal and be maintained for a period acceptable to the agency having jurisdiction.

#### **4.3 Evaluation for Contamination**

Whenever loss of container integrity and/or contamination of the contents in salvageable canned foods is suspected but, not visually indicated, samples of a size in keeping with the degree of safety required should be tested and evaluated. Microbiological evaluation of the contents should be carried out according to the procedures outlined in "Guideline Procedures to Establish Microbiological Causes of Spoilage in Canned Foods", or "Official Methods of Analysis of the Association of Analytical Chemists", 14th ed., sections 46.063 - 46.070.

#### **4.4 Visually Unaffected Containers Not Requiring Reconditioning**

It should not be assumed that the contents of containers appearing normal (i.e., visually unaffected, and do not require reconditioning) are free of contamination. Unless there is evidence that the containers and/or their contents are free of contamination, such containers and their contents should be evaluated in accordance with Section 4.3 above. Where the results of such an evaluation indicate that there is virtually no possibility of the contents being contaminated, the remaining normal appearing containers can be released for distribution and sale. Where the results indicate that the product may be contaminated, the product should be classed as unsalvageable and disposed of as detailed in Section 4.2. In some instances potentially contaminated product may be salvaged by reprocessing (see Section 4.6).

#### **4.5 Containers Requiring Reconditioning**

##### **4.5.1 Containers Not Reconditionable**

Some containers by virtue of their type or condition are not capable of being reconditioned without adversely affecting their contents. The following list some examples of not reconditionable containers:

- containers with any indication of swelling, with the exception of intentionally pressurized containers and some containers which by virtue of their shape, size or type of contents are prone to overfilling and appear slightly swollen.

- glass jars with any indication of a raised lid, raised button or showing evidence of loosening of the closures.
- containers with visible evidence of leakage.
  
- containers with punctures, holes or fractures. (These conditions may be indicated by the accumulation of product on or around the puncture, hole or fracture in a can, under the lip of a glass jar, in the seal or on the body of a flexible pouch).
- pull-top containers with fractures or dents on the score lines or in the rivet area.
- corroded containers with severe pitting such that any cleaning and disinfection may result in perforation.
- rigid containers crushed to the point where they cannot be stacked normally on shelves or opened with wheel-type can openers.
- cans severely dented at or in the immediate vicinity of either an end or side seam.
- cuts or fractures through at least one layer of metal on the doubleseam of cans.
- containers with gross seam or seal defects.

Containers which are not reconditionable should be disposed of according to Section 4.2. Under certain circumstances further salvage operations may be undertaken to recover product in such containers. However, before any further action is taken, the contents should be evaluated for the possibility of contamination as stated in Section 4.3. If test results indicate that the contents may be contaminated then the containers should be classed as not salvageable and disposed of in accordance with Section 4.2. Where the test results indicate that the contents are not contaminated, the product may be recanned in accordance with Section 4.6. Since these containers do require reconditioning, special care should be taken to avoid contamination of the product during the process of recanning.

In some cases, for example, containers with external pitted corrosion only, the product may be expedited for immediate consumption as long as the contents have been shown to be free of contamination.

#### 4.5.2 Reconditionable Containers

Prior to reconditioning, the contents of this group of containers should be evaluated for the possibility of contamination in accordance with Section 4.3. When the test results indicate that the contents may be contaminated then the containers should be disposed of in accordance with Section 4.2. However, depending upon the nature and extent of the contamination, the containers may be reconditioned followed by reprocessing (Section 4.6) and as long as that reprocessing will produce a product safe and suitable for human consumption.

All salvageable and reconditionable containers of food which have been in contact with not potable water or other deleterious substances as the result of flood, sewer backup or similar mishaps should be reconditioned by methods approved by the agency having jurisdiction. (Guidance for cleaning and disinfection is found in the *General Principles of Food Hygiene* (CXC 1-1969)). Surface corrosion should be removed from reconditionable containers by cleaning. The containers should then be treated and stored in a manner to minimize further deterioration.

**(Note:** Certain types of containers which have been in contact with not potable water, foam, or other deleterious substances as a result of fire fighting efforts, flood, sewer backups or similar mishaps present special problems in reconditioning and require expert evaluation).

In those instances where salvage is confined to separation of normal appearing from mechanically damaged containers and where there is no possibility of contamination of the contents, the normal appearing containers should, if necessary, be reconditioned and then upon approval of the agency having jurisdiction be released for distribution and sale.

Where there is a possibility of contamination of the contents of normal appearing containers, appropriate testing

in accordance with Section 4.3 should be carried out on both normal appearing and rejected containers. The sampling, analyses and evaluations should be carried out by persons trained and experienced in carrying out such procedures with canned foods.

In some circumstances recanning of the contents of the normal appearing containers may be necessary. In other circumstances reprocessing of the containers may be sufficient.

#### 4.6 Recanning or Reprocessing

Recanning or reprocessing should be carried out in compliance with the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CXC 23-1979)*. The prior history of the product should be considered in the development of an appropriate scheduled process for recanning or reprocessing. For instance, the heating characteristics of the product may be changed as a result of the heat process originally applied.

#### 4.7 Coding

Before a salvaged canned food is released for sale or distribution in its original container, each container shall be permanently marked with a legible, visible and specific code to permit its subsequent identification as a salvaged product.

### 5. QUALITY ASSURANCE

It is important that all salvage operations be properly established, correctly applied, sufficiently supervised, monitored and documented.

Section 8 of the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CXC 23-1979)*, is applicable with the following substitution for 8.2.4.

Records should be kept identifying each lot of salvaged canned foods as well as the conditions under which the original food became suspect and the means by which it was salvaged.

### 6. STORAGE AND TRANSPORT OF SALVAGED PRODUCT

As given in the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CXC 23-1979)*, with the following addition:

Where such foods are released for export, the agency having jurisdiction in the importing country should be notified that the product has been salvaged.

### 7. LABORATORY CONTROL PROCEDURES

As given in the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CXC 23-1979)*.

