General Principles of Food Hygiene

Code of Practice

First Edition

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Canadian Food Inspection System Implementation Group

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PREFACE

CODE OF PRACTICE
GENERAL PRINCIPLES OF FOOD HYGIENE

Introduction

Effective hygiene controls are vital to prevent the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage.

The Canadian Code of Practice - General Principles of Food Hygiene provides a firm foundation for good manufacturing and hygienic practices to be applied by the food industry in Canada. The Code includes the key controls necessary for manufacturers to control the safety and suitability of food during manufacturing or processing.

The Canadian Code is based on the Recommended International Code of Practice - General Principles of Food Hygiene adopted by the Codex Alimentarius Commission in 1969 and revised in 1997. This is consistent with the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures that directs Members to base their sanitary and phytosanitary measures on international standards, guidelines and recommendations. For food safety, the international standards, guidelines and recommendations established by the Codex Alimentarius Commission are recognized under the SPS Agreement and include Codex codes and guidelines of hygienic practice.
The Codex, Code of Practice-General Principles of Food Hygiene can be found at: http://www.codexalimentarius.net/standard_list.asp

Scope

The Code is not meant to take precedence over Federal, Provincial/Territorial or municipally based legislation. In the case of shared jurisdictions, ie., Federal - Provincial, it may be used as the basis for a common inspection strategy.

The Code is generic in nature and the principles found herein may be applied to all food processing or manufacturing establishments regardless of size or food products produced. It is anticipated that Provincial/Territorial and other governmental jurisdictions may use the code as a primary reference document.

The Canadian Food Inspection Agency (CFIA) will utilize this Code to assist in assessing compliance with requirements under the *Food and Drugs Act and Regulations* for establishments not specifically regulated under federal trade and commerce legislation i.e., *Meat Inspection Act, Fish Inspection Act, and Canada Agriculture Products Act.*

It is recognized that additional guidance may be needed to amplify the hygiene requirements associated with specific products or manufacturing processes and this guidance will be developed as needs are identified.

Each chapter of the Code includes sections and sub-sections describing specific

requirements. Numbers appearing after each section refer to section numbers of the Codex Code. Each sub-section includes a principle statement, rationale, and assessment criteria.

Although the Code is not meant to serve as a Hazard Analysis Critical Control Point (HACCP) plan, it could be used as a reference in the development of such food safety system. Additional reference material for use in the development of HACCP isnpection systems can be found on the CFIA website at: http://www.inspection.gc.ca

Principle Statement

Principle statements are outcome based generic statements of the objectives to be achieved and are similar to those found in the Codex Code. They are intended to capture the objective while allowing flexibility to address specific products or processes.

Rationale

Rationale included in the control of operation, equipment and record chapters of the Code explain the nature of the concern or potential hazard(s) and the need for their control. Only where the principle statement is not self explanatory, a rationale is added.

Assessment Criteria

Assessment criteria included in the Code provide information on the factors that may be considered in assessing adherence to the objectives of the principle statements of the Code. These will be assessed by the CFIA during the course of its risk-based investigation or inspection activities in the non-federally registered sector.

1.0 CONTROL OF OPERATION (5.) *

1.1 PRODUCT FORMULATION (5.1) *

1.1.1 Product Formulae

Current written formulae are available for each product processed.

Rationale
Current written formulae provide a basis for assessment of food additives, composition, labelling, nutritional requirements, food allergens and the scheduled process.
NOTE: Master formulae include the related documentation.

Assessment Criteria
- written formulae are available for each product.
- The formulae contain all details of the formulation as follows:
  - identification of specific ingredients and additives (e.g. concentration, type);
  - amounts of additives and ingredients.
- The formulae are current for the products being processed.

1.1.2 Factors Critical to Processing in Product Formulation

Any factors in the product formulation that are critical to the delivery of a safe process are identified.

Rationale
Inadequate identification of critical ingredients and their specifications or critical preparation/process steps may indicate lack of awareness or control of critical factors that could result in an inadequate process.

Assessment Criteria
- Ingredients critical to process safety are identified with their specifications and limits.
- Process and preparation steps critical to the safety of the finished product are identified with their critical factors.

1.1.3 Food Additives

Food additives are controlled to meet the requirements of the *Food and Drugs Act and Regulations*.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Rationale
Inadequate control of food additives could result in chemical or biological hazards.

Assessment Criteria
- The manufacturer ensures that all food additives used are permitted for use in the particular food and meet the requirements of the *Food and Drug Regulations*.
- The manufacturer has specifications for all food additives.
- Where there are no grade requirements in the *Food and Drugs Act and Regulations*, the manufacturer requires that all food additives be Food Chemical Codex (FCC) grade or equivalent e.g. specification sheets, clear identification of the grade on the additive package, or blanket guarantees.
- The manufacturer has verified and can demonstrate through calculations that food additives are used within the maximum level specified in the *Food and Drug Regulations*.

1.1.4 Nutritional Requirements

The addition of nutrients to food products is controlled to meet the requirements of the *Food and Drugs Act and Regulations* and controls are in place to ensure that products meet Canadian regulatory nutritional requirements and Canadian nutrition labelling requirements.

Rationale
The manufacturer has control over the formulation to ensure that all nutritional requirements and claims are met. Formulation controls are necessary to prevent hazards which could result from excesses, inadequacies and omissions of nutrients, e.g. special dietary foods, infant formulae, meal replacements, fortified foods and foods for which there are nutritional claims (e.g. calorie-reduced, low sodium). Nutrition labelling provides consumers with the information necessary to make informed choice towards healthy eating goals.

Assessment Criteria
- Nutrients used are permitted and in accordance with the *Food and Drug Regulations*.
- The nutrient content of the product is accurately reflected on the label and in compliance with the *Food and Drug Act and Regulations* (list of ingredients and Nutrition Information Panel or Canadian "Nutrition Facts" table).
- The manufacturer has specifications for nutrients.
- The manufacturer has received certification from the supplier as follows:
  - a certificate of analysis accompanies each lot of nutrient;
  - for nutrients used in foods that are the sole source of nutrition, each certificate is verified through analysis;
  - for nutrients used in foods for which there are nutrient content claims and health claims meet the Canadian compositional and labelling requirements under the *Food and Drug Regulations* for those claims (see Guide to Food Labelling and

Advertising) and the manufacturer verifies, as often as necessary, that the nutrition information table is accurate and within tolerance.

- The manufacturer has verified through testing and can demonstrate through calculations that nutrients are used within the limits specified in the *Food and Drug Regulations*.

1.1.5 Label Accuracy

The manufacturer ensures that the label information is complete, meets the applicable requirements of the *Food and Drugs Act and Regulations*.

Rationale
Accurate labels inform and protect segments of the population which may be allergic to certain foods, or have specific dietary needs. Controls are necessary to ensure that the label is in compliance and that the information is accurate and does not mislead the consumers as to the product composition.

Assessment Criteria
Procedures are in place to ensure that labels accurately represent product formulation and composition. The following are examples of such procedures:
- new label development and verification;
- incoming label review;
- review and approval of formulation changes/substitutions;
- accuracy/correctness of information/order of ingredients.

NOTE: The Letter dated March 31, 1998, to food manufacturers, importers, distributors and their associations on Labelling of Food Causing Allergies and Sensitivities lists the allergens to be assessed. The letter can be found on the CFIA Website: www.inspection.gc.ca.

1.2 PROCESS DESIGN (5.2)*

1.2.1 Process Design

The manufacturer demonstrates the process is designed in a manner to ensure the safety of the product.

Rationale
Written verification is necessary to demonstrate that each process used is adequate to ensure a safe product. An inadequate process could result in the lack of control of pathogenic organisms, toxins and other hazards.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Assessment Criteria

- For every product, a written description of the process, including procedures, is available upon request.
- The process is established using accepted scientific methods. Details of actual experimental methods are available.
- All critical control points (CCP) for each product, including the critical limits for each CCP are identified, tested and evaluated in the development of the process.

NOTE: The degree of testing and evaluation required is relative to the risk of the operation.

