# CODE OF HYGIENIC PRACTICE FOR REFRIGERATED PACKAGED FOODS WITH EXTENDED SHELF LIFE

## CXC 46-(1999)

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# INTRODUCTION

Refrigerated packaged foods with extended shelf life are foodstuffs that are kept refrigerated to preserve them for more than five days as described in item 2.1 Scope. In general, the heat or other preservation treatments that these products receive is not sufficient to ensure their commercial sterility. Refrigeration is an important hurdle that retards food spoilage and growth of most pathogens. It is the responsibility of the manufacturer to ensure that the product produced is safe throughout its shelf-life, taking into consideration the potential for temperature abuse. This may warrant the use of hurdles to microbial growth in addition to refrigeration.

There are possibilities for temperature abuse during manufacture, storage, distribution, sale, and handling by the consumer. These temperature abuses may allow the growth of pathogenic microorganisms unless additional hurdles are built into the product to prevent potential microbial growth. Moreover, refrigeration alone is not always sufficient to minimize microbiological risk, since some microorganisms are psychrotrophic (grow at refrigeration temperatures), for example, certain strains of Listeria monocytogenes or certain strains Clostridium botulinum, which can grow at temperatures of 4°C or lower. Therefore, in the absence of additional hurdles, there is likelihood that some of these undesirable microorganisms will proliferate at refrigeration temperatures.

There are other potential hazards associated with certain refrigerated foods. For example, with modified atmosphere packaged (MAP) foods, the anaerobic environment limits growth of aerobic microorganisms which compete with pathogenic microorganisms. Since these aerobic microorganisms are limited or do not grow in MAP foods, certain pathogenic microorganisms may proliferate. Aerobic microorganisms are also often the microorganisms that cause product spoilage. Because significant growth of aerobic microorganisms is prevented, MAP products may become unsafe without any visible signs of spoilage if not appropriately refrigerated or in the absence of additional hurdles.

Microbiological hazards can be controlled by a combination of inhibiting factors, called hurdles. These hurdles can assist in retarding or preventing growth of some microorganisms, including pathogenic microorganisms. Some of the hurdles in addition to refrigeration include: decreased pH and aw, and addition of preservatives.

# 1 OBJECTIVES

The purpose of this code is to set out recommendations for processing, packaging, storage and distribution of refrigerated packaged foods with extended shelf-life. Its aim is preventing the outgrowth of pathogenic microorganisms and it is based on the principles of Hazard Analysis and Critical Control Point (HACCP). Section 5.1 of this code discusses the application of HACCP principles to refrigerated packaged foods with extended shelf life. The HACCP approach is described in Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Annex to CXC 1-1969, Rev 3-1997). It should be noted that HACCP is product, process and facility specific.

For refrigerated foods, an important safety hurdle to control microbial growth is refrigeration (for example, +4°C). Any recommendation for specific temperatures should be considered guidelines only. The actual temperatures used will depend upon the requirements for the product, and processes used in terms of safety. However, a wide variety of refrigerated foods also make use of additional hurdles to achieve a synergistic effect for the control of microbial growth. When using the hurdle concept for product development, even where refrigeration is the sole hurdle, the effect of the hurdle(s) on product safety and shelf life should be considered thoroughly. Predictive microbiological models may be used to estimate both the effectiveness of preservation conditions and the effects of modifying product composition and varying handling/storage conditions on safety. Unless scientific evidence previously exists, challenge studies should be conducted to confirm the effectiveness of the chosen hurdle(s) against the pathogen(s) of concern. Such studies, in which specific organisms are inoculated into products, should use the worst case conditions of expected storage and distribution. The results of these studies should be used to determine the appropriate shelf life for the product under consideration.

# 2 SCOPE AND USE OF THE DOCUMENT

## 2.1 SCOPE

This code covers low-acid refrigerated foods that are heat treated[1] and are susceptible to outgrowth of pathogenic microorganisms during their extended shelf-life.

The foods which the provisions of this code addresses are products that:

- are intended to be refrigerated during their shelf life to retard or prevent the proliferation of undesirable microorganisms;
- have an extended shelf life of more than 5 days[2];
- are heat treated or processed using other treatments to reduce their original microbiological population;
- are low acid, that is, with pH > 4.6 and have high water activity aw > 0.92;
- may use hurdles in addition to heat or other treatments and refrigeration, to retard or prevent the proliferation of undesirable microorganisms;
- are packaged, not necessarily hermetically, before or after processing (heat or other preservation treatments);
- may or may not require heating prior to consumption.