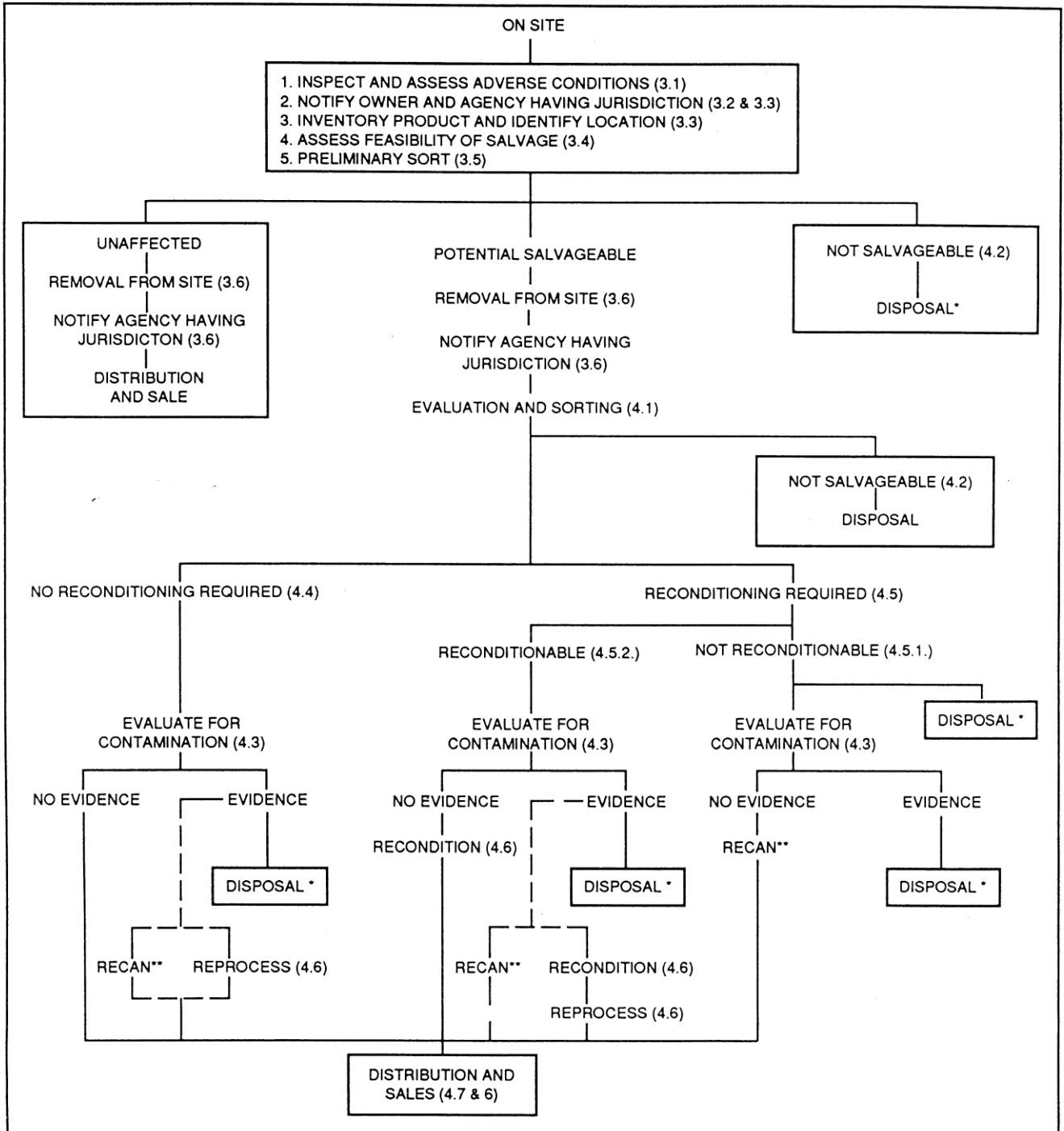
### 8. END PRODUCT SPECIFICATIONS

As stated in the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CXC 23-1979)*.



APPENDIX 1

**FLOW CHART SHOWING THE SEQUENCE OF EVENTS IN THE SALVAGE OF CANNED FOODS EXPOSED TO ADVERSE CONDITIONS (DETAILS PROVIDED IN TEXT OF MAIN DOCUMENT)**



(The solid lines indicate the usual courses of action. The broken lines indicate alternate actions which may be undertaken under special circumstances and should always be carried out under the direct supervision of person(s) knowledgeable and experienced in the particular aspects of salvage as well as the methods of sampling and evaluating the possibility of contamination).

- \* Notify the agency having jurisdiction and product owner of removal from site and plan for disposal.
- \*\* Cleaning and/or disinfection of the containers prior to opening may be necessary.

## **GUIDELINE PROCEDURES TO ESTABLISH MICROBIOLOGICAL CAUSES OF SPOILAGE IN LOW-ACID AND ACIDIFIED LOW-ACID CANNED FOODS**

### **Cautionary Note on the Use of these Guideline Procedures**

**The proper diagnosis of the causes of microbiological spoilage requires considerable training and experience. Anyone not experienced in spoilage diagnosis should use these guidelines and identified references only in consultation with canned food laboratory experts.**

#### **1. SCOPE**

These guidelines summarize procedures to establish the causes of microbiological spoilage in low-acid and acidified low-acid canned foods; references to appropriate techniques are supplied. It is intended that these procedures be used in the investigation of the causes of microbiological spoilage and not to establish the total absence of viable organisms in a single container or to determine commercial sterility of a lot. These methods may also be used for the initial identification of potential safety problems. They have no role in establishing commercial sterility.

Water activity controlled foods (e.g., canned bread, cheese spread, chorizo sausage and pasta in pouches), aseptically processed and packaged foods, and perishable cured meat products require special consideration and are not covered in this text. Spoilage diagnosis should be carried out in consultation with experts in that commodity.

#### **2. EXPLANATORY PREFACE**

##### **Microbiological End-Product Specifications**

Canned foods should be commercially sterile and not contain any substances originating from microorganisms in amounts which may present a hazard to health (*Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods* (CXC 23-1979), Section XI). The key is the term "commercial sterility", which is defined in the Code of Hygienic Practice.

Strict adherence to the procedures presented in the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods* will give reasonable assurance that a lot of canned food will meet this end-product specification. While sampling and analysis of the end-product is not recommended for establishing the commercial sterility of a lot, they are important procedures in the investigation of lots which may contain spoiled food.

#### **3. INTRODUCTION**

The primary reasoning behind the spoilage diagnosis procedure is to distinguish between post-process contamination (leakage) and insufficient thermal processing. The spoilage diagnosis procedure relies on the fact that vegetative cells (including yeasts) have little or no heat resistance. Bacterial spores are heat resistant, so a pure culture of spore forming organisms usually means insufficient thermal processing. A mixed flora of different vegetative organisms usually means leakage. Therefore to distinguish between thermally resistant and sensitive organisms, heat treatment of inocula for cultural examination is necessary. Heat treatment can be performed before or after cultural examination. Interpretation of results from the heat treatment step should take into consideration the possibility that all spores present may have germinated and would thus be heat sensitive. Figures 2 and 3 reflect only the heat treatment step performed after culturing. Since microbiological examination of canned foods is an integral part of any investigation of the cause of spoilage, it is important that reliable and reproducible procedures for the examination of both the container as well as its contents be employed. Such procedures can be used by a processor, an independent laboratory or a regulatory agency.

It should be remembered that spoilage can also indicate a potential hazard to the health of the consumer. If there is evidence that a search for a specific pathogen is necessary, appropriate procedures should be applied. Methods for the identification and enumeration of various pathogens associated with foods can be found in a number of texts on the subject. Various texts which have been found generally useful are referenced at the end of the document.

As spoilage of canned foods may result from poor handling of ingredients prior to processing, under-processing, or post-thermal processing leaker contamination, procedures to establish the cause of spoilage ought not to be limited solely to examination of the food contents for viable organisms. They should also include the physical examination of the container and an evaluation of its integrity, as well as, where possible, the examination of pertinent cannery records of the can seam teardown, the processing and shipping history of the product. The results of these should be taken into account, together with the microbiological results, in arriving at a final conclusion.

#### **4. PROCEDURES FOR DETERMINING THE CAUSE OF SPOILAGE IN LOTS OF CANNED FOOD**

The identification of the lot, the compilation of its history including can seam teardown and thermal processing records, together with knowledge of distribution are needed, as well as the sampling, inspection and examination of containers and contents.

##### **4.1 Lot Identification and History**

It is important to compile as much information as possible about the suspect product lots. This should not be restricted solely to the acquisition of microbiological data. It is also important that the information and data be examined for the presence of trends or patterns before arriving at any conclusions. A check list of the information required is helpful to ensure that essential data are not missed. An example of information needed in such a check list is given in Appendix 1.

A note should be made as to the source of the can (sample), e.g., from an inspector, or from a domicile or establishment where there has been an outbreak of food poisoning.

##### **4.2 Laboratory Examination**

An outline of procedures for examining a product and its container are shown in the following flow diagram (figure 1). Specific information relating to each of the stages in this procedure is contained in the following sections of the text. While certain of the procedures relate mainly to the examination of rigid metal cans, they can be adapted for all types of containers used for packaging thermally processed foods. There are sections in the report concerning the interpretation of the results of these procedures and guidance on where hygiene problems may exist so that corrective action can be taken.

