CODE OF HYGIENIC PRACTICE FOR ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID FOODS

CAC/RCP 40-1993

CONTENTS

PAGE

Its application requires knowledge and experience of packaging 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 ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID FOODS

CAC/RCP 40-1993

INTRODUCTION

Aseptic processing and packaging means the processing and packaging of a commercially sterile product into sterilized containers followed by hermetically sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product. Aseptic processing and packaging differs from canning in that in canning the food is placed in the can, sealed and heat processed in that order.

The provisions of this code will provide guidance for identification of Critical Control Points for establishment developed HACCP plans as recommended in the Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System (CAC/GL 18-1993). Establishments engaged in aseptic processing and packaging are encouraged to develop and operate under a HACCP plan.

1.0 SECTION I - SCOPE

This code of practice is concerned with the aseptic processing and packaging of low-acid foods as defined in this code. It does not apply to those low-acid foods in hermetically sealed containers processed by conventional canning procedures nor to those that require refrigeration for their preservation, nor to acid and acidified low-acid products.

Acidified low-acid and conventionally canned low-acid foods are dealt with in the Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods.

2.0 SECTION II - DEFINITIONS

For the purpose of this Code:

2.1 ***Aseptic*** means commercially sterile.

2.2 ***Aseptic processing and packaging*** means the processing and packaging of a commercially sterile product into sterilized containers followed by hermetic sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product.

2.3 ***Aseptic zone*** means the area required to be made and maintained sterile such that sterile product and containers will not be recontaminated by microorganisms. This zone is bounded by physical barriers such as structural features or sterile air flows.

2.4 ***Canned food*** means commercially sterile food in hermetically sealed containers.

2.5 ***Cleaning*** means the removal of food residues, dirt, grease or other objectionable material.

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

2.7 ***Commercial sterility*** means the absence of microorganisms capable of growing in the food at normal nonrefrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.

2.8 ***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.

2.9 ***Equilibrium pH*** means the pH of a finished food once all components have attained pH uniformity.

2.10 ***Flow diversion system*** means product piping and valving designed to divert potentially non-sterile product from the filler or aseptic surge tank.

2.11 ***Headspace*** means the volume in a container not occupied by the food.

2.12 ***Hermetically sealed containers means*** containers which are designed and intended to protect the contents against the entry of viable microorganisms after closing.

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

2.12.2 ***Semi-rigid container*** means that the shape or contours of the filled, sealed container are not affected by the enclosed product under normal atmospheric temperature and pressure but can be deformed by an external mechanical pressure of less than 0.7 kg/cm^2 (10 psi), i.e., normal finger pressure.

2.12.3 ***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^2 (10 psi), i.e., normal finger pressure.

2.13 ***Hold Section*** means the section (for example, hold tube) of the food product sterilizing system in which the heated food is maintained for a time and temperature sufficient to attain commercial sterility of the food.

2.14 ***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.

2.15 ***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.

2.16 ***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 "Guidelines for Drinking Water Quality - Volume 1", World Health Organization.

2.17 ***Preproduction sterilization*** means the commercial sterilization of all necessary equipment before commencement of production.

2.18 ***Product-to-product regenerator*** means the equipment designed to exchange heat between hot product and cold product aseptically.

2.19 ***Scheduled process*** means all the conditions needed to achieve and maintain commercial sterility of equipment,containers and food.

2.20 ***Seals*** mean those parts of a container which are formed, bonded or fused together in order to close the container.

2.21 ***Steam seal*** means an enclosure that utilizes steam as a barrier to entry of microorganisms.

2.22 ***Sterilant*** means any physical and/or chemical treatment used to achieve commercial sterility.

2.23 ***Sterile*** means commercially sterile.

2.24 ***Sterility*** means commercial sterility.

2.25 ***Sterilization temperature*** means the temperature of the thermal process as specified in the scheduled process.

2.26 ***Sterilization time*** means the time specified in the scheduled process.

3.0 SECTION III - HYGIENE REQUIREMENTS IN THE PRODUCTION/HARVESTING AREAS

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.

4.0 SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 Location

Establishments should be located in areas which are free from objectionable odors, 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 harboring of pests and the entry of environmental contaminants such as smoke, dust, etc.

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

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

4.3.7 In food handling areas: Floors, where appropriate, should be of water-proof, non-absorbent, washable, non-slip and non-toxic materials, without crevices, and should be easy to clean and disinfect. Where

appropriate, floors should slope sufficiently for liquids to drain to trapped outlets.

Walls, where appropriate, should be of water-proof, non-absorbent, washable and non-toxic materials and should be light colored. 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 covered to facilitate cleaning.

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

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

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

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

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

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

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

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

4.4 Sanitary facilities

4.4.1 Water Supply

4.4.1.1 An ample supply of water, in compliance with Sub-Section 7.3 of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 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 Sub-Section 7.3 of the General Principles referred to in Sub-Section 4.4.1.1, and should be manufactured, handled and stored so as to protect it from contamination.

4.4.1.3 Steam used in direct contact with food and 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 color, and with no cross-connection with or back-siphonage into the system carrying potable water (see also Sub-Section 7.3.2).