- Any changes to the product formulation or the process are assessed to ensure there is no impact on the safety or composition of the product.

See subsection 7.2.1 for expected process design records

7.2.1 Process Design Records

Records are available to demonstrate the adequacy of procedures and methods used in process development.

Rationale

Absent or inadequate records do not permit verification that critical factors and critical limits are adequate to produce a safe product.

Assessment Criteria

- Records are available upon request to verify that reliable procedures have been followed in designing the process.

1.3 INCOMING MATERIAL CONTROL (5.3)*

1.3.1 Ingredients

The manufacturer controls incoming ingredients such that no biological, physical or chemical hazards result in the food and to prevent labelling inaccuracies.

Rationale

Prevention of health hazards begins with control of incoming materials. Inadequate incoming ingredient controls could result in product contamination, inadequate processing, or misrepresentation of the product. **NOTE:** The degree of control exercised is appropriate to the level of risk posed by the ingredient to the safety or compositional integrity of the food.

Assessment Criteria

The manufacturer controls incoming ingredients through one of the following programs or equivalent.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

The first three options apply to ingredients that may be critical factors where further processing is not likely to eliminate a hazard. The fourth option applies to ingredients that are not likely to impact on the safety of the food.

Note: Specifications for food additives and nutrients are assessed in subsections 1.1.3 and 1.1.4.

OPTION 1 ***Periodic Evaluation of Incoming Ingredients***

- The manufacturer has written specifications and ensures that all components of the ingredients are declared to the exception of components exempted under the *Food and Drug Regulations*.
- Purchasing specifications include a provision for compliance with the *Food and Drugs Act and Regulations*.
- The manufacturer obtains a certificate of analysis for each lot.
- A representative sample is taken and analysed to verify the accuracy of the certificates of analysis at a scheduled frequency, e.g. monthly.
- The manufacturer maintains a documented history of adherence to specifications for each supplier, e.g. analytical results.
- A new history of adherence to specifications is established when a manufacturer changes suppliers, purchases ingredients from a new supplier, purchases a new ingredient from an existing supplier or when the manufacturer's sample results do not agree with the certificate of analysis.

OPTION 2 ***100% Lots Inspected***

- The manufacturer has written specifications and ensures that all components of the ingredients are declared.
- Each incoming lot is sampled according to a pre-determined sampling plan and analyzed for adherence to specifications.

OPTION 3 ***Vendor Certification***

When the manufacturer relies on vendor certification the following minimum requirements are in place:

- The manufacturer has written specifications and ensures that all components of the ingredients are declared.
- The manufacturer has documentation to demonstrate adequate knowledge of the supplier's process. This may include, for example: process flow charts, on site evaluations, identification of critical control points, specifications, control limits, monitoring programs and frequencies, corrective action and verification procedures.
- The manufacturer has data to demonstrate the capability of the supplier's process to consistently manufacture within specifications. This may include process capability studies. Statistical process control charts for each critical control point must be available upon request from each supplier.
- Prior to implementation of a periodic monitoring program, the manufacturer analyzes an appropriate number of consecutive lots to establish an historical data base and confirm adherence to specifications.
- The manufacturer conducts periodic monitoring to verify adherence to specifications, e.g. annually.
- The manufacturer conducts vendor audits to validate the status of the vendor certification program.

OPTION 4 ***Specification Requirements***

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Where incoming ingredients are not likely to impact on the safety of the food:

- The manufacturer has written specifications and ensures that all components of the ingredients are declared.
- Purchasing specifications include a provision for compliance with the *Food and Drugs Act and Regulations*.
- The manufacturer conducts periodic monitoring to verify adherence to specifications, e.g. annually, or obtains a certificate of analysis.

Non-Conforming Ingredients

- When ingredients are found not to meet specifications, the manufacturer investigates and identifies the root cause. If the ingredients do not meet specifications but have not been used, it is not considered a deviation. However, if it is possible that ingredients not meeting specifications have been used, the manufacturer initiates corrective action as per section 1.9, Deviations and Corrective Action.

1.3.2 Packaging Materials

The manufacturer controls incoming packaging materials to meet the requirements of the *Food and Drugs Act and Regulations* and such that no biological, physical, or chemical hazards result in the food.

Rationale

Controls are necessary to ensure that packaging materials meet the manufacturer's specifications. Inadequate controls could result in the use of containers that may contaminate or permit contamination of the product with physical, chemical or biological hazards.

Assessment Criteria

- The manufacturer demonstrates that the packaging material is suitable for the use intended. The suitability of packaging material will vary with the product and process and the associated contamination risks.
- The manufacturer has written specifications for packaging materials:
  - physical dimensions;
  - material specifications;
  - performance specifications.

  NOTE: Additional requirements for evaluation of incoming packaging materials will depend on product type, process, and product sensitivity.
- The manufacturer controls packaging materials through one of the following programs or equivalent.

  The first three options apply to packaging associated with health and safety risks related to microbiological or chemical functions. Option four applies to packaging which performs a physical function not related to health and safety.

OPTION 1 ***Periodic Evaluation of Incoming Packaging Material***

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

- Purchasing specifications include a provision for compliance with the *Food and Drugs Act and Regulations*.
- The manufacturer obtains a certificate of analysis for each lot.
- A representative sample is taken to verify the accuracy of the certificates of analysis at a scheduled frequency appropriate to the risk, e.g. monthly.
- The manufacturer maintains a documented history of adherence to specifications for each supplier, e.g. analytical results.
- The manufacturer establishes a new history by verifying adherence to specifications when a manufacturer changes suppliers, purchases packaging from a new supplier, purchases new packaging material from an existing supplier or when spot checks do not agree with the certificate of analysis.

OPTION 2 ***100% Lot Inspection***

- Each incoming lot is evaluated to ensure that specifications are met and packaging is free from defects.

OPTION 3 ***Vendor Certification***

When the manufacturer relies on vendor certification the following minimum requirements are in place:

- The manufacturer has documentation to demonstrate adequate knowledge of the supplier's process. This may include process flow charts, on site evaluations, identification of critical control points, specifications, control limits, monitoring programs and frequencies, corrective action and verification procedures.
- The manufacturer has data to demonstrate the capability of the supplier's process to consistently manufacture within specifications. This may include: statistical process control charts for each critical control point and process capability studies.
- Prior to implementation of a spot check program, the manufacturer analyzes an appropriate number of consecutive lots to establish a historical data base and confirms adherence to specifications, e.g. annually.
- The manufacturer conducts periodic monitoring to verify adherence to specifications.
- The manufacturer conducts supplier audits to validate the status of the supplier certification program.

NOTE: Packaging materials in use comply with Division 23 of the *Food and Drug Regulations*.

OPTION 4 ***Specification Requirements***

Where packaging materials perform a physical function not related to the safety of the food:

- The manufacturer has written specifications for the packaging material.
- Purchasing specifications include a provision for compliance with the *Food and Drugs Act*.

See subsection 7.2.2 for expected incoming material control records

7.2.2 Incoming Material Control Records

The manufacturer has records available that demonstrate the adequacy of incoming materials control.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Rationale
Absent or inadequate records do not allow verification of the manufacturer's control over biological, physical or chemical hazards.

Assessment Criteria
The minimum record requirements for the following monitoring and/or certification options are:

Periodic Evaluations
- History of adherence to specifications, ie. analytical results.
- Spot checks, ie. analytical results.

100% Lot Inspection
- Analytical results for each incoming lot.

Vendor Certification
- Records which demonstrate knowledge of the supplier's process, e.g. process flow charts, critical control point identification, process specifications, critical limits, monitoring and verification reports, corrective action plans and reports, and on site evaluation reports.
- Records which demonstrate the capability of supplier's process, e.g. capability studies. Statistical process control charts are available upon request.
- Historical data base, e.g. analytical results on consecutive lots.
- Periodic monitoring, e.g. analytical results.
- Supplier audits, e.g. audit reports.