###### **4.2.1 External inspection**

4.2.1.1 Each container in the sample should be examined visually before and after removal of any labels. All identifying marks and stains or signs of corrosion on the containers and labels should be carefully and accurately recorded. The label, after removal in one piece and inspection of both sides, should be identified with the same reference as the container and be retained.

4.2.1.2 The visual examination should be carried out under good illumination and preferably with the aid of a magnifying lens before opening or attempting any seam measurements. With respect to metal cans, particular attention should be paid to the examination of the seams for the defects, such as cutovers, dents (adjacent to or on the seam), droops, vees or spurs, pleats, knocked down flanges and for lap faults. Other less noticeable defects may occur, for example, faults in tin plate, score marks caused by supermarket case opening knives, small pin holes in welded side seams, rust holes, etc. Therefore, careful visual examination of the whole of the container is essential. A list of some of the visual external defects commonly found to occur in metal cans is given in Table 1.

4.2.1.3 During examination of the container an attempt should be made to establish whether the defects are the result of damage caused by mishandling during shipment or is a result of damage within the processing

establishment. All observations should be recorded.

The location of any defect on the can is important and should be marked on the can and recorded.

4.2.1.4 Non-destructive measurements of seals or seams should be carried out. For example, for cylindrical cans, measurements of double seam height and thickness, and countersink should be carried out at at least three locations approximately 120° apart around the double seam, exclusive of the juncture with the side seam. Blown, badly distorted or damaged containers are usually only suitable for visual examination since the seams are often too distorted for proper seam measurements to be made. However, they should not be discarded, for even badly distorted cans should be retained for detailed structural and possibly other, (e.g., chemical), examination and until the investigating authority and the manufacturer are quite satisfied that they need not be kept any longer. Tests or measurements, e.g., tap-test, countersink or centre depth can be used to give comparative measures of the internal vacuum with respect to a normal can.

#### 4.2.1.5 Determination of Net Weight

The gross weight of the container and contents should be measured and recorded at this stage. The determination of the net weight is delayed.

The net or drained weight, whichever is appropriate, should be determined for each container in the sample. (A close approximation of net weight can be obtained by subtracting the average weight, if known, of empty containers plus the second cover from the gross weight of the filled, sealed container.)

#### 4.2.1.6 Over-filling

Over-filling reduces the headspace and may adversely affect the vacuum when the container is sealed. With solid products it may cause containers to have a zero internal vacuum and even result in bulging of the container ends giving the appearance of a swollen can. Over-filling may decrease the effectiveness of a thermal treatment. This is particularly true when agitating sterilization or flexible containers are used. It causes excessive strain on seals or seams during processing. Over-filling of a container may be indicated when the net weight exceeds a reasonable tolerance of the declared or target net weight or of the average net weight determined by examination of a significant number of containers of normal appearance.

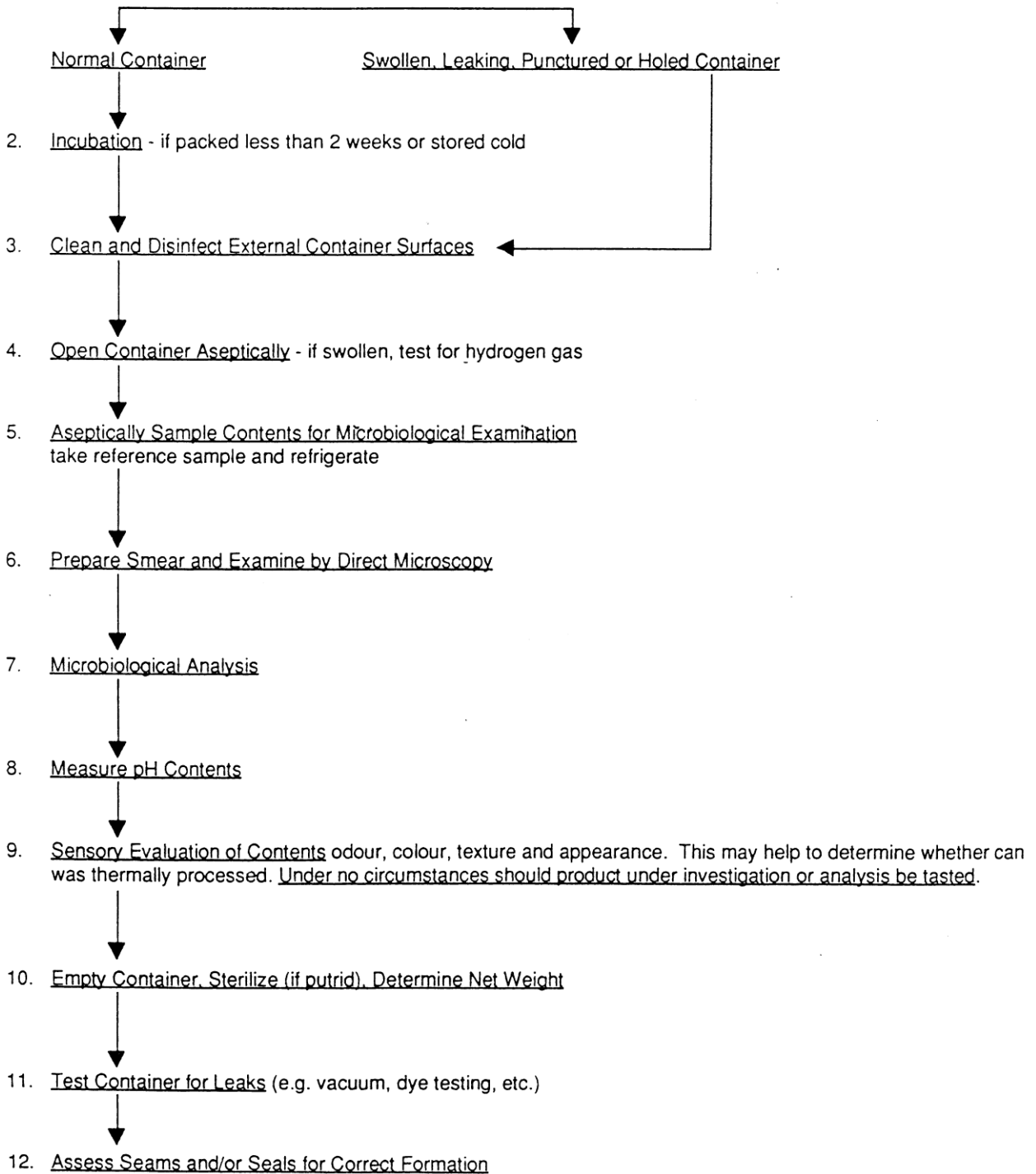
#### 4.2.1.7 Under-filling

Under-weights may indicate that either the container was underfilled or leakage has occurred. Other evidence that leakage may be the cause of under-weight should be sought, e.g., stains or product residues on the container surface, label or surrounding containers in the same carton. Panelled cans may indicate loss of liquid during thermal processing.

Figure 1

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

1. External Visual Inspection and Physical Non-Destructive Measurements  
(Inspect label, read code, then weigh can and contents. Mark can and label; remove label; inspect inside of label for location of stains and can for corrosion. Inspect seams for product leakage and visible defects such as knocked down flange, solder voids, etc.)