4.4.2 Effluent and waste disposal

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

4.4.3 Changing facilities and toilets

Adequate, suitable and conveniently located changing facilities and toilets should be provided in all establishments. Toilets should be so designed as to ensure hygienic removal of waste matter. These areas should be well lit, ventilated and where appropriate heated and should not open directly on to food handling areas. Hand washing facilities with potable 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. Potable 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 colors 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 the air flow should never be from a dirty area to a clean area. Ventilation openings should be provided with a screen or other protecting enclosure of material which will not corrode. 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, odor 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. Processors should have suitable systems for transporting container materials. System design, structure and installation should ensure that container material does not become contaminated or unacceptable because of damage.

4.5.2.2 Containers for inedible material and waste should be leakproof, 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 **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.

4.7 **Sterile Gas Supply**

Air, or other appropriate gases should be filtered for removal of extraneous material (dust, oils and the like) and rendered sterile. Sterilization may be achieved by double filtration within one filter housing or two separate filter housings, or by a combination system such as incineration followed by filtration. The system used to deliver the commercially sterile air or other gas to the point of use should be capable of being sterilized prior to use and being maintained in a sterile condition during operation.

4.7.1 The filters used should have a demonstrated and verified capability to provide the degree of removal of microorganisms and extraneous material required under the conditions of use. They should be examined before installation and after removal for evidence of damage which may result in malfunction. They should not be affected by the gases in any manner which would reduce their efficacy or shorten their working life. Filters used for commercial sterilization should be installed, maintained and changed in accordance with the manufacturer's instructions. Their performance should periodically be verified using appropriate test methods and records maintained.

4.7.2 If incineration is used to provide sterile air, critical factors such as final air temperature and flow rate should be controlled and recorded.

5.0 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, vapor and surplus water.

5.2 Cleaning and Disinfection

Cleaning and disinfection should meet the requirements of Appendix I of the General Principles of Food Hygiene referred to in Sub-Section 4.4.1.1 of this Code.

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

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

5.2.3 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.

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

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

5.3 Hygiene Control Programmer

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 programmer 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, containers, container materials, equipment and utensils from contamination. After application, contaminated equipment, containers, container materials 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 (e.g. hydrogen peroxide) which may represent a hazard to health should be suitably labeled with a warning about their toxicity and use. They should be stored in locked rooms or cabinets used only for that purpose and dispensed and handled only by authorized and properly trained personnel or by persons under strict supervision of trained personnel. Extreme care should be taken to avoid contaminating food.

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

5.9 Personal Effects and Clothing

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

6.0 SECTION VI: PERSONNEL HYGIENE AND HEALTH REQUIREMENTS

6.1 Hygiene Training

Managers of establishments should arrange for adequate and continuing training of all food handlers in hygienic handling of food and 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 diarrhea, is permitted to work in any food handling area in any capacity in which there is any likelihood of such a person directly or indirectly contaminating food with pathogenic microorganisms. Any person so affected should immediately report to the management that he is ill.

6.4 Injuries

Any person who has a cut or wound should not continue to handle food or food contact surfaces until the injury is completely protected by a water-proof covering which is firmly secured, and which is conspicuous in color. 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 potable water. 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 coverings and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in 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 jewelry that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewelry when engaged in food handling.

6.7 Personal Behavior

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

6.8 Gloves

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

6.9 Visitors

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

6.10 Supervision

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

7.0 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 materials which will not be reduced to acceptable levels by normal plant procedures of sorting and/or preparation of processing.

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

7.1.3 Raw material 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 aseptic processing, 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 preparation of the food should be performed under conditions which will minimize or prevent contamination, and deterioration, and minimize the growth of microorganisms in the food.

7.2 **Prevention of Contamination of Raw and Semi-Processed Product Ingredients**

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 before use or prior to contact with food which has been further processed.

7.3 **Use of Water**

7.3.1 As a general principle only potable water should be used in food handling.

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

7.3.3 Water re-circulated or re-used 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.

7.3.4 In systems which utilize heat alone to sterilize containers and water is necessary to cool containers before they are filled with product, the water used must be sterilized, cooled, and delivered sterile to the point of use.

7.4 Packaging

7.4.1 Storage and characteristics of container materials

7.4.1.1 All container 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 container 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 sealed jars.

7.4.1.2 All empty containers or container material used in aseptic systems should be as clean as possible. Soiled or damaged aseptic packaging materials, may impede sterilization and proper sealing and should not be used. Aseptic container material may be affected by changes in physical parameters such as relative humidity and should be stored so as to minimize such changes. All storage and handling procedures should minimize the chance of contamination or damage of packaging material.

7.4.2 Inspection of container materials and containers

7.4.2.1 Appropriate sampling and inspection schemes should be used by both container manufacturers and food processors 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.

7.4.2.2 If container or container material cleaning methods are available, they may be used providing the cleaning process does not prevent proper sterilization of container material or its barrier properties after filling and sealing. 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. 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 and resterilization. Faulty containers may leak during or after processing and storage.