Non-Conforming Incoming Materials
- Identification of the material.
- Identification of the deficiency.
- Preventative and corrective action taken.

1.4 PACKAGING CONTROL (5.4)*

1.4.1 Packaging

Handling and use of packaging is controlled to prevent product contamination.

Rationale
Inadequate control of packaging may result in the use of damaged, defective or contaminated packaging and contamination of the product.

Assessment Criteria
The manufacturer has an effective system in place to prevent the use of contaminated, damaged or defective containers. This can be accomplished through either of the options below.
- The manufacturer has controls in place to minimize damage and verifies the effectiveness of these

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

controls through periodic audits, for example:
- receiving controls, e.g. driver handling, unloading, identification of damage problems and corrective action;
- storage controls, e.g. stacking restrictions, heights, spacing, protection from damage and contamination;
- depalletizing and conveying controls, e.g. careful loading, removal of damaged packaging during de-shrouding, effectiveness of damage control, synchronization of line speeds, transfer points;
- prior to use, packaging is examined for damage and contamination;
- packaging is handled and transferred in a manner that minimizes damage and contamination, e.g. conveyors, transfer points etc.

- The manufacturer has controls in place to prevent contamination of clean packaging.
  - Packaging is used for its intended purpose only.
- Where appropriate, the manufacturer has in place an effective cleaning system.

1.5 PRODUCT PREPARATION/BLENDING (5.1)*

1.5.1 Critical Factor Control

Critical factors specified in the formulation are controlled during preparation and blending to minimize physical, chemical, nutritional and biological hazards, and to ensure accuracy of composition and nutrient content.

Rationale
Inadequate control of critical factors associated with product preparation/blending could result in inadequate processing, formation of toxins, presence of undeclared allergens, violative levels of food additives, product not meeting compositional standards and/or inaccurate nutrient content.

Assessment Criteria
The manufacturer has controls in place to prevent hazards associated with product preparation/blending. Critical areas include:

Preparation/Blending Microbial Control
The manufacturer controls conditions (e.g. time, temperature, pH, water activity) during preparation, blending and holding of in-process materials to prevent undesirable microbial growth or the production of metabolic byproducts of microbial growth.
The manufacturer has controls for critical factors identified for the process. Examples of critical factors are:
- size control, e.g. dicing, grinding, slicing;
- temperature treatment control, e.g. heating, blanching (textural changes), defrosting, cooling;
- moisture control, e.g. rehydration, concentration (viscosity, brix);
- proportioning control, e.g. weighing, volumetric control (metering);
- pH/Acidity control, e.g. pH measurement, titratable acidity;

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

- preservatives, e.g. nitrite.

Allergens
The manufacturer has controls in place to prevent the presence of undeclared allergens. Allergens are those ingredients that will elicit an allergic response in sensitive individuals. Areas that may require control include:
- misdirection of ingredients;
- use of rework;
- contamination by undeclared ingredients;
- ingredient carryover;
- ingredient substitutions;
- carryover from equipment, e.g. product changeovers.

Food Additives
The manufacturer has controls in place to ensure that food additives are permitted and are used within allowable levels. These include:
- clear identification of additives;
- accurate measurement;
- adequate blending for homogeneity.

Nutrient Addition
The manufacturer has controls in place to ensure nutrient levels comply with regulatory and label requirements including:
- clear identification of nutrient;
- proper storage and handling to maintain nutrient potency;
- accurate measurement;
- adequate blending for homogeneity.

Composition
The manufacturer has controls in place to ensure the composition of the product accurately reflects the formulation. Areas that may require control include:
- misdirection of ingredients;
- use of rework;
- ingredient carryover;
- ingredient substitutions;
- carryover from equipment, e.g. product changeovers.

See subsection 7.2.3 for expected product preparation/blending records

7.2.3 Product Preparation/Blending Records

Critical factor control records are maintained and are available on request.

Rationale

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Absent or inadequate records do not permit verification of control of critical factors in preparation/blending.

Assessment Criteria
Records are available upon request to demonstrate control of product preparation/blending as follows:
- records to demonstrate adherence to critical limits specified in the formula, e.g. records for critical factors specified in the process, for the filling, and for nutrients in foods.

1.5.2 Cleaning/Sorting Contamination Control

Raw materials and ingredients are cleaned, sorted, and/or prepared in such a manner as to prevent contamination.

Rationale
Adequate cleaning and sorting of raw materials and ingredients is necessary to prevent or remove contamination with biological, physical or chemical hazards.

Assessment Criteria
The manufacturer controls the following hazards where appropriate:

- ***Biological Hazards***
  - Inspection controls - visual, sensory, etc. e.g. removal of decomposed product.
  - Control by washing, e.g. reduction of the microbial load.
- ***Physical Hazards***
  - Metal contamination controls, e.g. magnets, metal detectors.
  - Other extraneous matter controls, e.g. sifting, sorting/cleaning by gravity, air or water.
- ***Chemical Hazards***
  - Control of natural toxins by sorting, e.g. by colour (glycoalkaloids in potatoes).

1.6 PRODUCT CODING CONTROL (5.1)*

1.6.1 Control Factor

Each prepackaged food is identified with code marks or lot numbers on the label or container.

Rationale
Coding control permits products to be traced through the distribution chain, provides information on shelf life and safety of consumption, and prevents damage which could compromise container integrity.

Note: Mandatory coding requirements vary between commodity specific legislation. It is suggested that manufacturers consult with inspection authorities in order to confirm specific requirements applicable to

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

products being produced or manufactured.

Assessment criteria

- The manufacturer has a system of coding which ensures that each prepackaged food has permanent, legible code or lot identification.
- The coding system allows for the identification of the establishment, the day, month and year in which the food was produced.
- Code marks used and the exact meaning of the code are available.
- Where used, case codes are legible and represent the container code within.
- Where applicable, the code accurately reflects the best before date, expiration date, or shelf life of the food.
- Where applicable, the manufacturer controls the application of codes to ensure that the integrity of the container is not compromised.

1.7 PROCESS CONTROL (5.2)*

1.7.1 Control of Critical Factors

All critical processing factors are controlled to ensure the safety of the product.

Rationale
Inadequate process control of critical processing factors could result in microbial, chemical or physical hazards.

Assessment Criteria

- The manufacturer evaluates the process and identifies all critical factors.
- The manufacturer ensures all appropriate critical processing factors are addressed, and that they are controlled within acceptable limits.
- The manufacturer monitors the critical factors at a scheduled frequency. The frequency of monitoring will depend on the type of process and the associated risk.

See subsection 7.2.4 for expected process control records

7.2.4 Process Control Records

Written records that adequately reflect the control of critical processing factors are available upon request.

Rationale
Absent or inadequate records do not permit verification of the safety of the process and product

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

composition.

Assessment Criteria
- The manufacturer has records that demonstrate control of the critical processing factors and the composition of the product.
- Deviations are noted on the records by the operator.

Note: Minimum information required on records may vary depending on the type of process.

1.8 LABELLING CONTROL (5.1 AND CODEX STAN 1-1985)*

1.8.1 Control Factor

The manufacturer has controls in place to prevent mislabelling.

Rationale
Control of labelling is important to ensure that the correct label is applied to each product. Use of incorrect labels could mislead the consumer and cause potential health hazards to segments of the population which may be allergic to certain foods.

Assessment Criteria
The manufacturer has controls in place to prevent the mislabelling of products. Typical controls may include:
- effective separation of product types during changeovers, e.g. appropriate breaks between products, use of marked containers or visual inspection to ensure products are not mixed prior to labelling;
- different product labels or prelabelled packaging are effectively separated and the number of product label types is kept to a minimum;
- use of identifying marks and/or colours on labels to ensure correct labels are being loaded into the labeller or manually put on the product;
- tops and bottoms of label bundles are visually checked for mixed labels prior to use;
- prevention of mixing of individual or bundles of labels during storage, e.g. storage in separate boxes, no loose labels, and ensuring that unused labels are returned to the correct boxes;
- controls are in place to ensure the product being supplied or added to the labelling operation corresponds to the labels in use.