**TABLE 1**  
**SOME VISUAL EXTERNAL DEFECTS FOUND IN METAL CANS\***

Place where fault <u>Probably</u> occurred	Position on Can	Type of Defect	
Can Manufacture	Can end/body	Cut, hole, fracture in tin plate	
	Can Body	Side seam faults	
	Easy open strip	Fractured score line, excessive score line	
Cannery	Seamer	Can end	Deep coding, compound squeeze, damage to key fixing
		Double seam	First operation roll, skidder, false seam knocked down flange, jumped seam, broken chuck Second operation roll, cutover, droop, split droop, deformed end seam, spur, knocked down curl
		Can body	Perforated, pierced, cut dents
	Filling	Peaked, flipper, springer	
	Cooling	Peaked, Panelled	
	Can runways	Cable burn, abrasions, dents under rim of double seam	
Storage		External corrosion (rust), physical damage	
Transit/Retail		Cuts, dents	

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

#### 4.2.2 Incubation

Swollen, punctured, or holed containers must not be incubated.

Consideration should be given as to whether the container(s) should be incubated before opening for microbiological examination of the contents. The aim of incubation is to increase the likelihood of finding viable microorganisms in subsequent microbiological examinations. Incubation results alone should not be used to decide the fate of the affected lot.

Considering the length of time involved in international shipments of canned foods, incubation may not be necessary. Containers should be incubated at, for example, 30°C for 14 days and/or 37°C for 10 to 14 days. Note that a number of leakage spoilage organisms will not grow above 30°C. In addition, if the product is intended to be distributed in areas of the world with tropical climate or is to be maintained at elevated temperatures (vending machines for hot product), containers should also be incubated at higher temperatures, e.g., for 5 days at 55°C. Since thermophiles may die during such incubation period, it is desirable to examine containers periodically for the evidence of gas production before the end of incubation.

#### 4.2.3 Cleaning, disinfection and opening of containers

##### 4.2.3.1 Swollen containers

The external surfaces of containers should be cleaned with a suitable detergent and rinsed. Containers should be disinfected for at least 10 to 15 minutes in freshly prepared 100-300 ppm chlorinated water, buffered to approximately pH 6.8, or by flooding the end with an appropriate alcoholic iodine solution (e.g., 2.5% w/v iodine in ethanol) and leaving for 20 minutes. Alternatively the end can be decontaminated by flooding or spreading with a 2% solution of peracetic acid in an appropriate wetting agent (e.g., 0.1% polysorbitan 80) for 5 minutes. Containers should be dried immediately after disinfection, using clean sterile disposable paper tissues or towels. Appropriate safety precautions should be taken when using any of these chemical disinfectants.

All containers should be handled as if they contained botulinum toxin or pathogens. Horizontal laminar flow cabinets which blow air over the operator should not be used. A safety cabinet may be used when opening containers suspected of not being commercially sterile. Swollen containers should be opened within the cabinet while inside a sterile bag or by using the sterile inverted funnel method to contain any spraying of the contents. When not sampling the contents, cover the open end with a sterile cover (e.g., sterile half Petri dish or other suitable sterile covers).

It is usual to open the non-coded end of the metal container. For cans containing liquid or semi-liquid components, a sterile stainless steel spike with a shield can be used to pierce the container and the contents sampled using a sterile pipette or equivalent apparatus. For opening cans containing solid product a sterile disc cutter should be used, or alternatively the side may be aseptically pierced and the can opened by aseptically cutting round the body. It is essential that damage to the seams and seals be avoided when opening containers. Open plastic containers from the bottom or side to prevent damage to the seal area and/or lid. After disinfection lightly flame dry avoiding damage to the plastic container and with a small heated sterile device such as a soldering iron equipped with a sharp tip, cut a hole large enough for the aseptic removal of the samples.

If a safety cabinet is not used, it is recommended that a face shield be worn and that the side seam point away from the person opening the container. To test for hydrogen, gas may be collected in a test tube over the point of puncture and the open end of the tube immediately exposed to a flame. A loud "pop" indicates the presence of hydrogen. If the can to be used for gas analysis is also to be used for cultural analysis, precautions should be taken to prevent external contamination.

Describe and record any unusual odours from the contents which may be noticed immediately after opening. However direct sniffing must be avoided.

Unless a swollen can is suspected of containing gas-producing thermophilic anaerobes, it may be stored at 4°C before opening to reduce the internal pressure and reduce spraying of the contents. However prolonged storage at such temperatures should be avoided as it may effectively reduce the number of viable organisms and hamper attempts to isolate the causative microorganisms.

#### 4.2.3.2 Flat (not swollen) containers

With liquid foods, stratification or sedimentation of the microorganisms may occur. To ensure mixing of any contaminating microorganisms, it is advisable to shake the container just before opening.

The end of the container which is to be opened for sampling should first be decontaminated by the methods described in 4.2.3.1 and/or by flame sterilizing the end. Open with a sterile opening device. Describe and record any unusual odours from the contents which may be noticed immediately after opening, and as for the swollen cans, direct sniffing must be avoided.

When not sampling the contents, cover the open end of the container with a sterile cover (e.g., sterile half Petri dish or other suitable sterile cover).

#### 4.2.4 Microbiological Analysis

Appendix 2 and standard texts, e.g., Speck (1984), C.F.P.R.A. Technical Manual No. 18 (1987) and Buckle (1985) should also be consulted.

##### 4.2.4.1 Reference sample

A reference sample of at least 20 g or ml should be aseptically removed from the contents and transferred to a sterile container, sealed and held at a temperature below 5°C until required. The reference sample may be required to permit confirmation of results at a later stage. Care should be taken to avoid freezing as this may kill a significant number of bacteria in the reference sample. If thermophilic contamination or spoilage is the concern the reference sample should not be refrigerated. The reference sample also provides material for non-microbiological tests or analyses, e.g., for analysis for tin, lead, toxins, etc., but if these are anticipated appropriate amounts must be taken. For solid, and in some instances semi-solid foods, the reference sample should be made up from samplings taken from various suspect points, e.g., the centre core, product surfaces in contact with the end or double seam (specially that in contact with the cross-over), product in contact with the side seam, (if there is one). Transfer all samplings to a sterile container and store as described above.

##### 4.2.4.2 Analytical sample and inoculation of media

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

###### 4.2.4.2.1 Liquid products

These products may be sampled using suitable sterile, plugged pipettes with wide-bore tips. (Pipetting by mouth suction should be avoided.) The sample should be inoculated into both liquid and solid media.

It is recommended that each tube of liquid medium be inoculated with at least 1 to 2 ml of the sample of the container contents. Each solid media plate should be streaked with at least one loopful (approximately 0.01 ml) of the sample of the container contents.

###### 4.2.4.2.2 Solid and semi-solid products

For such products both core and surface samplings should be taken.



For taking a core sample, a suitable sterile device (e.g., a large bore glass tube or a cork borer) having an adequate diameter and length should be used.

In the case of spoilage resulting from underprocessing, the most likely location in which microorganisms may be expected to survive would be the geometric centre of the can contents. Thus the central portion of the core sample is of prime interest. Sufficient product should be aseptically excised from the central portion of the core to provide 1 to 2 g for each tube of liquid media to be inoculated and for the streaking of each plate of solid media. For multiple tubes and pour plates, the central portion can be chopped or blended with a suitable diluent.

Post-process contamination may give rise to localized surface contamination and growth in solid products. If this is suspected the surface should be sampled. Using a sterile scalpel, knife or other suitable device scrape product from the surface, paying particular attention to those areas which were in contact with the double or side seams and any easy opening feature. The scraped product should be put into a sterile container. As an alternative or additionally, it may be sufficient to swab those areas of the double and side seams plus any easy opening feature of the containers which had come into contact with the product. After swabbing, the swab should be placed into a suitable sterile diluent and shaken vigorously; portions should be used to inoculate the tubes and for streaking the plates.