7.4.2.4 The food processor 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 aseptic operation and subsequent handling, these should be established in consultation with the container or closure manufacturer.

7.4.3 Cleaning of container materials

7.4.3.1 Container materials to be sterilized chemically as with hydrogen peroxide should be stored in accordance with 7.4.1.2 so that the necessity for cleaning is avoided.

7.4.4 Proper use of containers

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

7.4.5 Protection of container materials during plant cleaning

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

7.4.6 Forming of product containers

In-line formation of containers from container materials should be accomplished according to container material and/or packaging machine manufacturer's specifications and should be formed by a method which maintains container integrity and prevents aseptic zone and container contamination.

7.4.7 Filling of product containers

During filling, contamination of seal or seam areas with product should be avoided unless equipment is specifically designed to remove product from seal areas prior to sealing. (Overfilling and splashing can lead to contamination of seams or seals and adversely affect container integrity).

7.4.8 Closing operations

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

7.4.8.2 Seam or seal areas should be kept as clean and dry as necessary to obtain a satisfactory closure.

7.4.9 Inspection of closed containers

7.4.9.1 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 inspector, or other person competent to inspect containers and their closures, should examine the filled, sealed containers for product leakage or the presence of defects which may affect container integrity. Records of observations should be maintained and, where irregularities are found, corrective action should be taken. Additional visual closure

inspections should be made immediately following a machine malfunction, adjustment or start-up following a prolonged shut down.

The specifications of the container materials and closing equipment manufacturers, the food processor and those of the agency having jurisdiction for examining each container should be followed exactly.

7.4.9.1.1 **Inspection of glass container closures**

For glass containers see 7.4.8.1 of the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods. 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 taken should be maintained.

7.4.9.1.2 **Inspection and tear-down of double seams**

For metal containers, see 7.4.8.1.2 of the Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods.

For plastic containers with metal ends, consult the container manufacturer.

7.4.9.1.3 **Inspection of heat seals**

Appropriate inspections and tests should be conducted 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. Inspection may include some physical testing for strength of the seals. There are several ways of checking seal integrity, for example, burst-pressure testing, and seal thickness measurements. Appropriate methods should be obtained from the container material and closing equipment manufacturers of these containers or materials.

7.4.9.1.4 **Other mechanical closures**

Appropriate tests should be carried out by competent, trained and experienced personnel at intervals of sufficient frequency to ensure consistent, reliable hermetic sealing. These tests should be conducted in accordance with the container material and/or equipment manufacturer's instructions; and should include at least tests to check that critical sealing components, such as seal rings and membranes, are intact and are of a number, material and location required to ensure maintenance of a hermetic seal.

7.4.9.1.5 **Closure defects**

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

7.4.10 **Handling of containers after closure**

7.4.10.1 At all times containers should be handled in a manner that protects containers and closures from damage which may cause defects and subsequent microbial contamination. Design, operation and maintenance of container handling methods should be appropriate for the types of containers and materials used. Where necessary, containers should be overwrapped. They should be kept dry and clean prior to overwrapping.

The risk of microleakage may be increased by inadequately designed, controlled and maintained container conveyor, handling, labeling and packaging equipment which may result in increased container abuse. Conveying systems and equipment should be designed to minimize abuse, and conveyor and equipment surfaces should be appropriately cleaned and disinfected and may need to be kept dry. Mechanical shock or abuse must be avoided by proper design. Careful attention to layout, operation and maintenance of conveyance systems is necessary if abuse is to be reduced to a minimum.

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

7.4.11 **Coding**

7.4.11.1 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.

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

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

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

7.4.12 **Washing and drying of filled, sealed containers**

7.4.12.1 Only potable water as described in 7.6.8.1 Draft Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods should be used for washing containers.

7.4.12.2 Methods and equipment for washing and/or drying of filled sealed containers should not cause damage. The equipment should be readily accessible for cleaning and disinfection.

7.4.13 **Cooling of filled, sealed containers**

Where filled, sealed containers are cooled, procedures as described in 7.6.8 of the Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods should be followed.

7.5 Sterilization of equipment, containers and food

7.5.1 General considerations

7.5.1.1 Scheduled processes must be established by competent persons having expert knowledge of aseptic processing and packaging and having adequate facilities for making such determinations. It is absolutely necessary to establish the required processes using accepted scientific methods.

7.5.1.2 Low-acid foods with pH values above 4.6 may be able to support the growth of many kinds of microorganisms including heat resistant sporeforming pathogens such as *Clostridium botulinum*. It should be emphasized that the aseptic processing and packaging of low-acid foods is a very critical operation, involving public health risks and appreciable losses of finished product if inadequate sterilization occurs.

7.5.2 Establishing the scheduled process

7.5.2.1 The scheduled process will consider the following elements:

1. Product

2. Product contact surfaces

3. Container materials

4. Gases

5. Equipment

Complete records concerning all aspects of the establishment of the scheduled process, including any associated incubation tests, should be retained permanently.