Examples of such products are:

- cooked refrigerated ready to eat meals,
- cooked refrigerated ready to eat meats, poultry, seafood and their products, sauces, dips, vegetables, soups, egg products, pasta, ...

This Code excludes: raw foods, frozen foods, low acid canned foods, acid and acidified foods stored at ambient temperature, smoked fish, milk and milk products, yellow fats and fat spreads.

It should be noted that this code is not intended to cover products such as: fermented meats and meat products, cured meats and meat products (including poultry), fermented vegetables, dried and/or salted fish and meats.

In addition, it excludes those food products for which there is a specific Codex Alimentarius Code of Practice. Foods that contain one or more ingredients that are excluded and one or more ingredients that are included are covered by this Code.

## 2.2 USE

This document follows the structure of the Codex International Code of Practice - General Principles of Food Hygiene (CXC 1-1969, Rev. 3-1997) The General Principles of Food Hygiene must be used with this Code. Each section provides recommendations specific to safety of refrigerated packaged foods with extended shelf life.

## 2.3 DEFINITIONS

Refer to the International Code of Practice - General Principles of Food Hygiene.

1 New technology such as microwave heating, ohmic heating, oscillating magnetic field, high hydrostatic pressure, irradiation, etc., may provide equivalent treatment.

2 The Codex Code of Hygienic Practice for Precooked and Cooked Foods in the Mass Catering (CXC 39-1993) should be consulted for foods having a shelf life of 5 days or less.

For purposes of this code, the terms and expressions below are defined as follows:

Container (i.e. primary package): any box, tin, plastic or other receptacle, or wrapper in direct contact with the food product.

Cooling equipment: equipment to reduce a product's temperature.

Filling and sealing: operation consisting of placing a food product in a container and closing it.

Hermetically sealed container: Containers which are designed and intended to protect the contents against the entry of viable microorganisms after closing.

High Risk (HR) Area: An area that requires a high level of hygiene, where the practices concerning personnel, materials, equipment and the environment are managed so as to prevent contamination by pathogenic microorganisms and should be designated and segregated. The HACCP approach will allow the identification of when the use of a High Risk area is necessary.

Hurdle: microbial growth limiting, retarding or preventative factor.

Hurdle technology: the use of a combination of factors to effect control of microbial growth.

Modified atmosphere: atmosphere in a packaged product (vacuum or gas) that differs from the ambient atmosphere.

Packaging: any operation consisting of placing the food in containers (i.e. primary packaging) or placing the food containers in further packaging material.

Packaging material: materials such as cardboard, paper, glass, plastic film, metal, etc., used to manufacture containers or packaging for refrigerated packaged food.

Pasteurization value: the length of time at a given temperature required to obtain a specified level of destruction of a microorganism whose heat resistance characteristics are known.

The heat resistance of a microorganism is characterized by D and z values defined as follows:

D = time (in minutes) to achieve a 90% or one log reduction of a microbiological population at a given temperature;

z = the number of degrees required for the thermal destruction curve to traverse one log cycle (expressed in degrees Celsius or Fahrenheit).

Rapid cooling: lowering the temperature of the food in a way such that the critical zone for microbiological proliferation (60°C -10°C) is passed through as rapidly as possible and the specified temperature is attained.

Refrigerated food: Food which is kept at cold storage temperatures to maintain its safety, quality and suitability, for the intended shelf life.

Refrigerated storage facility: facility designed to keep refrigerated foods at the intended temperature.

Shelf life: The period during which the product maintains its microbiological safety and sensory qualities at a specific storage temperature. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used.

Use-by-date: The date after which the product should not be consumed. It is determined from the date of production, utilizing the product shelf life, building in a margin of safety as determined by the manufacturer.

# 3 PRIMARY PRODUCTION

Refer to the International Code of Practice - General Principles of Food Hygiene.

For recommendations relative to incoming materials see Section 5.3.

# 4 ESTABLISHMENT : DESIGN AND FACILITIES

Refer to the International Code of Practice - General Principles of Food Hygiene.

This section deals with the areas where foods are prepared, cooked, chilled, and stored.

Prevention of contamination calls for every reasonable measure to be taken to avoid direct or indirect contact of food with sources of potential contamination. There should be a strict separation in the plant of the High Risk area(s) from other production area(s).

## 4.1 LOCATION

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 4.2 PREMISES AND ROOMS

### 4.2.1 Design and layout

Refer to the International Code of Practice - General Principles of Food Hygiene.