The core sample and the surface samplings should be treated as separate analytical units.

Wherever possible identical microbiological analyses should also be done on at least one apparently normal can of the same code lot or batch for comparative purposes. Where cans from the same code lot or batch are not readily available, apparently normal cans from codes or batches as close as possible to the suspect lot or batch should be used.

A flow diagram of aerobic and anaerobic microbiological analysis of canned foods is found in figures 1 and 2, (see also Appendix 2). These may be useful in the interpretation of the microbiological examination.

#### 4.2.4.3 Direct microscopic examination

This is a very useful test in the hands of an experienced worker.

Different techniques can be used for direct microscopic examination, e.g., stain with 1% aqueous crystal violet or 0.05% polychrome methylene blue, phase contrast technique, fluorescent stain procedure.

It may be necessary to defat some oily foodstuffs on the slide using a solvent, e.g., xylene.

There is an advantage in using both wet film and dry stain techniques. Remember when using a Gram stain that old cultures often give a variable Gram reaction. Therefore report morphology only.

A slide of the can contents should be prepared for examination. Control slides prepared from the contents of apparently normal cans of the same code lot or batch should also be prepared, particularly if the analyst is unfamiliar with the product or if numbers of cells per field are to be compared.

#### **It is important to note the following:**

It is easy to confuse particles of product with microbial cells, therefore it may be prudent to dilute the sample before preparing the smear.

Dead microbiological cells resulting from incipient (pre-process) spoilage or autosterilization may show up on smears at this stage and no growth will be evident in the inoculated culture media.

Do not assume that apparent absence of microbial cells in a single field means that none are present in the product.

The entire smear or wet mount should be carefully scanned to locate areas of microbiological interest from which at least five fields should be examined in detail. Record observations giving approximate numbers of each morphological type observed in each field.

#### 4.2.5 Measurement of pH of contents

The pH of the contents should be measured in accordance with existing methodology (see Appendix II, Recommended International *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods* (CXC 23-1979) and compared to that of normal cans. A significant change in the pH of the contents from that of normal product may indicate that there has been microbial growth. However absence of such change does not always indicate that no growth has occurred.

#### 4.2.6 Sensory examination

This is an important part of the examination of canned foods. During this procedure note should be taken of any evidence of product breakdown, off or unusual colour, odour or in the case of liquid components (brine) cloudiness or sedimentation. Under no circumstances should the product be tasted.

Normal changes in texture of solid products can be perceived by feeling or squeezing the product with a rubber or plastic gloved hand. For proper organoleptic evaluation, product temperature should not be less than 15°C and preferably not more than 20°C. Where possible, the results of the sensory evaluation should be compared to the same evaluation of the contents from apparently normal cans from the same or neighbouring code lots or batches.

#### 4.2.7 Emptying and sterilization of the suspect container

The remaining contents should be emptied out into a suitable waste receptacle. It is important that cans containing spoiled product be disinfected or autoclaved prior to washing and further testing, e.g., leak testing, seam teardown etc. After washing, examine the internal surfaces for any evidence of discolouration, corrosion or other defects.

If required for the determination of the net or drained weight, the empty container should then be dried and then weighed, (see 4.2.1.5).

The empty container and any parts should be clearly identified and retained as long as there is any chance that it may be required for further examination or evidence.

#### 4.2.8 Leak detection methods

A number of methods may be used for determining leakage in containers. The method chosen is often determined by the degree of accuracy required, the number of suitable containers available for testing and the need to simulate conditions thought to exist when the containers originally leaked. Often more than one type of test is employed in combination with microbiological testing to determine the type and cause of the spoilage being investigated. Data obtained from tests for container leaks are often used to corroborate microbiological test results obtained on product from the same containers. The information may be useful for preventing problems from the same cause.

Each leak testing method has its advantages and disadvantages. For example, air pressure testing, while usually rapid, may be criticized for not testing the can in its natural vacuum state. Helium testing may be too sensitive and indicate leakage when none actually occurred. Also it does not indicate the point of leakage. The hydrogen sulphide test is useful for determining the location and size of the leakage as well as provide a permanent record; some find the method too slow for testing a large number of cans. Preparing the cans for testing as well as the ability of the operator to conduct the test properly and interpret the results accurately are as important as choosing the appropriate test for leakage.

It is not always possible to recreate leakage in containers that may have leaked at some time during or after processing. Product often plugs the leakage path and it may not be possible to remove it when cleaning the can prior to testing.

In these instances, many more suspect cans than were tested microbiologically may have to be tested to establish leakage in a lot. It is sometimes helpful to leak test cans from the same lot which are not suspect

when leakage cannot be recreated in cans with spoiled product.

Procedures and discussions of various methods of container leakage testing may be found in the following references: U.S. F.D.A. (1984), N.C.A. (1972), C.F.P.R.A. (1987), AFNOR-CNERNA (1982), H.W.C. (1983) and Buckle (1985).

#### 4.2.9 Seam tear-down

The procedures for examining and assessing double seams of canned foods subject to investigation for cause of spoilage are the same as those given in Section 7.4.8.1.2 of the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods* (CXC 23-1979)

However the interpretation of results from such seam examinations may be different for spoilage investigation than for process control. When microbiological results indicate recontamination spoilage, the presence of obvious seam abnormalities often confirms leakage. On the other hand, recontamination may occur in the absence of obvious seam defects. Examples of other sources of recontamination are: seam damage after closure, temporary leakage, sealing compound effects, and plate pinholes and fractures. In such instances the additional procedures given under leak testing as well as the microbiological results are necessary.

For these reasons, results from seam tear-down as part of spoilage investigation must be considered only in context with all other spoilage investigation efforts and require expert interpretation.

## 5. GUIDELINES FOR THE INTERPRETATION OF LABORATORY DATA

The interpretation of the laboratory data in Tables 2 and 3 as well as figures 2 and 3 (Appendix 2) should be considered together with the overall pattern of the particular spoilage incident being investigated and the product history.

## 6. GUIDELINES TO ASSIST IN IDENTIFYING CAUSES OF SPOILAGE

It is important that all available data be used in identifying causes of spoilage. It is essential that a complete assessment be made for each incident of spoilage. Data must be gathered (see Appendix 1) from the processing plant and the laboratory analyses and other sources by the appropriate expert(s). A careful and comprehensive analysis of such data is imperative in the accurate identification of the cause of spoilage. The following guidelines, though not all inclusive, should assist this identification.

- |     |                              |   |
|-----|------------------------------|---|
| 6.1 | Number of spoiled containers | <ul style="list-style-type: none"> <li>a) Isolated container - usually a random leaker and containers rarely the result of under-processing.</li> <li>b) Several containers - mixed microflora, probably due to post-process contamination and leakage.<br/>Leaker spoilage may occur with or without defective seams or visible dents and may be related to over-cooling, inadequate chlorination, contaminated cooling water and/or dirty, wet post-processing equipment. Handling cans while warm and wet or excessive rough can handling practices may increase likelihood of leaker spoilage. If there is a high proportion of spoiled containers and only sporeformers are present, under-processing is usually indicated. However, leakage should not be ruled out.</li> </ul> |
| 6.2 | Age of Product and Storage   | <ul style="list-style-type: none"> <li>a) Excessive age and/or excessively high temperature may give rise to hydrogen swells. This is more likely to occur with canned vegetables e.g., artichoke hearts, celery, pumpkin and cauliflower.</li> <li>b) Corrosion or damage causing perforations of container may lead to leaker spoilage and secondary damage to other cans.</li> <li>c) Thermophilic spoilage may result from storage at high temperatures, e.g., 37°C (99°F) and above.</li> </ul>  |