7.5.2.2 The required thermal process to achieve commercial sterility of a food should be established on the basis of factors such as:

Microbial flora including *Clostridium botulinum* and spoilage microorganisms;

Product composition or formulation;

Levels and types of preservatives;

Equilibrium pH;

Water activity;

Likely storage temperature of the product.

Since for these systems, food products are thermally processed before packaging, traditional methods for deriving and verifying a thermal process used in conventional canning must be modified. The essential elements in the establishment of an adequate thermal process are the heating characteristics of the food product and the inactivation kinetics (thermal resistance) of specific target microorganisms. The product is brought to sterilization temperature and held at that temperature for a time necessary to achieve commercial sterility. In continuous product flow systems the time for which the product must be held at the sterilization temperature to attain commercial sterility is achieved in the hold section or tube. The flow rate of each and every particle in the hold section or tube is critical. Therefore, it is essential that the rate of flow for the fastest particle or the shortest particle retention time be accurately determined for each product flow rate; length, dimension and design of the hold section; and, product type and characteristics. Methods, such as dye or salt injection, are available to determine minimum residence time. Mathematical models (formulae) have been developed which can be used to calculate the minimum residence time required by a product to achieve commercial sterility. These models incorporate the flow rate, physical dimensions and design of the hold section and the rheological properties of the product. For situations where flow characteristics of the product are unknown, verify the calculations by actual measurement. Properly designed and conducted product studies may be used in support of the establishment and validation of the thermal process. The inoculated pack test is one method commonly used to validate the calculated process.

Determination of the hold or residence time for products containing discrete particles includes consideration of the thermal properties, shape, dimension, mass, etc. of each type of particle and particle to fluid ratio.

For those systems where product is batch sterilized followed by aseptic transport and filling, the sterilization is affected by hold time and temperature in the heating vessel. In this case, sterilization time can be precisely controlled. Batch type systems are used primarily for processing of products containing discrete particles. The hold time will depend (as with hold tubes) on the time needed to sterilize every particle of food. Thus, the heating rate of each type and size of discrete particle must be determined and used in the calculation of the minimum hold time and temperature for each product.

These principles also apply to systems which utilize resistance heating, microwave heating or other forms of energy to heat the food. The amount of energy needed to heat every portion of every particle of food to a temperature adequate to achieve commercial sterility must be determined. Delivery of this energy to the product must be controlled, monitored and recorded. All product characteristics (such as conductivity, particle size, etc.) which may affect the delivery of the process must be defined, controlled, monitored and recorded.

Any changes in product composition or formulation should be evaluated as to their effect on the adequacy of the process. If the scheduled process is found to be inadequate, the thermal process must be re-established.

If steam injection or steam infusion is used, the addition of water (from the condensation of steam) increases the product volume by approximately 1% per 5.6°C (10°F) temperature increase above initial product temperature as it enters the product sterilizer. Volume increase may also be affected by thermal expansion of the food. This increase in product volume due to the addition of water and thermal expansion should be compensated in the establishment of the process. Product feed rate may be controlled by a positive displacement pump or continuously monitored and recorded using an accurate flow meter recording device. If a flow meter recording device is used to monitor and record product feed rate after steam injection or infusion, the device should be calibrated, using appropriate methods such as volumetric flow or injection tracing (e.g., salt or dye) methods, at a frequency sufficient to ensure accurate flow of the specific products being processed.

7.5.2.3 **Preproduction equipment sterilization**

7.5.2.3.1 **Processing, holding and filling equipment**

Before production begins, all piping, valves, pumps, surge tanks and product fillers and other product contact surfaces downstream from the hold section or tube must be brought to a condition of commercial sterility, and this condition must be maintained until production is completed. Clean food contact surfaces can be sterilized by exposure to high temperature water under pressure, or saturated steam, or other appropriate treatments. Temperatures reached during the sterilization cycles should be determined by accurate temperature measuring devices, e.g., calibrated thermocouples, at the critical points in the system or at least at the slowest heating (coldest point) of the system. Sufficient temperature measurements should be taken during establishment of pre-production sterilization procedures to ensure that the coldest point in the system has been identified. Valve clusters, which may be used on reservoirs and as flow diversion devices, should be evaluated when identifying the coldest point in the system. If the valve cluster is found to be the coldest point in the system, temperature should be measured and recorded at this point. If surge tanks or reservoirs and fillers are sterilized separately, appropriate temperature sensor locations should be identified using similar techniques. Sterilization of flow diversion devices is discussed in subsection 7.6.1.6 and sterilization of surge tanks or reservoirs is discussed in 7.6.1.7.

7.5.2.3.2 **Packaging equipment**

The aseptic zone of filling and packaging equipment must be cleaned and brought to a condition of sterility prior to the initiation of product filling and must be maintained in a condition of sterility throughout production. The aseptic zone should be re-sterilized when conditions occur which may result in loss of sterility.

The aseptic zone may be sterilized by heat such as in those systems which utilize superheated steam, or by physical or chemical means such as in those systems which employ hydrogen peroxide or other agents. Superheated steam is steam for which the temperature is above that of dry saturated steam at the same pressure. For those systems using heat, the time and temperature at the coldest locations within the aseptic zone will be the critical factors and should be monitored and recorded. For hydrogen peroxide or other physical or chemical systems, the quantity or level used, concentration, temperature, contact time, method of delivery and other factors may be critical and, therefore, should be monitored and recorded.