**In HR areas:**

- High risk areas should be designed to minimize the potential for build-up of contamination and to maximize the ease of cleaning and disinfection.
- To keep raw materials, in-process products and final products in optimal condition and protected from cross-contamination, storage and processing facilities should also follow the principles of "one-way- flow" and "first in, first out" and be equipped to maintain temperature, humidity and ventilation

### 4.2.2 Internal structures and fittings

Refer to the International Code of Practice - General Principles of Food Hygiene.

**In HR areas:**

- entrances should be provided with cleaning and/or changing facilities for shoes and protective clothing, and hand washing and sanitizing stations.
- windows should not be capable of being opened. Doors should be close-fitting and their condition, sitting and use should not compromise food safety.
- where appropriate the premises should be equipped with temperature monitoring and recording devices and a reliable system, to signal loss of control, for example, an audible alarm or blinking light.
- air should be filtered and under positive pressure in locations where foods are handled in order to limit contamination.
- systems for steam removal and humidity control should be effective, hygienically designed and well maintained to minimize condensation or other cross contamination between raw materials and processed products.

### 4.2.3 Temporary/mobile premises and vending machines

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 4.3 EQUIPMENT

### 4.3.1 General

Refer to the International Code of Practice - General Principles of Food Hygiene.

**In HR areas:**

- Equipment used for processing, handling or transport within the HR area should be used solely in this area. No equipment should enter the area without being cleaned and disinfected.
- Equipment used for handling heat-treated products should be solely for this purpose and should be kept separate from equipment used to handle material before heat or other preservation treatments. If reusable trays are used, once they are cleaned and sanitized they should not pass through an area where they may be contaminated unless they are appropriately protected.

### 4.3.2 Food control and monitoring equipment

Refer to the International Code of Practice - General Principles of Food Hygiene.

**In HR areas:**

- All apparatus used should be regularly checked and calibrated according to an established procedure.
- Equipment for processing, thermal or otherwise, should be located so as to prevent cross- contamination between raw materials and processed products.
- All processing apparatus, thermal or otherwise, should be designed to be hygienic and should be provided with suitable instrumentation.

### 4.3.3 Containers for waste and inedible substances

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 4.4 FACILITIES

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 4.4.1 Water supply

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 4.4.2 Drainage and waste disposal

Refer to the International Code of Practice - General Principles of Food Hygiene.

**In HR areas:**

- Drainage from HR areas should flow directly to a main drain via suitable traps to prevent back flow. Drainage from other areas should not flow via HR area drains.

- Waste water from refrigeration equipment, installations for hand washing and machinery should be piped to the drainage system so as to minimize contamination of products. Particular attention should be paid to splashing and/or aerosol from these sources.

### 4.4.3 Cleaning

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 4.4.4 Personnel hygiene facilities and toilets

Refer to the International Code of Practice - General Principles of Food Hygiene.

#### 4.4.4.1 Cloakrooms and toilets

Cloakroom and toilets should not open directly into any food handling areas.

#### 4.4.4.2 Processing areas

For hand disinfection stations, it is preferable to have taps that do not require hand operation.

### 4.4.5 Temperature control

Refer to the International Code of Practice - General Principles of Food Hygiene.

The plant should be designed and equipped in such a way that the interior temperature is compatible with keeping products at a temperature that controls proliferation of microorganisms during the various operations, regardless of the outside temperature.

#### 4.4.5.1 Refrigeration facilities

All refrigerated rooms should have devices to monitor and record the temperature and a reliable system, such as an audible or visual alarm, to signal loss of control. These monitoring devices should be clearly visible and placed so that the maximum temperature in the refrigerated area is recorded as accurately as possible.

#### 4.4.5.2 Cooling facilities

Establishments should also have rooms or equipment which permit rapid cooling methods to be used, as well as refrigerated storage for a quantity of prepared food equal at least to the maximum daily production of the establishment.

Choice of cooling equipment depends on the products being processed. Their characteristics, (cooling capacity, etc.) should be selected based on the quantities of products produced in order to allow for:

- refrigeration without delay after the heat treatment, as soon as the internal temperature reaches 60°C and
- an even temperature distribution in the batch when it is cooled.

**In HR areas:**

- Rapid chilling of cooked products (not filled and sealed) should be in a room and/or equipment that is designed and operated to prevent contamination.

### 4.4.6 Air quality and ventilation

Refer to the International Code of Practice - General Principles of Food Hygiene.

**In HR areas:**

- The air supplying the premises should be treated to remove dust.
- The ventilation system should be designed and used so as to prevent condensation and circulation of dust.
- Air in HR areas should be filtered and kept under positive pressure.

### 4.4.7 Lighting

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 4.4.8 Storage

Refer to the International Code of Practice - General Principles of Food Hygiene.