- 6.3 Location of Spoilage
- a) Spoilage in centre of container stacks, or near ceiling, may indicate insufficient cooling resulting in thermophilic spoilage.
  - b) Spoilage scattered throughout the stacks or cases may indicate post-processing leakage or under-processing.
- 6.4 Processing Records
- a) Records showing poor control of thermal processing may correlate with spoilage from under-processing.
  - b) Adequate processing records may eliminate under-processing spoilage and indicate post-processing leaker contamination.
  - c) Incorrect retort operation, i.e., leaking air or cooling water valves, broken thermometers and incorrect reel speed of rotary cookers may lead to under-processing.
  - d) Delays coupled with unhygienic pre-process conditions may result in incipient or pre-process spoilage.
  - e) High thermophilic counts in blanchers may correlate with thermophilic spoilage.
  - f) Changes in product formulation without reevaluation of process parameters may lead to under-processing.
  - g) Inadequate sanitation may lead to a build-up of microorganisms, which either result in pre-process spoilage or render the scheduled process inadequate. Post-process leaker contamination may also be caused by inadequate sanitation.
- 6.5 Laboratory data
- a) See Tables 2 and 3 and Figures 2 and 3 which correlate with the verification of positive tubes as discussed in Appendix 1.

## 7. CONCLUDING REMARKS

The foregoing is concerned with the cause of spoilage in canned foods. Such determinations are, of necessity, different from those required to establish that commercial sterility has been achieved within a given code lot of product.

It is not within the scope of this procedure to give any guidance as to the disposal of lots which have been demonstrated to be not commercially sterile.

The reasons for spoilage are many and varied. Therefore, a decision as to the disposal of such lots needs to be made on a case-by-case basis, utilizing much of the information obtained in assessing the status of the lot from which the container was obtained. Whether or not a lot can be salvaged will depend, for example, on factors such as the reason for spoilage, the ability and reliability of physically separating satisfactory from unsatisfactory products, etc. These factors will of course, vary widely. Therefore, the general principles outlined in the "Guidelines for the Salvage of Canned Foods Exposed to Adverse Conditions" apply and in some cases may be used for lots in which spoilage has been identified.

**TABLE 2**  
**INTERPRETATION OF LABORATORY DATA CONCERNING A LOW-ACID CANNED FOOD**

Condition of Can	Odour	Appearance (3)	pH (1)	Smear	Key Points from Cultures (2)	Possible interpretations
Swell	Sour	Frothy, Possibly ropy brine	Below normal	Cocci and/or rods and/or yeasts	Positive aerobe and/or Anaerobe; growth at 30°C and/or 37°C	Post-process leakage
Swell	Slightly off (sometimes ammoniacal)	Normal to frothy	Slightly to definitely abnormal may be higher	Rods (spores sometimes seen)	Positive; aerobe and/or Anaerobe; growth at 30°C; often pellicle formation in aerobic broths	Post-process leakage or gross underprocessing
Swell	Sour	Frothy possibly ropy brine. Food firm and uncooked	Below normal	Mixed Population (often spores)	Positive; aerobe and/or anaerobe; growth at 30°C and 37°C and often at 55°C	No thermal process given
Swell	Normal to sour or	Pale colour or distinct colour change, frothy	Slightly to definitely below normal	Medium to long rods, often granular, spores seldom seen	Positive anaerobic growth at 55°C. No growth 30°C, possibly growth at 37°C	Thermophilic anaerobe; inadequate cooling or storage at elevated temperatures
Swell	Normal to cheesy to putrid	Unusually frothy with disintegration of solid particles	Slightly to definitely below normal	Rods (spores may be seen)	Growth and gas in anaerobic culture at 37°C and/or 30°C but no growth in aerobic cultures	Under-processing, mesophilic anaerobic HIGH RISK consider survival of <i>Clostridium botulinum</i>
Swell	Normal to metallic	Normal to frothy	Normal to slightly elevated	Normal	Negative	Low filling temperature; insufficient exhausting of can before seaming; over-fill or hydrogen swell**
Swell or flat	Little or no gas on opening; fruity odour	Normal	Normal to below normal	Large numbers of evenly stained cocci and/or rods	Negative	Pre-process (incipient) spoilage

Condition of Can	Odour	Appearance (3)	pH (1)	Smear	Key Points from Cultures (2)	Possible interpretations
Swell	Sour to cheesy	Frothy	Often below Normal	Poorly stained cocci and/or rods	Negative	Leaker spoilage followed by auto-sterilization
Apparently sound	Sulphurous	Contents blackened	Normal to below normal	Rods	Anaerobic growth without gas at 55°C only	Thermophilic sulphur stinker; inadequate cooling
Apparently sound	Normal to sour	Normal to cloudy brine	Normal to below normal	Cocci and/or rods	Positive; aerobe and/or anaerobe; growth at 30°C, and usually at 37°C	Post-process leakage
Apparently sound	Normal to sour	Normal to cloudy	Below normal	Rods (often granular)	No growth below 37°C. Aerobic growth without gas at 55°C; may get no growth if samples old or incubated for long period	Thermophilic aerobes (flat sour) <i>Bacillus spp.</i> . Inadequate cooling or storage at elevated temperatures
Apparently sound	Normal to sour	Normal to cloudy	Below normal	Rods, (spores may be seen)	Positive; aerobic growth at 37°C and 30°C	Under-processing or leakage. Mesophilic aerobic spore-formers. ( <i>Bacillus spp</i> )
Apparently sound	Normal to sour	Normal to cloudy brine	Below normal	Granular rods	Negative	Under-processing or auto-sterilization; thermophilic spores
Apparently sound	Normal to sour	Normal	Normal to below normal	Large numbers of evenly stained cocci and/or rods per field	Negative	Pre-process spoilage
Apparently sound	Normal	Normal	Normal	Negative or occasional rods and/or cocci, i.e. normal	Negative	No microbiological problem

- (1) The pH may rise particularly with microbial growth in meat or protein rich food.
- (2) There may be difficulty in isolating *Flavobacterium spp* from milk or milk-based products at 25°C as they may not grow in aerobic broths
- (3) These refer principally to brined product. For other products, abnormal colour, texture and appearance may also indicate defects but are product-related and therefore cannot be tabulated.

\* Based upon M.L. Speck, Compendium of Methods for the Microbiological Examination of Foods, 1984, American Public Health Assoc.

\*\* Nitrite detinning can result in swollen containers.