The presterilization procedure for aseptic zones within packaging equipment should be sufficient to ensure that sterility of the finished product is maintained. Establishing this portion of the scheduled process should involve adequate challenge testing using appropriate test organisms and methods. Equipment modifications should be evaluated to determine the need to perform additional challenge tests.

7.5.2.3.3 **Monitoring sterilization and maintenance**

Appropriate inspection and tests should be carried out to monitor the sterilization and its maintenance and records kept as specified in 8.1.4, 8.1.6, 8.1.7 and 8.1.8 of this code.

7.5.2.4 **Package sterilization**

7.5.2.4.1 The sterilization process applied to the packaging material should achieve sterility. Establishing this process should involve adequate challenge testing using appropriate test organisms and methods. Packaging material and procedural modifications should be evaluated to determine the need to perform additional challenge tests.

Packaging material, preformed containers and their closures are typically sterilized either inside the packaging machine or sterilized externally and introduced aseptically into the aseptic zone of the packaging

machine. If the process is performed or completed inside the packaging machine, it is usually accomplished by heat or through use of a combination of chemical and physical treatments such as hydrogen peroxide and heat or U.V. radiation. If the sterilization of packaging material is done completely or partially off-site, it may be sterilized using the heat of extrusion for packaging material or use of a physical treatment such as steam sterilization or irradiation.

7.5.2.4.2 Appropriate inspections and tests should be carried out to monitor the sterilization of packaging materials and maintenance of sterility of the aseptic zone of the packaging machine. Records should be kept as specified in sub-section 8.1.4, 8.1.6, 8.1.7, and 8.1.8 of this code.

7.5.3 **Processing and packaging room operations**

7.5.3.1 Scheduled processes should be readily available to the system operator, and to the agency having jurisdiction.

7.5.3.2 It is extremely important that the operators are under the supervision of personnel who understand and are trained in the principles of aseptic processing.

7.6 **Equipment and Procedures for Processing Systems**

7.6.1 **Equipment design**

7.6.1.1 All equipment to be used for aseptic purposes must be designed for adequate cleaning. Equipment which is not cleaned adequately is more difficult to sterilize.

7.6.1.2 Processing equipment should be constructed of suitable materials for food contact.

7.6.1.3 If the scheduled process is controlled by the outlet temperature of a hold tube, it should be designed so that no portion of the tube between the product inlet and the product outlet from the tube can be heated. Hold tubes must slope upwards at least 2.0 cm/m. (0.25 inch per foot) of piping. The heating characteristics of product in the hold tube must be sufficiently understood with respect to product flow and temperature variations, and to environmental control around the section, to ensure that any appropriate temperature controls are installed to guarantee the scheduled process.

7.6.1.4 For continuous flow systems, product feed rate should be constant, reproducible and quantifiable. A means of preventing unauthorized changes in product feed rate must be provided (for example, an alarm, lock or seal). The product feed rate should be checked with sufficient frequency to ensure that it is as specified in the scheduled process.

7.6.1.5 Any equipment downstream from the hold section with rotating or reciprocating shafts such as pumps or valve stems are potential points of product contamination by microorganisms. Such points within the system should be equipped with steam seals or other appropriate barriers and the operator should be able to monitor the proper function of such barriers, for example, by observing steam discharge from properly located and oriented bleeder ports or observation of leak detection ports.

7.6.1.6 If the system is equipped with a flow-diversion device, it should be installed in the product piping located before the product filler or aseptic surge tank and should be designed to automatically divert flow away from the product filler or surge tank in the event that critical factors such as sterilizing temperature in the hold section and/or proper pressure differential in regenerative heat exchangers drops below specified limits. This

device must be designed such that the valve seat which separates the diverted product flow pattern from the forward flow route is sterilized on all sides simultaneously, and all sides of the valve must be maintained in an aseptic condition during production. Gravity drain type flow diversion valves should never be used in aseptic systems, as microorganisms will grow through, or be drawn through, the valve seat from the non-sterile side and contaminate sterile product. If the system is designed such that product in an aseptic surge tank is to be packaged while the processing system is in a divert mode, the flow diversion system must separate sterile product from potentially non-sterile product by more than one valve seat with a sterile zone between sterile product and potentially non-sterile product. This is usually accomplished by establishing a steam barrier between sterile product and the potentially non-sterile area of the processing system.

7.6.1.7 Proper removal of gas (air) from the tank is essential in achieving sterilization. The tank should be instrumented to document proper delivery of the sterilization cycle. At the completion of the sterilization cycle, the flow of sterile gas (see section 4.7 of this code) should be initiated to prevent the tank from experiencing a negative pressure during cooling or production. If an aseptic surge (hold) tank is used in the system, the tank must be maintained under a positive pressure at all times following the initiation of the sterilization cycle until production is completed.