1.9 DEVIATIONS AND CORRECTIVE ACTION (5.1)*

1.9.1 Deviation Control

When critical limits are exceeded or defects occur which could affect product safety, procedures are in place to identify, isolate and evaluate products.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Rationale
Deviations from critical limits and procedures, or the occurrence of defects may affect the safety of the product. Inadequate deviation procedures or non-adherence to procedures could result in the sale of unsafe product.
NOTE: Where appropriate, deviation procedures apply to all sections of this standard.

Assessment Criteria
The manufacturer controls deviations as follows:

Identification of Deviation
- The manufacturer has a system in place to identify deviations when they occur.

Isolation of Affected Product
- The manufacturer has effective procedures in place to isolate, clearly mark and control all product manufactured during the deviation period:
  - all unsatisfactory product is isolated back to the point where the process was last in control, this could be beyond the last satisfactory record;
  - Isolated product is clearly marked, e.g. tags firmly attached with the following information; hold number, product, the amount, date held, the reason for the hold, the name of the person holding the product;
  - the manufacturer maintains control of the product from the hold date to the date of final disposition.

Evaluation of Affected Product
- Product evaluation is conducted by a qualified person, e.g. process deviations are evaluated by qualified personnel.
- Disposition of affected product, e.g. sorting of suspect lots, disposal, etc. is conducted in an appropriate manner by adequately trained personnel.
- Evaluation is adequate to detect potential health hazards, e.g. sampling is adequate to identify the extent of the problem, the tests are appropriate, the judgement is based on sound science and the product is not released until the evaluation has determined that no potential health hazard exists.

1.9.2 Corrective Action

Corrective action taken following any deviation is effective to ensure the safety of the product and to prevent recurrence of the deviation.

Rationale
Corrective action procedures are necessary to determine the cause of the problem, take action to prevent recurrence and follow-up with monitoring and reassessment to ensure that action taken is effective. Appropriate corrective action will address the root cause of deviations of critical control points and minimize health risks.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Assessment Criteria
The manufacturer's corrective action program includes the following:
- investigation is completed to determine the cause of the deviation;
- effective measures are taken to prevent recurrence of the deviation;
- the manufacturer verifies the effectiveness of the corrective action taken.

See subsection 7.2.5 on expected deviations and corrective action records

7.2.5 Deviations and Corrective Action Records

Records are available to demonstrate the control of deviations and the effectiveness of corrective actions taken.

Rationale
Inadequate records do not permit verification that the manufacturer has control of deviations and has effective corrective actions.

Assessment Criteria
The following minimum information is recorded in the deviation and corrective action records:

Deviation/Hold
- Product/code.
- Date produced/held/released.
- Reason for the hold.
- Amount of product held, e.g. back to the point where the process was last in control.
- Results of evaluation/sort, e.g. amount analyzed, analysis report of the number and nature of defects.
- Disposition of held product, e.g. amount sorted, destroyed, employee sales, distress or salvage, reconditioning, and retail sales.
- Signature of personnel responsible for hold and evaluation.
- Signed authorization for disposition.

Corrective Action
- Cause of deviation identified.
- Corrective action taken to correct deficiency.
- Follow-up/assessment of effectiveness of corrective action.
- Date corrective action was taken and verified.
- Signature of person responsible.

1.10 VERIFICATION OF PRODUCT SAFETY (5.1)*

1.10.1 Verification Procedures

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

The manufacturer uses appropriate methods of evaluation to verify controls affecting product safety.

Rationale
The purpose of verification is to assess the effectiveness of existing controls in preventing health hazards and to indicate areas where improvements are required.

Assessment Criteria
The manufacturer verifies the effectiveness of controls affecting product safety.
NOTE: The verification methods will vary with, and must be appropriate to the hazards associated with the product and process. Where appropriate, verification applies to all sections of this standard.

Examples of Verification Methods
- Sampling and analysis of in-process and finished product for the appropriate chemical, microbiological or physical hazards.
- Sampling and analysis to verify that specific manufacturing controls are effective, e.g. microbiological checks of treated cooling water, microbiological checks of surfaces.
- Independent, external audits.
- Internal audits.
- Incubation testing to confirm commercial sterility/hermetic seal.
- Visual/mechanical/electronic screening.
- Analysis of consumer complaint trends.
- Vendor audits.

Frequency of Verification
- The manufacturer conducts verification of the manufacturing controls at a frequency appropriate to the hazards associated with the product and process.

Responsibility for Verification
- Individuals or organizations responsible for verification are identified. These individuals or organizations are suitably qualified.

See subsection 7.2.6 for expected verification records

7.2.6 Verification Records

Records are available to demonstrate the adequacy of verification procedures.

Rationale
Records show the results of verification and confirm the effectiveness of manufacturing controls.

Assessment Criteria

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

- Records of verification include methods, date, individuals/organizations responsible, results/findings and action taken.

2.0 EQUIPMENT (4.3)*

2.1 GENERAL EQUIPMENT (4.3.1)*

2.1.1 Design, Construction and Installation

All equipment and utensils are designed, constructed and installed to function as intended, to permit effective cleaning and sanitation and to prevent contamination.

Assessment Criteria

- Equipment is designed, constructed and installed to ensure that it is capable of delivering the requirements of the process.
- Equipment is designed, constructed and installed to be accessible for cleaning, sanitizing, maintenance and inspection.
- Equipment is designed, constructed and installed to prevent contamination of the product during operations, e.g. location of lubricant reservoirs.
- Where necessary, equipment is exhausted to the outside to prevent excessive condensation, e.g. filler bowls, blanchers, retorts.
- Equipment is designed, constructed and installed to permit proper drainage and where appropriate, is connected directly to drains.

Note: Equipment design, construction and installation is not considered deficient if the situation can be effectively addressed by the sanitation program.

2.1.2 Food Contact Surfaces

Food contact surfaces are constructed of appropriate materials and are maintained in a manner to prevent contamination of food.

Assessment criteria

- Food contact surfaces of equipment and utensils are smooth, non-corrosive, non-absorbent, non-toxic, free from pitting, cracks or crevices and can withstand repeated cleaning and sanitation.
- Coatings, paints, chemicals, lubricants and other materials used for food contact surfaces or equipment where there is a possibility of contact with food are listed in the "Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Agents", published by the Canadian Food Inspection Agency or the manufacturer has "a letter of no objection" from Health Canada. The Reference Listing can be found on the CFIA's website, www.inspection.gc.ca.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

2.1.3 Equipment Maintenance and Calibration Program

An effective maintenance and calibration program is in place to ensure that equipment performs consistently as intended and prevents contamination of product.

Assessment Criteria

- The manufacturer has an effective written preventative maintenance and calibration program to ensure that equipment that may impact on food safety functions as intended. This includes:
  - a list of equipment requiring regular maintenance;
  - the maintenance procedures and frequencies, e.g. equipment inspection, adjustments and part replacements are based on the equipment manufacturer's manual or equivalent, or are based on operating conditions that could affect the condition of the equipment.
- Written protocols, including calibration methods and frequencies, are established by the manufacturer for equipment monitoring and/or controlling devices that may impact on food safety.
- Equipment is maintained to ensure that no physical or chemical hazard potentials result, e.g. inappropriate repairs, flaking paint and rust, excessive lubrication.
- Maintenance and calibration of equipment is performed by appropriately trained personnel.
- The preventative maintenance program and written protocol are adhered to.

7.3.1 Equipment Maintenance and Calibration Records

Records are available to demonstrate adherence to the maintenance program for critical equipment.

Rationale

Records permit verification of the effectiveness of the equipment maintenance and calibration program.

Assessment criteria

- Typical information expected in maintenance records for critical equipment:
  - identification of equipment;
  - maintenance activity;
  - date, person;
  - reason for activity.
- Typical information expected for calibration records for critical equipment:
  - identification of equipment;
  - date, person;
  - calibration results.

2.1.4 Instrumentation Maintenance and Calibration Program

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Instrumentation is designed, constructed, installed, calibrated and maintained such that the equipment is capable of delivering the required process to ensure product safety.