**TABLE 3**  
**INTERPRETATION OF LABORATORY DATA CONCERNING ACIDIFIED LOW-ACID CANNED FOOD**

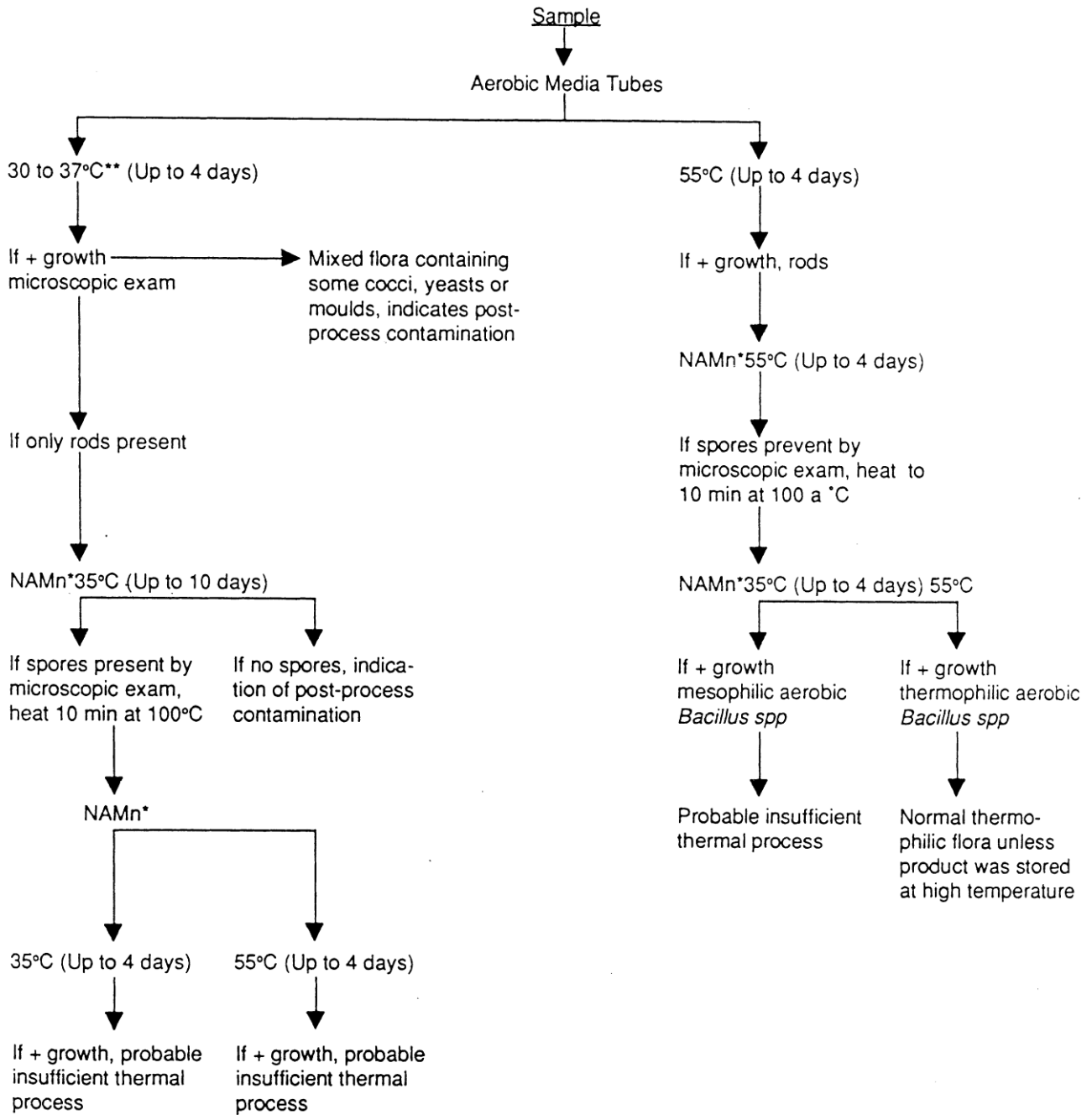
Condition of Can	Odour	Appearance*	Normal ph Group	Smear	Key Points from Cultures	Possible interpretations
Swell	Normal to metallic	Normal to frothy	4.6 and below	Normal	Negative	Hydrogen swell
Swell	Sour	Frothy Possibly ropy brine	4.6 and below	Rods and/or cocci and/or yeasts	Positive aerobic and/or anaerobic growth at 30°C	No process given or post-process leakage
Swell	Sour	Normal to frothy	4.6 and below	Rods	Growth and/or gas aerobically and/or anaerobically at 30°C	Lactobacilli; grossly insufficient processing or post-process leakage
Swell	Butyric	Normal to frothy	4.6 to 3.7	Rods (spores may be seen)	Growth and gas in anaerobic culture at 30°C	Under processing; mesophilic aerobe
Apparently sound	Sour	Normal to cloudy juice	4.6 to 3.7	Rods (often granular)	Aerobic Growth without gas at 37°C and/or 55°C	Thermophilic/mesophilic aerobe. Aciduric flat sour ( <i>B. coagulans</i> )
Apparently sound	Normal to sour	Normal cloudy juice possibly mouldy	4.6 and below	Rods and/or cocci and/or moulds	Positive aerobe and/or anaerobe growth at 30°C	Leakage, under-processing
Apparently sound	Normal	Normal	4.6 and below	Normal	Negative	No microbiological problem

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



Figure 2

**FLOW SHEET FOR THE AEROBIC CULTURAL EXAMINATION OF LOW-ACID CANNED FOODS FOR SPOILAGE AND DIAGNOSIS OF RESULTS**

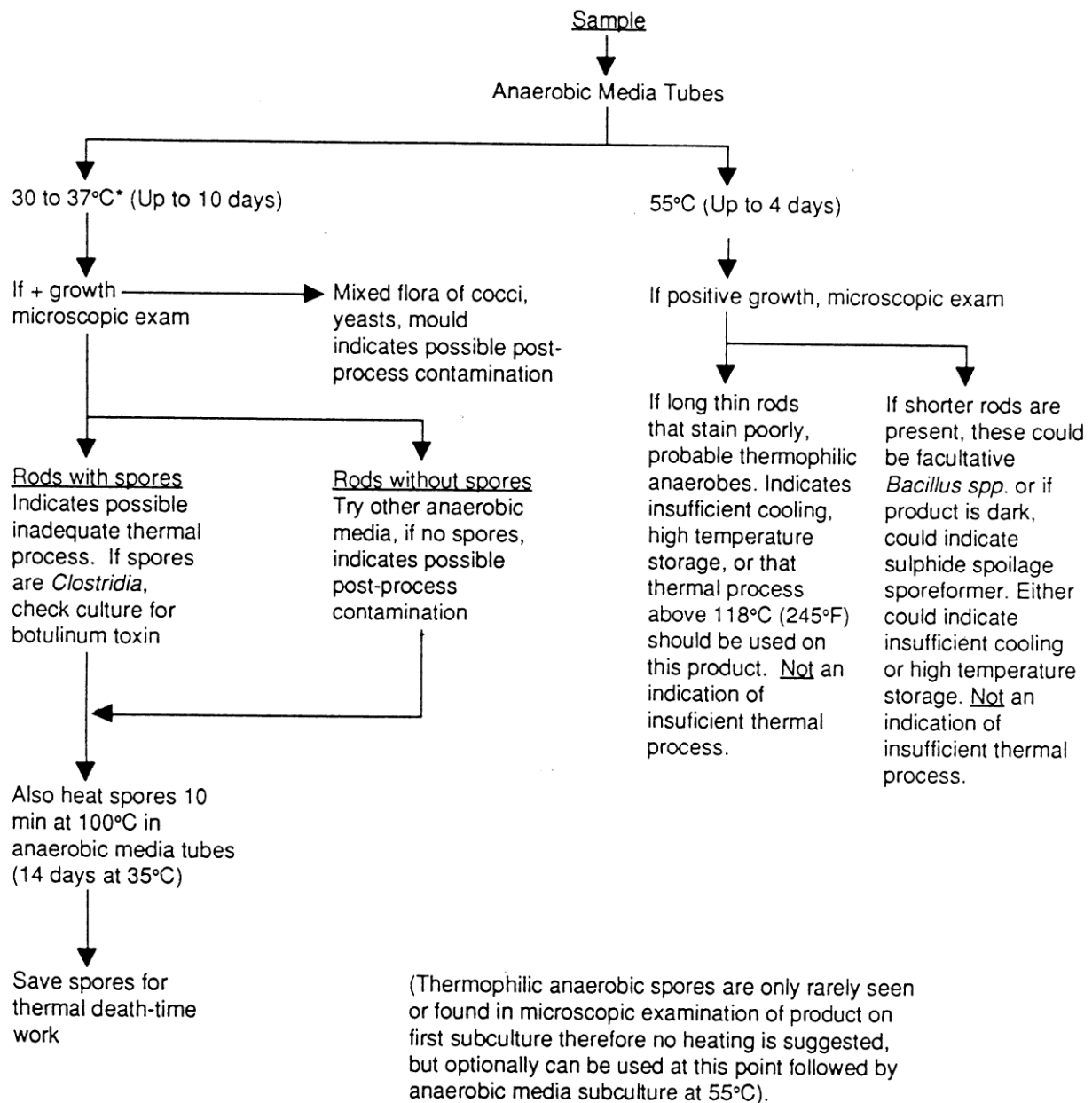


(\* NAMn = Nutrient agar plus manganese)

(\*\* Conditions for microbial growth are optimal at 30 to 35°C. However incubation temperatures of 36°C or 37°C may be used depending upon regional environmental conditions.)