7.6.1.8 In aseptic systems, commercial sterility of the food is accomplished by raising the temperature of the product and maintaining this specific temperature for an exact period of time. Both time and temperature are critical factors in satisfying the scheduled process. In those systems using a hold tube, it is necessary to apply a back pressure sufficient to prevent product boiling (flashing). Product flashing can adversely affect the time and temperature relationship of the scheduled process and subsequent attainment of commercial sterility. Back pressure is commonly maintained with use of a valve, orifice or other device which restricts flow through the tube downstream from the heater and at the exit of the hold tube.

7.6.1.9 **Product-to-product regenerators**

Where a product-to-product regenerator (see definition 2.21) 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 reduces the chance that any leakage in the regenerator will be from the unsterilized product into the sterilized product.

7.6.2 **Instruments and controls for aseptic systems**

7.6.2.1 **Temperature indicating devices**

Each product sterilizer should be equipped with a sufficient number of accurate, calibrated, reliable temperature indicating devices and suitably located. Devices should respond to temperature changes to sufficiently ensure that the scheduled process is delivered. Devices may be subject to the approval of the official agency having jurisdiction. Such devices should have divisions that are easily readable to 0.5°C (1°F) and if, an analog type, have a graduated scale containing not more than 4.0°C per cm. (17°F per inch). Temperature indicating devices including associated instrumentation (for example, potentiometers) should be tested for accuracy against a known accurate standard thermometer. This should be done in steam or water as appropriate and in a similar position or aspect to that which it is installed in the product sterilizer. Such tests should be performed 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 device that deviates more than 0.5°C (1°F) from the standard should be replaced if it cannot be readjusted. A daily inspection of temperature indicating devices should be made to detect and replace defective devices.

7.6.2.2 **Temperature/time recording devices**

Each product sterilizer should be equipped with a sufficient number of accurate, calibrated, reliable temperature/time recording devices which are used in conjunction with the reference temperature indicating devices. Recording devices may becombined with the controllers and may be a recording-controlling instrument. Devices should be sufficiently sensitive to respond to temperature changes in a manner which will ensure that the delivery of the scheduled process is accurately recorded. It is important that the correct chart is used for each device. For analog devices, each chart should have a working scale of not more than 12°C per cm (55°F per inch) within a range of 10°C (20°F) of the sterilizing temperature. The recorder accuracy should be equal to or better than + 0.5°C (1°F) at the sterilizing temperature. The recorder(s) should agree as closely as possible [preferably within 0.5°C (1°F)] and should not be higher than the temperature indicating device(s) during sterilization. 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.

7.6.2.3 **Location of temperature indicating sensing elements**

For continuous flow type aseptic systems the sensing element(s) of the temperature indicating device should be installed in the product hold section outlet in such a way that it does not alter product flow and result in the improper delivery of the scheduled process.

For batch systems, a sufficient number of sensing elements should be so located as to ensure that the scheduled process is delivered to the entire batch.

7.6.2.4 **Location of temperature recording sensing elements**

The sensor(s) should be located in the hold section in such a way that it does not alter product flow and result in the improper delivery of the scheduled process. In addition, a separate temperature indicating device sensing element should be located in close proximity to the temperature sensing device probe. The probes for hold tubes must be located so that (a) the conductivity of the piping structure does not interfere with the accurate determination of product temperature, (b) the internal obstruction created by the probes is minimized, and (c) for hold tubes, the probe should be located at or after the point where the upward slope of the tube falls to less than 2 cm per meter (0.25 inch per foot) of piping as described in 7.6.1.3.

7.6.2.5 **Location of controller sensing elements**

Controller sensing elements should be located in such a way as not to alter product flow and result in improper delivery of the scheduled process. It should be capable of ensuring that the desired product sterilization temperature is maintained.

7.6.2.6 **Pressure recorder**

Where pressure is a critical factor in the scheduled process, the product zone should be equipped with an accurate, calibrated, reliable pressure recording device. The pressure recording device should be checked for accuracy against a standard at least once a year. The pressure recording device should have a range from 0 kg per cm^2 (lbs. per square inch) such that the safe working pressure is about two-thirds of the full scale and, if an analog type, be graduated in divisions not greater than 0.14 kg per cm^2 (2 lbs. per square inch).

7.6.2.7 **Differential pressure recorder**

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^2 (2 lbs per square inch) on a working scale of not more than 1.4 kg/cm^2/cm (20 lbs per square inch per inch). The controller should be tested for accuracy against a known accurate standard pressure indicator, prior to use and at a frequency sufficient to ensure its accuracy but not to exceed one year and in accordance with the requirements of the agency having jurisdiction. 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.

7.6.2.8 **Product process timing methods and recording**

A method (for example, monitoring metering pump speeds) should be used to control the product feed rate as specified in the scheduled process.

7.6.3 **Startup**

Operators should check to see that the following conditions are met before beginning production on an aseptic system.