# 5 CONTROL OF OPERATION

Refer to the International Code of Practice - General Principles of Food Hygiene.

Refrigerated packaged foods are manufactured using a wide variety of raw materials, process technologies and types of packaging. Biological, chemical and physical hazards may vary significantly from one product to another. Each product type has its specific shelf life that the manufacturer determines based on scientific data.

In each production establishment, it is necessary to define the particular procedures that allow product safety to be ensured, with consideration given to conditions specific to the plant (raw materials, environment, processing techniques, organization of labour, etc.) and product characteristics. The application of HACCP principles is the system recommended for development of theses procedures for a specified product in a specific plant.

The overall responsibility for all measures planned to ensure the safety of the product should be designated to qualified personnel.

## 5.1 CONTROL OF FOOD HAZARDS

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 5.1.1 Application of the HACCP Principles

The processor should apply HACCP principles as described in Codex the Hazard Analysis Critical Control Point System and Guidelines for its Application (annex to CXC 1-1969, Rev. 3-1997) for all existing product types, and for new product design and development.

Specific hazards associated with food production/storage, and the control measures should be identified. Further, it is necessary to determine the operational steps that can be controlled to eliminate hazards or to minimize the probability that they will arise, to establish critical limits and a monitoring system to ensure their control, and to establish corrective action to be taken when deviations occur and procedures for verification to demonstrate that the control method is appropriate. Effective record keeping procedures need to be specified and maintained.

The manufacturer will find in the following sections additional information that would be useful to facilitate HACCP plan development. Moreover, it is very important to establish the shelf life of the product, using scientific data, taking into account the scheduled heat or other preservation treatments, the use of hurdles and anticipated distribution and storage temperatures.

### 5.1.2 Consideration of design elements

Product shelf life, scheduled heat or other preservation treatments, hurdles, and cooling methods should be established according to scientific and technological methods. This requires qualified, knowledgeable and experienced personnel having access to adequate information, facilities and equipment.

The HACCP approach will allow the identification of when the use of High Risk area is necessary.

#### 5.1.2.1 Determination of product shelf life

Product shelf life depends on a number of factors, such as:

- product formulation (might include decreased pH, decreased aw, other hurdles - see Appendix );
- scheduled heat or other preservation treatments;
- cooling methods applied to product;
- type of packaging (e.g., hermetically sealed or not, MAP);
- storage temperature;
- other hurdles.

### 5.1.2.2 Development of scheduled heat or other treatments

The scheduled heat or other treatment should at least produce the desired log reduction of target microorganism(s) to achieve the desired level of safety. It is calculated for the coldest point of the product during treatment. It should take into account the worst-case scenario with regard to type of contamination, microbial load and transfer of heat in products, such as frozen raw materials or large pieces of food.

During the establishment of the scheduled heat or other treatments, the following factors should be taken into account:

- type and maximum number of microorganisms in raw materials;
- any potential for growth before heat treatment;
- desired number of log reduction of target microorganism(s);
- temperature of product before heat treatment begins;
- amount of heat required to bring the product to the desired level of safety;
- temperature distribution in heat treatment vessel;
- composition (solid to liquid ratio) and consistency (viscosity) affecting rate of heat penetration;
- type of product or container that can lead to stratification of product during heating or to a change in dimensions of container during heating;
- size of container, type of material, weight of individual portion and maximum weight for filling;
- recommended cooking by end-user before consumption (as long as the cooking temperature results in a reduction of microorganisms of public health significance).

When changes in the composition, processing and use of the product are proposed, the necessary changes to the scheduled heat treatment should be established and validated by a qualified person.

Other treatments (e.g. microwave heating, ohmic heating, oscillating magnetic field, high hydrostatic pressure, irradiation, etc.) to achieve the required reduction of the target microorganism(s) may be used, if approved for use by the regulatory agency having jurisdiction, where required.

### 5.1.2.3 Development of Cooling Method

For these products, the intention of cooling is to achieve the specified storage temperature throughout the product as soon as possible to minimize the growth of foodborne pathogens. The cooling should be carried out so that the product reaches the specified temperature as quickly as possible. Products should be cooled so that their temperature remains for a minimum of time between 60°C and 10°C, the temperature range most favourable for microbiological proliferation. When feasible, it is recommended to bring the temperature at the centre of the product to under 10°C in two hours or less.

Alternative cooling procedures may be used provided that they are consistent with maintaining food safety and based on scientific evidence.