Rationale
Inadequate processing, food additive, nutrition, or composition violations may result from improper design, installation, calibration or maintenance of instruments.

Assessment criteria
Instruments which control factors critical to product safety are designed, installed, constructed, calibrated and maintained as necessary to ensure that they function as intended.

The following are some examples of instrumentation that may be required to control factors critical to the process:

Temperature Measuring Devices

- The manufacturer uses one temperature scale consistently throughout the processing system, e.g. Celsius or Fahrenheit.
- Temperature measuring devices are calibrated against a known standard just prior to installation, a minimum of once per year, or more frequently as recommended in the equipment manufacturer's manual and maintained as necessary to ensure accuracy, e.g. Resistance Temperature Detectors (RTD's), bimetal thermometers.

MIG Thermometers

- Mercury in glass thermometers are calibrated against a known standard just prior to installation, a minimum of once per year, or more frequently as necessary to ensure their accuracy. If there is a deviation of more than 0.5^0C (1^0F) from the standard thermometer, corrective action is taken based on the directives found in subsection 1.9.2 Corrective Action.
- Thermometer scales are within the operating range, are easily readable to 0.5^0C (1^0F), and do not contain more than 4^0C/cm (17^0F/in).

Temperature Recorders

- The scale of the temperature recording chart is not more than 12^0C/cm (55^0F/in) within the range of 10^0C (18^0F) of process temperature and the chart graduation does not exceed 1^0C (2^0F) within 6^0C (11^0F) of processing temperature. The accuracy of temperature recorders is verified upon installation, a minimum once per year or more frequently as necessary to ensure their accuracy.

Timing Devices

- Timing devices and recorders are verified upon installation, annually, or more frequently as necessary to ensure accuracy.
- Where timing devices are not equipped with a power backup, controls are in place to verify that process time requirements are met.
- Official timing device is located so that it can be easily and accurately read by the operator.

Pressure Gauges

- Each pressure gauge is calibrated at least annually or more frequently as necessary to ensure

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

accuracy.

Electronic Devices

- The capability of electronic devices is at least equivalent to that of traditional devices used for measuring and controlling critical parameters such as time, temperature and pressure (traditional devices include for example, temperature recorder controllers).

Magnets

- The strength and type of magnets is appropriate to the use.
- Magnets are installed in a manner to effectively remove ferrous metal prior to or after certain operations, e.g. dicing, slicing or filling.
- The strength of magnets is confirmed with the use of probes or other effective devices as necessary.
- Magnets are monitored as necessary to ensure effective operation and surface exposure.

Metal Detectors

- Metal detection equipment is designed, constructed, installed, calibrated and maintained in accordance to the equipment manufacturer's manual to ensure effective removal of metals. This may include: adjustment for product effect, selection of target metal and size, timing of the reject mechanism and suitability for environmental conditions.

Scales/Metering Devices

- The sensitivity is appropriate to the use.
- Scales are designed and installed to withstand the environmental conditions or are adequately protected, e.g. away from drafts, rust, corrosion, etc.
- Scales and meters are calibrated in accordance to the equipment manufacturer's manual to ensure accuracy at all times.

Other Instrumentation

- Other specialized instrumentation necessary for the control of critical factors are in place and calibrated as necessary, e.g. pH meters, refractometer.

Note: The manufacturer should initiate corrective action as per section 1.9, Deviations and Corrective Action whenever products could have been affected and found not to meet specifications.

3.0 PREMISES (4.1)*

3.1 BUILDING EXTERIOR (4.1.1)*

3.1.1 Outside Property and Building

Buildings and surrounding areas are designed, constructed and maintained in a manner to prevent conditions which may result in the contamination of food.

Assessment Criteria

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Grounds, Roadways and Drainage

- The surrounding land is maintained to control sources of contamination such as debris and pest harbourage areas.
- The building is not located in close proximity to any environmental contaminants.
- Roadways are properly graded, compacted, dustproofed and drained.
- The surrounding property is adequately drained.

Exterior Building Structure

- The building exterior is designed, constructed and maintained to prevent entry of contaminants and pests, e.g. no unprotected openings, air intakes are appropriately located, and the roof, walls and foundation are maintained to prevent leakage.

3.2 BUILDING INTERIOR (4.2 and 4.4)*

3.2.1 Design, Construction and Maintenance

Building interiors and structures are designed, constructed and maintained in a manner to prevent conditions which may result in the contamination of food.

Assessment Criteria

Floors, Walls, Ceilings

- Floors, walls, and ceilings are constructed of material that is durable, impervious, smooth, cleanable, and suitable for the production conditions in the area and will not result in the contamination of the environment or food..
- Where appropriate, wall, floor and ceiling joints are sealed and angles are coved to prevent contamination and facilitate cleaning.
- Floors, walls and ceilings are composed of materials that will not result in the contamination of the environment or food.
- Floors are sufficiently sloped to permit liquids to drain to trapped outlets.
- Ceilings, overhead structures, stairs, and elevators are designed, constructed and maintained to prevent contamination.

Windows and Doors

- Windows are sealed or equipped with close fitting screens.
- Where there is a likelihood of breakage of glass windows that could result in the contamination of food, the windows are constructed of alternative materials or are adequately protected.
- Doors have smooth, non-absorbent surfaces and are close fitting and self-closing where appropriate.

Process Flow Separation

- Adequate separation of activities is provided by physical or other effective means where cross

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

contamination may result.

- Buildings and facilities are 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.

3.2.2 Lighting

Lighting is adequate for the activity being conducted. Where appropriate, light bulbs and fixtures are protected to prevent contamination of food.

Assessment criteria

- Lighting is appropriate such that the intended production or inspection activity can be effectively conducted. The lighting does not alter food colour and is not less than the following:
  - 540 lux (50 foot candles) in inspection areas;
  - 220 lux (20 foot candles) in work areas;
  - 110 lux (10 foot candles) in other areas.

  (Inspection areas are defined as any point where the food product or container is visually inspected or instruments are monitored, e.g. empty container evaluation, product sorting and inspection).
- Light bulbs and fixtures located in areas where there is exposed food are of a safety type or are protected to prevent contamination of food in case of breakage.

3.2.3 Ventilation

Adequate ventilation is provided to prevent excessive heat, steam, condensation, and dust, and to remove contaminated air.

Assessment criteria

- Ventilation provides sufficient air exchange to prevent unacceptable accumulations of steam, condensation or dust.
- Ventilation openings are equipped with close fitting screens or filters as appropriate to prevent the intake of contaminated air. Filters are cleaned or replaced as necessary.

3.2.4 Waste disposal

Sewage, effluent and waste storage and disposal systems are designed, constructed and maintained to prevent contamination.

Assessment criteria

- Drainage and sewage systems are equipped with appropriate traps and vents.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

- Establishments are designed and constructed so that there is no cross-connection between the sewage system and any other waste effluent system in the establishment.
- Effluent or sewage lines do not pass directly over or through production areas unless they are controlled to prevent contamination.
- Adequate facilities and equipment are provided and maintained for the storage of waste and inedible material prior to removal from the establishment. These facilities are designed to prevent contamination.
- Containers used for waste are clearly identified, leak proof and where appropriate are covered.
- Waste is removed and containers are cleaned and sanitized at an appropriate frequency to minimize contamination potentials.

3.3 SANITARY FACILITIES (4.4)*

3.3.1 Employee Facilities

Employee facilities are designed, constructed and maintained to permit effective employee hygiene and to prevent contamination.

Assessment criteria

- Processing areas are provided with an adequate number of conveniently located handwashing stations with trapped waste pipes to drains.
- Washrooms have hot and cold potable running water distributed from a single nozzle, soap dispensers, soap, sanitary hand drying equipment or supplies and a cleanable waste receptacle.
- Washrooms are provided with a sufficient number of sinks to accommodate the number of employees using the facilities during the same period.
- Washrooms, lunchrooms and changerooms are maintained in a clean condition.
- Handwashing notices are posted in appropriate areas.