(a) All steam seals are functioning properly (for example, emitting steam);

(b) Proper preproduction sterilization with water and/or other medium has been conducted;

(c) Temperatures are correct in the hold tube;

(d) The pressure is greater on the sterile side of product-to-product regenerators, if used;

(e) There is at least 0.07 kg/cm^2 (one psi) pressure of sterile air in the aseptic surge tank;

(f) Monitor the speed of the variable speed product-metering pump to verify that the product feed rate does not exceed that specified in the scheduled process;

(g) Attention should be paid to belt speeds, sterilant bath levels, sterilant concentration, sterilant temperature, temperatures of incinerators, zone temperatures, fogging times and all other factors identified as critical to the production of a commercially sterile product;

(h) That records of these and any other critical factors are properly maintained;

(i) Container material storage, handling and closing are conducted as described in 7.4.

7.6.4 **Product container sterilization, filling and closing operations**

7.6.4.1 **Recording devices**

The systems for container and closure sterilization, as well as filling and closing should be instrumented to show that the scheduled conditions are achieved and maintained. During presterilization, as

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

7.7 Deviations in Aseptic Operations

7.7.1 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.

7.7.2 Procedures for handling deviations

Failure to meet any factor identified by the process authority, the processor, or the regulatory agency as being critical to the production of a commercially sterile food product should be interpreted as a deviation to the scheduled process. Whenever the in-process monitoring, records review, processor check or other means disclose that a low-acid food container system, or production equipment has received a thermal or sterilization treatment less than that stipulated in the scheduled process, the processor should:

(a) identify, isolate and immediately 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 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.

7.7.3 Temperature drop in product hold section

When product temperature in the hold tube drops below the temperature specified in the scheduled process, the potentially non-sterile product should be diverted to waste or recirculation. If the flow diversion system is designed as in 7.6.1.6, the processing system may be cleaned and resterilized followed by a resumption of the forward flow pattern without affecting packaging operations.

7.7.4 Loss of proper pressures in the regenerator

Where a regenerative heat exchanger is used the product may lose sterility whenever the pressure of sterilized product in the regenerator is less than 0.07 kg/cm^2 (1 lb per square inch) greater than the pressure of unsterilized product. Product flow should be directed either to waste or recirculated until the cause of the improper pressure relationship has been corrected and the affected system(s) has been returned to a condition of commercial sterility.

8.0 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

8.1.1 Commercial sterility processing of foods

Readings should be made and legible records maintained for the following:

(a) Temperature indicating device(s) at the hold section or tube outlet;

(b) Temperature recorder at hold section or tube outlet;

(c) Temperature recorder at the final heater outlet (entering the hold section or tube);

(d) Differential pressure recorder, if a product-to-product regenerator is used;

(e) Back pressure recording, if a back pressure monitoring system is used;

(f) Product flow rate (in liters or gallons per minute, cans per minute, etc,);

(g) Aseptic surge tank sterile air overpressure;

(h) Proper performance of steam seals (check to see that steam is being emitted);

(i) Proper seals at clamps downstream from hold tube (check for leakage);

(j) The sterilization of equipment during the "presterilization" cycle;

(k) The product formulation, pH, water activity or other factors of each batch of product (if critical to the process);

(l) Production date and code mark of the containers;

(m) Records of each diversion;

(n) Cleaning and resterilization records for the system following diversion;

(o) Other conditions or factors critical to the adequacy of the scheduled process.

8.1.2 **Commercial sterility processing of foods containing discrete particles**

If the product contains visible particulates in its formulation and the maximum size of the particles of each ingredient was listed in the scheduled process as a critical factor, records of the maximum size used should be listed, or how size was controlled for each batch. Records to show that pasta or similar product was completely rehydrated during the time period equal to the time the product reaches the final heater outlet should be retained. In addition to the above, the record keeping requirements contained in section 8.1.1 will also apply to particulate containing products.

8.1.3 **Container examinations**

Records of container examinations should be kept with accordance with 7.4.9.

8.1.4 **Container sterilization systems employing superheated steam**

Packaging systems which utilize superheated steam to sterilize equipment surfaces and packaging material must be instrumented or equipped to monitor those factors which are critical to the delivery of the sterilization treatment. As discussed in 7.5.2.3.2, the critical parameters will be established on the results of microbiological testing.

The coolest temperature in the sterilizer should be recorded along with the time the containers are in the sterilizer. The temperature of the lid sterilizer should be recorded along with the time the lids are in the sterilizer. The record of the sterilization of the water and its delivery tube should be recorded, if used to cool the containers prior to closing. Presterilization of the filling and closing areas should be documented along with the records to show that the scheduled temperature is maintained in this area during filling and closing.

8.1.5 **Sterilization using chemical sterilants**

Packaging systems which utilize chemical sterilants to sterilize equipment surfaces and packaging material must be instrumented or equipped to monitor those factors which are critical to the delivery of the sterilization treatment. As discussed in 7.5.2.3.2, the critical parameters will be established based on the results of microbiological testing.

Examples of critical factors which may need to be monitored include:

Sterilant concentration;
Consumption or application rate;
Drying air temperature;
Sterilant temperature;
Contact time;
Other conditions or factors identified critical to the adequacy of the scheduled process.