Factors to be taken into account in the establishment of the cooling method can include:

- temperature of product before cooling begins;
- temperature of cooling medium, circulation and temperature distribution in cooling system;
- time of cooling especially for products conveyed through cooling equipment;
- composition (solid to liquid ratio) and consistency (viscosity) affecting rate of cooling;
- size of container, type of material, weight of individual portion and maximum weight for filling;
- other packaging material affecting the rate of cooling,
- capacity/effectiveness of cooling equipment.

#### 5.1.2.4 Other Hurdles

The intention of using other hurdles is to prevent or restrict the growth of target pathogen(s) in the food.

Studies should be conducted to validate the effectiveness of the use of hurdles in product formulation that inhibit or minimize multiplication of pathogens and the synergy of these factors. See Appendix I for more information. Use of predictive microbiological modelling may assist in the design of the challenge studies.

When one or more hurdles are used in combination with heat or other preservation treatments, the critical limits need to be specified and met. Critical limits should be measured, checked and recorded as necessary.

## 5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

### 5.2.1 Time and temperature control

Refer to the International Code of Practice - General Principles of Food Hygiene.

In all steps of processing, critical temperatures for multiplication of microorganisms (10°C to 60°C) should be avoided or in any case passed through rapidly.

If there are delays in manufacture, perishable raw materials and in-process products must be maintained at a temperature which minimizes bacterial growth. This can be achieved by placing the product quickly into refrigerated storage areas and kept at the specified temperature or else kept at ♍60°C until normal production is resumed.

**In HR areas:**

- If the air temperature has been determined to be critical and is exceeded, the manufacturer should evaluate the product's safety and take appropriate action.

#### 5.2.1.1 Thawing

When total or partial thawing is necessary, the thawing procedures should be defined in terms of time and temperature and strictly controlled by the manufacturer. The time and temperature parameters should be selected so as to avoid conditions favourable for multiplication of microorganisms.

After thawing, raw materials should immediately be processed or held at the specified refrigerated temperature until they are used. When a microwave oven is used, manufacturer's instructions should be followed to prevent overheated areas and uneven thawing.

#### 5.2.1.2 Heat and other treatments

Heat and other treatments result in a reduction of microbiological population. The lethality of heat or other treatment should be quantified. Pasteurization values or lethal rate values can be used to calculate lethality of a heat or other treatment.

The application of the scheduled heat and other treatments should be carried out by competent, specially trained personnel.

Delivery of the heat or other treatments can be monitored by measuring the time-temperature relationship of:

- the product itself during treatment;
- or the heating medium in which the food is placed (hot water, sauce, air in oven, etc.) so as to reach the prescribed time-temperature relationship at the product's coldest point.

Equipment for heating or other treatment used to control a hazard should have devices for monitoring and recording temperature and time. The temperature monitoring and recording equipment should be checked at regular intervals against a known accurate standard and adjusted, repaired or replaced.

Heat-sensitive indicators, or other effective means, to indicate whether the products have been heat-treated should be used.

It is critical to ensure that the scheduled process is applied.

The factors which were taken into consideration for the development of the scheduled process (cf. 5.1.2.2) should be controlled and recorded, as necessary.

#### 5.2.1.3 Cooling

Delivery of the cooling can be monitored by measuring the time-temperature relationship of:

- the product itself during treatment; or
- the cooling medium in which the food is placed (e.g. cold water, cold air) so as to reach the prescribed time-temperature relationship at the product's warmest point.

Cooling equipment used to control a hazard should have devices for monitoring and records should be maintained for temperature and time as necessary. The temperature monitoring and recording equipment should be checked at regular intervals against a known accurate standard and adjusted, repaired or replaced. It is critical to ensure that the cooling applied conforms to the method specified.

### 5.2.1.4 Maintaining the cold chain

In order to ensure that safety and quality of the product are maintained during its stated shelf life, it is essential that it be kept continuously cold from the time it is packaged until it is consumed or prepared for consumption. The storage temperature should be that which will maintain product safety for the intended shelf-life of the product. If the temperature of the product is the principal means of preservation, that product should be kept at a temperature as low as possible. In any case, validation of the selected temperature must be carried out.

In addition, storage temperature may be required to meet criteria established or recognized by the agency having jurisdiction where the food is destined for consumption:

- if the temperature set out in the regulations is less than the temperature used to establish the shelf life, the temperature as per the regulations needs to be met and the shelf-life eventually re- evaluated accordingly;
- if the temperature set out in the regulations is greater than the temperature used to establish the shelf life, and the manufacturer wants to keep the same shelf life, then the manufacturer must ensure the temperature used during the shelf life determination is met. If the temperature used for shelf life determination is not met, the shelf life needs to be re-evaluated.