Figure 3

### FLOW DIAGRAM FOR THE ANAEROBIC CULTURAL EXAMINATION OF LOW-ACID CANNED FOODS FOR SPOILAGE AND DIAGNOSIS OF RESULTS



(\* Conditions for microbial growth are optimal at 30 to 35°C. However, incubation temperatures of 36°C or 37°C may be used depending upon regional environmental conditions.)

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**Appendix 1**  
**An Example of**  
**A PRODUCT IDENTIFICATION AND HISTORY ENQUIRY FORM\***

**Date:**.....

**Enquiry No**.....

**Compiled by**.....

**1. REASONS FOR INVESTIGATION**

1. Spoilage

1. How detected (consumer complaint, warehouse inspection, incubation study etc.)
2. Date when problem first became known
3. Nature of problem
4. Extent of the problem (incidence of affected and non-affected containers)
5. Number of burst, swollen or leaking containers observed.

2. Illness

(A more complete list of essential information for the investigation of foodborne illness can be found in the Procedures to Investigate Foodborne Illness, 4th Edition, 1986, International Milk, Food and Environmental Sanitarians Inc., P.O. 701, Ames, Iowa, 50010, U.S.A. The 3rd edition, published in 1976 is available in French and Spanish.)

1. Number of persons affected
2. Symptoms
3. Time of last meal or snack
4. Time elapsed before onset of symptoms
5. What other foods and beverages were also ingested for up to 4 days before onset of symptoms?
6. Number of containers of canned food involved
7. Identity of product, including codes
8. Complainant product and/or container available for analysis
9. Were other samples of product having same code taken?
10. How and where were samples sent for analysis?

**2. PRODUCT DESCRIPTION AND IDENTIFICATION**

1. Product name and type
2. Container type and size
3. Identification of code lot(s) involved
4. Date of thermal processing
5. Processing establishment
6. Supplier/importer - if imported, date of entry into country
7. Sizes(s) of implicated lot(s)
8. Location of lot(s)

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\* This form is only intended to be an example and may require modification for a specific investigation. For instance, the data to be collected and Section 1.2 (illness) should be expanded if food poisoning is suspected.

**3. PRODUCT HISTORY RELATING TO SUSPECT CODE LOT(S)**

1. Product composition
2. Container supplier and specifications
3. Production data (scheduled process) and records
  - a. Product preparation
  - b. Filling
  - c. Sealing
4. Equipment used in thermal processing
  - a. Thermal processing
  - b. Cooling
  - c. Additional quality control and assurance records
5. Storage and transportation
6. Current status of lot(s) under examination - if product not under direct control, describe area of distribution

**4. SAMPLE DESCRIPTION AND HISTORY**

1. Where, when and how was sample obtained
2. Sample size - number of containers
3. Total number of containers at the sample site
4. Number of containers having defects in the sample
5. List defects for each container
6. Describe conditions of storage and transportation
7. Sample identification (laboratory number assigned)

## Appendix 2

## PROCEDURES FOR MICROBIOLOGICAL ANALYSIS OF THE ANALYTICAL SAMPLE

A. Mesophiles1. Media and Incubation Conditions

Low-Acid Foods (pH > 4.6)					Acidified Low-Acid Foods (pH ≤ 4.6)	
1. Incubation Conditions	Aerobic		Anaerobic		Aerobic	
2. Media (2)	Liquid DTB PE2	Solid PCA DTA NAMn	Liquid PE2 CMM LB RCM	Solid LVA PIA RCA BA	Liquid OSB TJB APT APT	Solid PDA TJA SDA
3. Quantity of medium	15 ml/tube	15 ml/tube	15 ml/ tube	15 ml/ tube	15 ml/ tube for APT 200 ml/flask	15 ml/ tube
4. Replication	=> 2 tubes	=> 2 plates	=> 2 tubes	=> 2 plates	=> 2 tubes for APT => 3/flask	=> 2 plates
5. Incubation Temperature (3)	30°C	30°C	30°C	30°C	30°C (1)	30°C (1)
6. Incubation Time (4)	to 14 days	to 5 days	to 14 days	to 5 days	to 14 days	to 5 - 10 days

*Use at least one medium for each series of solid and liquid media incubated aerobically and anaerobically.*

Notes

(1) Lower temperature, i.e., 20°C or 25°C may be appropriate in some instances, for example, for yeasts.

(2) Abbreviations used for media

PCA - Plate count agar

OSB - Orange serum broth

DTA - Dextrose tryptone agar

CMM - Cooked meat medium

APT - Acid products test broth

NAMn - Nutrient agar plus manganese

LB - Liver broth

APT - All purpose tween

DTB - Dextrose tryptone broth

RCM - Reinforced clostridial medium

PDA - Potato dextrose agar

RCA - Reinforced clostridial agar

LVA - Liver veal agar

SDA - Sabourad dextrose agar

BA - Blood Agar

PIA - Pork infusion agar

TJB - Tomato juice broth

TJA - Tomato juice agar

PE2 - Peptone, yeast extract medium, Folinazzo (1954)

(3) A temperature of 35°C or 37°C may be used in addition or when ambient (room) temperature is near to or greater than 30°C or when specific organisms of concern have higher optimal growth temperatures.

(4) Examine tubes and plates periodically, e.g., at least every two days. Incubation is terminated when positive growth is observed.

## 2. Verification of suspect positive tubes

All suspect positive tubes should be examined as follows:

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

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

## 3. Identification of isolates

Facultative thermophiles can grow in cultures at 30°C to 37°C and hence be mistaken for mesophiles. Positive isolates from cultures grown at these temperatures must always be confirmed as true mesophiles by demonstrating that they will not grow at thermophilic temperatures, 55°C.

To assist in identifying the cause of spoilage it is useful to identify isolates. For this purpose standard microbiological procedures should be used (See Speck, (1984); ICMSF, (1980); US FDA BAM, (1984)).

### B. Thermophiles

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

Incubate for up to 10 days.

Thermophilic aerobes (flat sour) - Dextrose tryptone broth

*B. coagulans* (*thermoacidurans*) - Proteose peptone acid medium\* at pH 5.0 (may grow at 37°C)

Anaerobes not producing H<sub>2</sub>S - Corn liver medium\*

*C. thermosaccharolyticum* - Liver broth\*

Anaerobes producing H<sub>2</sub>S - Sulphite agar\* + reduced iron or iron citrate

\* (Hersom and Holland, 1980)

### C. Acid tolerant

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

#### 1. Liquid

- a) Acid broth (AB) - (See US FDA BAM, 1984)
- b) MRS broth, (de Man, Rogosa and Sharpe, 1960)

#### 2. Incubation

30°C for up to 14 days.