Proper functioning of atomizers, nozzles, etc., should be verified. If hydrogen peroxide or other chemical sterilants are used, the processor should assure that the sterilant is approved for contact with the container material, and that any maximum or minimum concentration and residual limits imposed by regulatory agencies are adhered to.

If sterile air or other sterile gas is necessary for the maintenance of aseptic zone integrity within the packaging machine, the presence of a positive pressure should be documented from the presterilization cycle until the end of packaging.

8.1.6 **Hydrogen peroxide and ultra-violet sterilization systems**

In addition to the records in 8.1.3 and 8.1.5, records should be kept of the control and strength of the ultraviolet treatment for container sterilization. Specifications of the service life of wave length emitting devices should be kept on file.

8.1.7 Containers or container material sterilized prior to arrival at the processors facility

Records of sterilization processes, such as irradiation, heat of extrusion, etc. which are delivered by packaging vendors, should be maintained by the vendor and supplied to the user. Records should be kept by the user such that code lots and sterilization records of packaging material can be traced to finished lots of food product. Sterilization processes for the packaging material should be established by individuals having expert knowledge regarding aseptic processing in accordance with the provisions contained in 7.5.2.3.

8.2 **Record Review and Maintenance**

8.2.1 **General**

The records described in Section 8.1 including recording charts should be identified by date, code lot and other data as necessary, so that they can be correlated with any given lot processed. Each entry on the record should be made and initialed by the processing system operator, or other designated person, at the time the specific condition or operation occurs. Prior to shipment or release for distribution, but not later than one working day after the actual process, a knowledgeable representative of plant management should review and ensure that all records suggested in 8.1 are complete and that the product should be commercially sterile based on these records. The records should be signed or initialed by the person conducting the review.

8.2.2 **Container closure records**

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

8.2.3 **Water quality records**

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

8.2.4 **Distribution of product**

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

8.3 **Retention of Records**

The records specified in 7.4.9, 7.6, 7.7, 8.1 and 8.2 should be retained for a period of not less than 3 years to assist in the investigation of problems when they arise. They should be held in a manner which will permit ready reference.

9.0 SECTION IX - STORAGE AND TRANSPORTATION 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. Processors should recognize that materials and containers used for aseptic packaging may not have the mechanical strength or rigidity of other containers. This may require special handling during such procedures as palletizing (e.g., stacking height, shrink wrapping, pallet overwrapping, etc.) to avoid damage to finished containers which would lead to contamination. 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 incubation conditions for the growth of thermophilic organisms.

9.2 Containers should not be kept at high humidities or at temperatures above 32.2°C (90°F) for a long period. Metals are subject to corrosion and films may become delaminated. Freezing should be avoided.

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 (see 5.7 Pest Control). Rapid temperature changes during storage should be avoided as this may cause the condensation of moist air on the containers and thus lead to corrosion of metal containers.

10.0 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.

10.5 Incubation tests, for example, 10 days at 35°C ± 3.0°C (95°F ±2 5°F) should be conducted on a representative sample of containers of product from each code; records of the test results on each code lot should be maintained, initialed, and passed to management for final signature. These records should be retained and appropriate action taken. Other time/temperature combinations may be chosen by the processor.

11.0 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 methodologies 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 products will be sold.

12.0 SECTION XII - REFERENCES

12.1 Recommended International Code of Hygienic Practice for Low-acid and Acidified Low-acid Canned Foods, CAC/RCP 23-1979.

12.2 References for the Tear-Down Evaluation of a Double Seam, CAC/RCP 23-1979, Appendix III.

12.3 Guidelines for the Salvage of Canned Foods Exposed to Adverse Conditions, CAC/RCP 23-1979 Appendix IV.

12.4 Guideline Procedures to Establish Microbiological Causes of Spoilage in Low-acid and Acidified Canned Foods, CAC/RCP 23-1979, Appendix V.

12.5 Additional information on aseptic processing and packaging may be found in the following publications:

12.5.1 Bernard, D.T., et.al., 1990. Validation of Aseptic Processing and Packaging. Food Technology 44 (12):119-122.

12.5.2 Campden Food and Drink Research Association (CFDRA), 1987, Good Manufacturing Practice Guidelines for the Processing and Aseptic Packaging of Low-Acid Foods (Part I and Part II), CFDRA, Chipping Campden, Gloucestershire, UK.

12.5.3 Elliott, P.H., Evancho, G.M. and Zink, D.C., 1992. Microbiological Evaluation of Low-acid Aseptic Fillers. Food Technology 46 (5):116-122.

12.5.4 Association of Official Analytical Chemists (AOAC), 1989 Flexible Packaging Defects, AOAC, Arlington, Virginia, USA.

12.5.5 Flexible Packaging Integrity Committee. 1989. Flexible Package Integrity Bulletin (41-L), National Food Processors Association, Washington DC, USA.

12.5.6 National Food Processors Association (NFPA), 1990. Automatic Control Guidelines for Aseptic Systems Manufacturers and Companies Using Aseptic Processing and Packaging for Preserving Foods, NFPA, Washington DC, USA.