In the course of these successive stages, there should be adequate stock rotation, based on the principle of "first in, first out".

Regular and effective monitoring of temperatures of storage areas, transport vehicles and store display cases should be carried out:

- where the product is stored, and
- within the product load, which could be done by using temperature indicating and recording systems.

This monitoring should take place, in particular, when the transport vehicle is loaded or unloaded.

Particular attention should be paid throughout storage and distribution :

- to periods of defrosting of refrigeration units;
- to temperature abuse;
- to overloading the cold storage facility; and
- to anything that could damage the containers and/or packaging material.

Storage areas should conform to applicable requirements in paragraph 4.4.5.1.

Products should not be stacked higher than the maximum level indicated in display cases or in front of air ducts or too close to heat generating lamps; there should be good circulation of cold air. Products that have reached the prescribed use-by-date or are spoiled or have damaged container should be removed from the display case, and not offered for sale.

In case of breakdown of the refrigeration unit of the display case, the products should be moved to another case or to a cold room. If the breakdown of the refrigeration unit of the display case takes place when the establishment is closed, temperature of the products should be checked. If acceptable, the products should be moved to a suitable area; if not, they should be removed from the case, not offered for sale, and destroyed if necessary.

### 5.2.2 Specific process steps

Refer to the International Code of Practice - General principles of Food Hygiene.

### 5.2.3 Microbiological and other specifications

Refer to the International Code of Practice - General principles of Food Hygiene.

### 5.2.4 Microbiological cross contamination

Refer to the International Code of Practice - General principles of Food Hygiene.

**In HR areas:**

- This area should be maintained at a high level of hygiene, and the practices concerning personnel, materials, equipment and environment managed so as to prevent contamination from pathogenic microorganisms.

### 5.2.5 Physical and chemical contamination

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 5.3 INCOMING MATERIAL REQUIREMENTS

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 5.3.1 Specifications for raw materials and packaging materials

Raw material specifications, including specifications for the materials used in the hurdles (see Appendix) and for the packaging materials should be determined through application of HACCP principles and validated during the design phase. Supplier specifications may cover labelling, packaging materials, conditions for transport and storage, as well as the sensory, physical, chemical, parasitological and microbiological characteristics of delivered goods. Measures to ensure compliance with specifications should be identified in the specifications manual.

Packaging materials should be suitable for the type of product, the conditions provided for storage and the equipment for filling, sealing and packaging, as well as transportation conditions.

### 5.3.2 Receipt of raw materials and packaging materials

Refer to the International Code of Practice - General Principles of Food Hygiene.

If the raw materials, ingredients and packaging materials do not conform to the specifications when goods are delivered, trained personnel should decide whether the raw materials should be immediately used for manufacture, stored for a limited period, returned to supplier, used in another way or discarded. Unacceptable raw materials and ingredients should be stored separately from raw materials and ingredients used for manufacture of refrigerated foods. Discarded raw materials should be clearly marked so as to identify them as unusable for manufacture of products.

### 5.3.3 Storage of raw materials and packaging materials

Raw materials should be stored in a suitable area as quickly as possible after delivery. Raw materials should be stored so that contamination of in-process or final products or packaging materials is prevented. R aw materials and ingredients stored within the establishment should be kept at conditions designed to prevent their spoilage, protect them from contamination by microorganisms, insects, rodents, foreign bodies and chemical products and minimize possible damage. They should be used in manufacture as soon as possible after delivery.

Raw materials that are subject to spoilage should be placed without delay in cold storage at the appropriate temperature.

There should be documented procedures specifying necessary action to be taken in case of deviation at a Critical Control Point (CCP).

All packaging materials should be stored in satisfactorily clean and hygienic conditions.

Non-edible materials, such as cleaning compounds, should be received and stored in separate locations, away from packaging materials and ingredients. Non-edible materials should not pass through or remain in processing areas during processing. All non-edible materials should be labelled clearly and distinctly so improper use is prevented.

There should be suitable rotation of stock of raw materials "first in, first out". To achieve this, all lots of raw materials should be coded and an appropriate procedure for stock management should be used. Appropriate documentation of stock rotation should be kept.

## 5.4 PACKAGING

Refer to the International Code of Practice - General Principles of Food Hygiene.

There may be a need to provide a method for cleaning and disinfecting containers before use, especially if there is no heat or other preservation treatments after filling and sealing.

Filling and sealing should be done so as to limit the potential for contamination (with consideration for technical constraints such as slicing, assembly, etc.). For cooled product, the ambient temperature should be controlled so as to maintain the product at the

appropriate temperature. Any increase in temperature of the product during these operations should be avoided.