3.3.2 Equipment Cleaning and Sanitizing Facilities

Facilities for cleaning and sanitizing equipment are adequately designed, constructed and maintained to prevent contamination.

Assessment Criteria

- Facilities are constructed of corrosion resistant materials capable of being easily cleaned and are provided with potable water at temperatures appropriate for the cleaning chemicals used.
- Equipment cleaning and sanitizing facilities are adequately separated from food storage, processing and packaging areas to prevent contamination.

3.4 WATER/ICE/STEAM QUALITY (5.5)*

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

3.4.1 Water and Ice

The potability of hot and cold water is controlled to prevent contamination.

Assessment Criteria

- Potable water meets the requirements of Health Canada's "Guidelines for Canadian Drinking Water Quality". Water is analyzed by the manufacturer or municipality at a frequency adequate to confirm its potability.
- There are no cross-connections between potable and non-potable water supplies or all hoses, taps and other similar sources of possible contamination are designed to prevent back-flow or back siphonage.
- Where it is necessary to store water, storage facilities are adequately designed, constructed and maintained to prevent contamination, e.g. covered.
- Water treatment chemicals, where used, are listed in the "Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products", published by the Canadian Food Inspection Agency or the manufacturer has a "letter of no objection" from Health Canada. The Reference Listing can be found on the CFIA's website, www.inspection.gc.ca.
- The chemical treatment, where used, is monitored and controlled to deliver the desired concentration and to prevent contamination.
- Recirculated water is treated, monitored and maintained as appropriate to the intended purpose. Recirculated water has a separate distribution system which is clearly identified.
- Ice used as an ingredient or in direct contact with food is made from potable water and is protected from contamination. Ice purchased by the manufacturer is treated as an incoming ingredient and is assessed under subsection 7.3.1 Incoming Material Control - Ingredients.

3.4.2 Steam

The potability of steam in direct contact with food or food contact surfaces is controlled to prevent product contamination. Steam supply is adequate to meet operational requirements.

Assessment Criteria

- Boiler treatment chemicals used are listed in the "Reference Listing of Accepted Construction Materials, Packaging Materials, and Non-Food Chemical Products" published by the Canadian Food Inspection Agency or the manufacturer has a "letter of no objection" from Health Canada. The Reference Listing can be found on the CFIA's website, www.inspection.gc.ca.
- Boiler feedwater is tested regularly and the chemical treatment is controlled to prevent contamination.
- The steam supply is generated from potable water and is adequate to meet operational requirements.
- Traps are provided as necessary to ensure adequate condensate removal and elimination of

foreign materials.

See subsection 7.4.1 for expected water/ice/steam quality records.

7.4.1 Water/Ice/Steam Quality Records

Written records that adequately reflect control of water and steam quality and treatment are available upon request.

Assessment Criteria
The manufacturer has records available upon request to demonstrate the adequacy of the microbiological and/or chemical safety of the water and steam supply as follows:

Water Potability Records	***Water Treatment Records***	***Boiler Feedwater Treatment Records***
– water source	- method of treatment	- method of treatment
– sample site	- sample site	- analytical results
– analytical results	- analytical results	- date
– analyst	- date	- analyst
– date	- analyst	

4.0 SANITATION AND PEST CONTROL (6.)*

4.1 SANITATION (6.2)*

4.1.1 Sanitation Program

An effective sanitation program for equipment and premises is in place to prevent contamination of food.

Assessment criteria
- The manufacturer has a written cleaning and sanitation program for all equipment which includes:
  - the identification of responsible person;
  - the frequency of the activity;
  - chemicals and concentration used;
  - temperature requirements.
  - Procedures for cleaning and sanitizing as follows:
    Cleaned Out of Place Equipment (C.O.P., e.g. hand-cleaned)
    - identify equipment and utensils;
    - disassembly/reassembly instructions as required for cleaning and inspection;

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

- areas on equipment requiring special attention are identified;
- method of cleaning, sanitizing and rinsing.

Cleaned in Place Equipment (C.I.P)

- identify lines and/or equipment;
- CIP setup instructions;
- method of cleaning, sanitizing and rinsing;
- disassembly/reassembly instructions as required for cleaning and inspection.

- The manufacturer has a written cleaning and sanitation program for premises (production and storage areas) which specifies areas to be cleaned, method of cleaning, person responsible and the frequency of the activity. Special sanitation and housekeeping procedures required during production are specified within the document, e.g. removal of product residues during breaks.
- Chemicals are used in accordance with the manufacturer's instructions and are listed in the "Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Agents", published by the Canadian Food Inspection Agency or the manufacturer has a "letter of no objection" from Health Canada. The Reference Listing can be found on the CFIA's website, www.inspection.gc.ca.
- Cleaning and sanitizing equipment is designed for its intended use and is properly maintained.
- The sanitation program is carried out in a manner that does not contaminate food or packaging materials during or subsequent to cleaning and sanitizing, e.g., aerosols, chemical residues.
- Effectiveness of the sanitation program is monitored and verified (e.g. by routine inspection of premises and equipment and/or microbiological testing) and where necessary, the program is adjusted accordingly.
- Operations begin only after sanitation requirements have been met.

See subsection 7.5.1 for expected sanitation records

7.5.1 Sanitation Records

Records are available to demonstrate the effectiveness of the sanitation program.

Assessment criteria

- The records of sanitation activities include the date, person responsible, the findings, corrective action taken, and microbiological test results where appropriate.

4.2 PEST CONTROL (6.3)*

4.2.1 Pest Control Program

Effective pest control programs are in place to prevent entry, detect and eliminate pests and to

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

prevent the contamination of food.

Assessment criteria

- There is an effective written pest control program for the premises and equipment that includes:
  - the identification of the person at the manufacturer assigned responsibility for pest control;
  - where applicable, the name of the pest control company or the name of the person contracted for the pest control program;
  - the list of chemicals used, the concentration, the location where applied, method and frequency of application;
  - a map of trap locations;
  - the type and frequency of inspection to verify the effectiveness of the program.
- Pesticides used are registered under the Pest Control Products Act and Regulations and are listed in the "Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Agents", published by the Canadian Food Inspection Agency. Pesticides are used in accordance with the label instructions. The Reference Listing can be found on the CFIA's website, www.inspection.gc.ca.
- Chemical treatment of equipment, premises or ingredients to control pests is conducted in a manner to ensure that the maximum residue limit of the *Food and Drugs Act and Regulations* is not exceeded, e.g. limiting the number of fumigation treatments per lot.
- Poisonous rodenticides are not used in food processing or storage areas.
- Birds and animals, other those intended for slaughter, are excluded from establishments.

See subsection 7.5.2 for expected pest control records.

7.5.2 Pest Control Records

Records are available to demonstrate the effectiveness of the pest control program.

Assessment Criteria

Minimum pest control records include:

- results of the inspection programs and the corrective action taken, e.g. findings in traps, location of insect infestation;
- record of pest control activities, e.g. pesticide used, method and location of application, dates of fumigation, etc.;
- date, person responsible.

5.0 PERSONNEL(7.)*

5.1 HYGIENE AND HEALTH REQUIREMENTS (7. And 7.1)*

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

5.1.1 Cleanliness and Conduct

All persons entering food handling areas maintain an appropriate degree of personal cleanliness and take the appropriate precautions to prevent the contamination of food.

Assessment Criteria

- All persons wash their hands upon entering food handling areas, before starting work, after handling contaminated materials, after breaks and after using toilet facilities. Where necessary to minimize microbiological contamination, employees use disinfectant hand dips.
- Protective clothing, hair covering, footwear and/or gloves, appropriate to the operation in which the employee is engaged, are worn and maintained in a sanitary manner, e.g. employees in production areas wear effective hair coverings.
- Any behaviour which could result in contamination of food, such as eating, use of tobacco, chewing gum, or unhygienic practices such as spitting, are prohibited in food handling areas.
- All persons entering food handling areas remove jewellery and other objects which may fall into or otherwise contaminate food. Jewellery which cannot be removed, including wedding bands and medical alerts, is covered, e.g. employees wear rubber gloves.
- Personal effects and street clothing are not kept in food handling areas and are stored in an appropriate manner.
- Access of personnel and visitors is controlled to prevent contamination. The traffic pattern of employees prevents cross-contamination of the product.

5.1.2 Communicable Diseases/Injuries

No person while known to be infected with a disease likely to be transmitted through food, or with open cuts or wounds, is permitted to work in food handling areas where there is a likelihood of such a person directly or indirectly contaminating the food.

Assessment Criteria

- The manufacturer has and enforces a policy to prevent personnel known to be suffering from, or known to be carriers of a disease transmissible through food, from working in food handling areas.
- The manufacturer requires that employees advise management when they are suffering from a communicable disease likely to be transmitted through food. Conditions which are to be reported include:
  - jaundice;
  - diarrhoea;
  - vomiting;
  - fever;
  - sore throat with fever;
  - discharges from the ear, eye or nose.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

- Employees having open cuts or wounds do not handle food or food contact surfaces unless the injury is completely protected by a secure waterproof covering, e.g. rubber gloves.

5.2 TRAINING (10.)*

5.2.1 General Food Hygiene Training

Every food handler is trained in personal hygiene and hygienic handling of food such that they understand the precautions necessary to prevent the contamination of food.

Assessment Criteria
The manufacturer has a written training program for employees which is delivered as follows:
- appropriate training in personal hygiene and hygienic handling of food is provided to all food handlers at the beginning of their employment;
- food hygiene training is reinforced and updated at appropriate intervals and each time the food handler changes duties.

5.2.2 Technical Training

Personnel are trained such that they have adequate technical knowledge and understanding of the operation(s) or process(es) for which they are responsible to ensure food safety.

Assessment Criteria
Training is appropriate to the complexity of the manufacturing process and the tasks assigned, for example:
- personnel are trained to understand the importance of the critical factors for which they are responsible; the critical limits, the procedures for monitoring, the action to be taken if the limits are not met, labelling requirements and the records to be kept;
- all employees, including maintenance and customer services employees, are trained on allergen controls;
- operators are trained to have current knowledge of equipment and process technology, e.g. apprenticeship training, retort operators, pasteurization operators;
- personnel responsible for maintenance of equipment impacting on food safety have been appropriately trained to identify deficiencies that could affect product safety and to take the appropriate corrective action, e.g. in house repairs, contract repairs. Individuals performing maintenance on specific equipment are appropriately trained;
- personnel and supervisors responsible for the sanitation program are appropriately trained to understand the principles and methods required for effective cleaning and sanitizing;
- personnel and supervisors responsible for water treatment and water safety monitoring are appropriately trained to understand and are competent in procedures to protect the safety of food.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

6.0 TRANSPORTATION AND STORAGE (8. and 4.)*

6.1 TRANSPORTATION (3.3, 8.1, 8.2 and 8.3)*

6.1.1 Food Carriers

Carriers used by the manufacturer are designed, constructed, maintained, cleaned and utilized in a manner to prevent food contamination.

Assessment Criteria

The manufacturer verifies that carriers are suitable for the transportation of food. For example:

- carriers are inspected by the manufacturer on receipt and prior to loading to ensure they are free from contamination and suitable for the transportation of food;
- the manufacturer has a program in place to demonstrate the adequacy of cleaning and sanitizing, e.g. for bulk carriers a written cleaning and sanitizing procedure is available;
- where the same carriers are used for food and non-food loads (e.g. dual use), procedures are in place to restrict the type of non-food loads to those that do not pose a risk to subsequent food loads after an acceptable cleanout or to food loads in the same shipment. For example:
  - the manufacturer receives a cleaning certificate and a record of the previous material transported prior to loading or unloading dual use tankers;
  - the manufacturer has a program in place to verify the adequacy of cleaning, e.g. tanker inspections, sensory evaluation of ingredients and/or analysis as appropriate;
- carriers are loaded, arranged and unloaded in manner that prevents damage and/or contamination of the food;
- bulk tanks are designed and constructed to permit complete drainage and to prevent contamination;
- where direct contact with food may occur, materials used in carrier construction are suitable for food contact.

6.1.2 Temperature Controls

Ingredients and finished product requiring temperature controls are transported in a manner to prevent temperature abuse that could result in deterioration affecting product safety.

Assessment Criteria

- Ingredients requiring refrigeration are transported at 4^0C (39^0F) or less and the temperature is appropriately monitored. Frozen ingredients are transported at temperatures that do not permit thawing and temperature is appropriately monitored.
- Finished product is transported under conditions to minimize microbiological, physical and chemical deterioration, e.g. in the case of low acid canned foods thermophilic spoilage, rusting or corrosion.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

6.2 STORAGE (3.3 and 4.4.8)*

6.2.1 Incoming Materials Storage

Storage and handling of incoming ingredients and packaging materials is controlled to prevent damage and contamination.

Assessment criteria

- Ingredients requiring refrigeration are stored at 4^0C (39^0F) or less and the temperatures are appropriately monitored. Frozen ingredients are stored at temperatures that do not permit thawing and the temperatures are appropriately monitored.
- Ingredients and packaging materials are handled and stored in a manner to prevent damage and/or contamination.
- Ingredient, and where appropriate, packaging material rotation, is controlled to prevent deterioration and spoilage.
- Humidity sensitive ingredients and packaging materials are stored under appropriate conditions to prevent deterioration.

6.2.2 Non-Food Chemicals Receiving and Storage

Non-food chemicals are received and stored in a manner to prevent contamination of food, packaging materials and food contact surfaces.

Assessment criteria

- Non-food chemicals are received and stored in a dry, well ventilated area.
- Non-food chemicals are stored in designated areas such that there is no possibility for cross-contamination of food or food contact surfaces.
- Where required for ongoing use in food handling areas these chemicals are stored in a manner that prevents contamination of food, food contact surfaces or packaging materials.
- Non-food chemicals are stored and mixed in clean, correctly labelled containers.
- Non-food chemicals are dispensed and handled only by authorized and properly trained personnel.

6.2.3 Finished Product Storage

Finished products are stored and handled to prevent damage and contamination.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

Assessment Criteria

- Finished product is stored and handled under conditions to minimize deterioration and prevent contamination, e.g. thermophilic spoilage, rusting or corrosion.
- Stock rotation is controlled to minimize deterioration and prevent spoilage that could present a health hazard, e.g. rusting, corrosion resulting in leakage, product exceeding shelf life.
- Finished products requiring refrigeration are stored at 4^0C (39^0F) or less and are appropriately monitored. Frozen finished products are stored at a temperature that does not permit thawing.
- Returned defective or suspect product is clearly identified and isolated in a designated area for appropriate disposition.
- Finished product is stored and handled in a manner to minimize damage, e.g. control of stacking heights and forklift damage.

7.0 RECORDS (5.7)*

7.1 GENERAL RECORDS (5.7)*

7.1.1 General Record Requirements

Information is recorded in a manner to represent an accurate history of the product or process. Records are retained for the required period of time.

Assessment criteria

The following are requirements for all record keeping activities:

- records are legible, permanent and accurately reflect the actual event, condition or activity;
- errors or changes are identified in a manner such that the original record is clear, e.g., strike out with a single stroke and initial the correction/change;
- each entry on a record is made by the responsible person at the time that the specific event occurred. The completed records are signed and dated by the responsible person;
- critical records are signed by a qualified individual designated by management prior to distribution of product, e.g. records related to the adequacy of the thermal process and the achievement of a hermetic seal. All other records are reviewed at an appropriate frequency to provide an early indication of potentially serious deficiencies;
- records are retained for at least one year after the expiry date on the label or container or if there is no expiry date, for at least two years after the date of manufacture;
- records are maintained and are available upon request.

7.2 RECORDS ON CONTROL OF OPERATION (5.7)*

NOTE: Subsections on records are found following the concerned subsections.