It is necessary to periodically check the integrity of the seal.

When necessary, some characteristics of packaging materials should be checked. It may be necessary to carry out visual examination and physical testing in order to measure their properties (maintaining a vacuum or the modified atmosphere in the container), and their resistance to mechanical, chemical and thermal stress encountered in the course of the product's shelf life.

### 5.5 WATER

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 5.6 MANAGEMENT AND SUPERVISION

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 5.7 DOCUMENTATION AND RECORDS

Refer to the International Code of Practice - General Principles of Food Hygiene.

Sufficient information should be available to demonstrate control at the critical control points. Such information may include:

- Procedures, data and calculations utilized in the establishment of the scheduled heat or other preservation treatments and cooling methods;
- If applicable, procedures, data and records establishing the efficacy of hurdles to maintain the microbiological safety of the product for the intended shelf life;
- Procedures, data and records relevant to the establishment of the shelf life of the product;
- Any modifications of the product, processing or in other factors (refer to Section 5.1.2.2) used in establishing the scheduled heat or other treatments;
- Records documenting the HACCP plan (including the hazard analysis and critical control points);
- Records of process monitoring at Critical Control Points as determined in the HACCP plan.

### 5.8 RECALL PROCEDURES

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 6 ESTABLISHMENT: MAINTENANCE AND SANITATION

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 6.1 MAINTENANCE AND CLEANING

Maintenance procedures and schedules should be established and followed especially for equipment used for thermal processing, refrigeration, cooling equipment and ventilation systems, and their controls.

### 6.1.1 General

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 6.1.2 Cleaning procedures and methods

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 6.2 CLEANING PROGRAMMES

Refer to the International Code of Practice - General Principles of Food Hygiene.

Equipment, materials, utensils etc. which come in contact with foods must be cleaned and where necessary disinfected. They may have to be taken apart at frequent intervals during the day, if necessary, at least after each break and when there is a change from one food to another. The cleaning and disinfecting should be carried out at the end of the working day and equipment dismantled when necessary to prevent microbiological proliferation.

All staff assigned to cleaning the establishment should be experienced in sanitation maintenance methods and should verify that proper methods have been used and recorded.

**In HR areas:**

- Cleaning equipment which may cause cross-contamination such as high-pressure spray cleaning equipment should not be used to clean drains or other surfaces without subsequent disinfection of the whole area and its use should be avoided during production periods.

## 6.3 PEST CONTROL SYSTEMS

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 6.4 WASTE MANAGEMENT

Refer to the International Code of Practice - General Principles of Food Hygiene.

Waste matter should be placed in receptacles specially designed and marked for this use. Receptacles should be kept in good condition and be easy to clean and sanitize. Reusable receptacles should be cleaned and disinfected before they are brought back into the processing areas.

### 6.5 MONITORING EFFECTIVENESS

Refer to the International Code of Practice - General Principles of Food Hygiene.

**For HR areas:**

- Environmental sampling for relevant microorganisms is recommended and appropriate corrective action taken when necessary.

## 7 ESTABLISHMENT: PERSONAL HYGIENE

Refer to the International Code of Practice - General principles of Food Hygiene.

### 7.1 HEALTH STATUS

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 7.2 ILLNESS AND INJURIES

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 7.3 PERSONAL CLEANLINESS

Refer to the International Code of Practice - General Principles of Food Hygiene.

Protective clothing should be changed frequently.

**In HR areas:**

- Personnel (including sanitation and service staff) working in HR areas should change into work uniforms in a specific room.
- They should wear protective clothing and footwear specific to the area.
- These clothes and footwear should not be removed from this area (except for laundering) and should be taken off in the cloakroom when personnel leave the production line for any reason.
- Clean clothing should be worn at the beginning of the work day and should be changed at the end of the work day, shift or more frequently if needed.
- Footwear should be suitably cleaned and sanitized.
- When gloves are used for handling foods, they should be sturdy, clean and hygienic. Gloves should be manufactured from non porous non absorbent material. Wearing gloves does not eliminate the need to carefully wash hands. Gloves should be disposable and changed as often as necessary or should be reusable and disinfected as often as necessary.

### 7.4 PERSONAL BEHAVIOUR

Refer to the International Code of Practice - General Principles of Food Hygiene.

Management should put in place a plan for movement of personnel, and also for visitors, to reduce the potential for cross-contamination. A system of colour coding may be used to identify personnel assigned to different areas of the plant.

### 7.5 VISITORS

Refer to the International Code of Practice - General Principles of Food Hygiene.

**In HR areas:**

- Visitors should be subjected to the same requirements for hygiene as employees.

## 8 TRANSPORTATION

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 8.1 GENERAL

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 8.2 REQUIREMENTS

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 8.3 USE AND MAINTENANCE

Refer to the International Code of Practice - General Principles of Food Hygiene.

The vehicle should be cooled prior to loading. Doors should be kept open for as short a time as possible. If there is an extended delay in the loading of the vehicle, the vehicle doors should be shut to maintain the cool temperature.

Transfer to cold storage or store display cases should be made as quickly as possible after unloading.

## 9 PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 9.1 LOT IDENTIFICATION

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 9.2 PRODUCT INFORMATION

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 9.3 LABELLING

Refer to the International Code of Practice - General Principles of Food Hygiene.

Labels should conform to the requirements of the official agency having jurisdiction. They should provide the following information:

- use-by-date;
- a statement regarding the need for refrigeration, e.g. "keep refrigerated at (required temperature) or less".

### 9.4 CONSUMER EDUCATION

Refer to the International Code of Practice - General Principles of Food Hygiene.

## 10 TRAINING

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 10.1 AWARENESS AND RESPONSIBILITIES

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 10.2 TRAINING PROGRAMMES

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 10.3 INSTRUCTION AND SUPERVISION

Refer to the International Code of Practice - General Principles of Food Hygiene.

### 10.4 REFRESHER TRAINING

Refer to the International Code of Practice - General Principles of Food Hygiene.

# APPENDIX – HURDLES

Microbial growth is dependent upon many environmental conditions such as: ingredients, nutrients, water activity, pH, presence of preservatives (e.g., curing salts), competitive microorganisms, gas atmosphere, redox potential, storage temperature and time. Control of these conditions can therefore be used to limit microbial growth.

The intention of using hurdles is to prevent or restrict the growth of target pathogen(s) in the food. For refrigerated foods, an important safety hurdle to control microbial growth is refrigeration A wide variety of refrigerated foods also make use of additional hurdles to control microbial growth.

To ensure the safety of refrigerated packaged foods having an extended shelf life, often more than one hurdle is used to control microbial growth, to inhibit spoilage and to prevent foodborne disease. Suitable combinations of hurdles can be devised so that the organisms of concern can no longer grow/survive in the product. The presence of a number of hurdles inhibiting or eliminating microorganisms may be synergistic. Therefore it may require less of each hurdle to control growth than would be expected by considering the effect of each individual hurdle.

When using the hurdle concept for product development, the effect of the hurdle(s) on product safety and shelf life should be considered thoroughly. For example, a certain type of modified atmosphere might inhibit the growth of spoilage organisms in refrigerated food. The growth of these microorganisms, which could inhibit toxin production or act as an indicator of poor storage conditions, is limited. Therefore the extension of the product's shelf life may lead to the growth of pathogenic microorganisms without any signs of spoilage.

Examples of hurdles, other than refrigeration, are:

### a) Water activity

Microorganisms vary in their ability to grow at reduced levels of aw and will be inhibited as the available water is reduced. A reduction of water activity can suppress the growth of pathogenic bacteria, particularly at low temperatures. Note that vegetative cells may show increased heat resistance at lower water activities.

### b) pH

Microorganisms vary in their ability to grow at reduced pH. A reduction in pH can suppress the growth of pathogenic bacteria. Note that microorganisms show decreased heat resistance at lower pH.

To illustrate these concepts, if a refrigerated food is to be packed in a reduced oxygen atmosphere and has a shelf life longer than 10 days, it is necessary to assess the potential risk from psychrotrophic strains of Clostridium botulinum and, if necessary, to control these strains through the appropriate use of hurdles in combination with a heat process, if the heat process is not equivalent to 90°C for 10 minutes. Examples of hurdles are:

- adjust water activity (aW) to below 0.97;
- increase acidity by lowering pH below 5.0;
- add sodium chloride to 5% in brine;
- use combinations of water activity, pH, modified atmosphere, storage temperature etc. that demonstrably will inhibit the growth of psychrotrophic strains of Clostridium botulinum within the shelf life and expected storage conditions.

Predictive models may be used to estimate both the effectiveness of preservation conditions and the effects of modifying product composition and varying handling/storage conditions on safety. Unless scientific evidence previously exists, challenge studies should be conducted to confirm the effectiveness of the chosen hurdles against the pathogen(s) of concern. Such studies, in which specific organisms are inoculated into products prior to storage, should use the worst case conditions of expected storage and distribution. It is advisable that scientific advice be sought.