7.2.1 Process Design Records

7.2.2 Incoming Material Control Records

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

7.2.3 Product Preparation/Blending Records

7.2.4 Process Control Records

7.2.5 Deviations and Corrective Action Records

7.2.6 Verification Records

7.3 RECORDS ON EQUIPMENT

7.3.1 Equipment Maintenance and Calibration Records

7.4 RECORDS ON PREMISES (5.7)*

7.4.1 Water/Ice/Steam Quality Records

7.5 RECORDS ON SANITATION AND PEST CONTROL

7.5.1 Sanitation Records

7.5.2 Pest Control Records

7.6 RECORDS ON COMPLAINT HANDLING AND RECALLS (5.7)*

7.6.1 Complaint Records

7.6.2 Distribution records

8.0 COMPLAINT HANDLING AND RECALLS (5.8)*

8.1 COMPLAINT HANDLING (Added requirement)

8.1.1 Product Complaints

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

The establishment has an effective system for handling and investigating complaints.

Rationale
Product complaints are an important indicator of possible deficiencies of manufacturing controls and/ or the distribution handling system. Deficiencies in the complaint handling system could result in failure to identify and eliminate health risks.

Assessment criteria
The manufacturer has a system to handle and investigate product complaints as follows:
- the manufacturer has identified the person or persons responsible for receiving, evaluating, categorizing and/or investigating complaints;
- complaints are accurately categorized according to health and safety risks;
- potentially serious complaints are forwarded immediately to appropriate personnel for action;
- safety and contamination complaints are investigated by appropriately trained technical personnel;
- examination of the complainant's specimen, retail product or other product of the same code is conducted on complaints related to food safety;
- the depth of the investigation is appropriate to the risk and similar complaint trends;
- appropriate corrective action is taken for deviations identified during the investigation.

See subsection 7.6.1 for expected complaint records

7.6.1 Complaint Records

Records of product complaints, investigation findings and action taken are available upon request.

Rationale
Records provide verification that the appropriate action was taken within a reasonable time frame.

Assessment criteria
The establishment maintains detailed records of consumer complaints received, investigation of findings and corrective action taken. The minimum information required for complaint records are as follows:

Consumer Information
- Name, address, telephone number, date received
- Details of complaint and/or illness
- Product name, code, size
- Retail outlet

Investigation
- Name of person responsible for investigation
- Product action taken, e.g. Corrective action, product recall etc. as a result of the investigation and

date of action taken
- Corrective action taken

8.2 RECALLS

8.2.1 Procedure

Every manufacturer of a food establishes a written procedure to permit the complete, rapid recall of any lot of food from the market.

Assessment criteria
The written procedure includes:
- the person or persons responsible, e.g. recall coordinator(s);
- the roles and responsibilities for coordination and implementation of a recall;
- methods to identify, locate and control recalled product;
- a requirement to investigate other products that may be affected by the hazard and that should be included in the recall;
- procedure for monitoring the effectiveness of the recall, e.g. effectiveness check to the appropriate level of distribution specified in the recall notice;
- immediate (including outside the working hours) notification of the Canadian Food Inspection Agency in the region where the manufacturer is located. This notification includes the following:
  - amount of product produced, in inventory and distributed;
  - name, size, code or lot numbers of food recalled;
  - area of distribution of product, e.g. local, national, international;
  - reason for the recall.

See subsection 7.6.2 for expected distribution records.

7.6.2 Distribution records

Product distribution records are available to enable the manufacturer to recall any lot of food in a timely fashion.

Assessment criteria
Distribution records contain sufficient information to permit traceability to a particular code or lot number.
The following minimum information is required for distribution records:
- product identification and size;
- lot number or code;
- quantity;

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

- customer names, addresses, and phone numbers to the initial level of product distribution.

8.2.2 Recall Capability

Recall procedures are tested periodically to verify the capability to rapidly identify and remove product from the market.

Assessment criteria
The manufacturer demonstrates capability of providing accurate information on a timely basis to verify that all affected product can be rapidly identified and removed from the marketplace. For example:

- periodic testing (internal simulations) to verify the capability of the procedure to rapidly identify and control a code lot of potentially affected product and reconcile the amount of product produced, in inventory and in distribution;
- any deficiencies in the recall procedure are identified and corrected.

* Numbers in parenthesis refer to sections of The Codex General Principles of Food Hygiene.

GLOSSARY

Adulterant -foreign substance in food, especially substances which are aesthetically objectionable, hazardous to health or which indicate that unsanitary handling or manufacturing practices have been employed. Adulterants include, but are not limited to, those that are specifically listed in the *Food and Drug Regulations.*

Allergens - any substance capable of producing an abnormal immune response in sensitive individuals.

Capability - a standardized evaluation of the inherent capability of equipment to consistently perform a specified function under actual operating conditions after significant causes of variation have been eliminated.

Certification - with reference to this document, certification refers to the guarantee a supplier (vendor) provides to a manufacturer that the material meets the manufacturers specifications, e.g., certificate of analysis.

Change control - the control that a manufacturer maintains over any changes to the formula, ingredients, equipment, packaging, thermal processing and manufacturing process to ensure the safety of the finished product is not directly or indirectly affected.

Control - means that an operation performs consistently within pre-determined limits based on process capability, meets process requirements, provides a mechanism to maintain the stability of the process and consistently results in a safe product.

Corrective action - the actions to be taken when the results of monitoring the critical control point indicate a loss of control. In addition this term refers to any action taken to bring the process into control and deal with any affected product when critical limits or other criteria are not met. The action should be prompt and appropriate to the seriousness of the deficiency.

Critical Control point - a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical equipment - equipment that performs a function whose impact on the process is such that a food safety hazard could be prevented, eliminated, or reduced to acceptable levels.

Critical factor - means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the safety of the product or the process.

Critical limit - a value which separates acceptability from unacceptability. Critical limits are not control limits or specification limits. Control limits indicate what the process is capable of delivering and are tighter than specification limits which are in turn tighter than critical limits.

Deterioration - for the purposes of this text deterioration can be used interchangeably with spoilage, however deterioration can also apply to non-food products such as packaging materials. For non food

items, deterioration is a physical or chemical change in the material that may adversely affect the safety of the food.

Deviation - failure to meet the critical limits or other specified requirements for a critical factor.

Deviation procedure - a pre-determined and documented set of corrective actions which are implemented when a deviation occurs to re-establish control of the process and to control the affected product.

Documents - for the purposes of this text, documents refer to written formulae, procedures or specifications used by or required of a manufacturer.

Hazard - the potential to cause harm. A biological, chemical or physical property that may cause an unacceptable consumer health risk.

Hermetically sealed container - means a container designed and intended to be secure against the entry of microorganisms, including spores.

Incubation - 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 or other problems occur under these conditions.

Inspection areas - (definition with respect to lightning requirements), inspection areas are defined as any point where food products or containers are visually inspected or instruments are monitored.

Lot - means the amount of product of a specific container size, product style and code produced by a food establishment during a specified period of time.

Low acid food - means a food, other than an alcoholic beverage, where any component of the food has a pH greater than 4.6 and a water activity greater than 0.85.

Master formula - the master formula is the official formula referenced by a manufacturer for a given product. The thermal process and all working formulas (recipes) are based on the master formula.

Monitoring - a planned sequence of observations or measurements to assess whether a CCP (or other activity) is under control.

Process deviation - a change in any critical factor of the scheduled process which reduces the sterilizing value of the process or which raises a question regarding safety.

Recall, Periodic testing - internal activities conducted on a periodic basis to verify the capability of the manufacturer to rapidly identify and control a given lot of product. These activities do not necessarily require the manufacturer to contact customers.

Records - observations and measurements recorded by a manufacturer to determine adherence to critical limits or other specified requirements for critical factors.

Risk - an estimate of the likelihood of occurrence of a hazard.

Spoilage - a process whereby food is rendered unacceptable through microbiological or chemical reaction.

Vendor - for the purpose of this text vendor is equivalent to supplier.

Vendor certification - the process of acceptance of incoming materials that does not rely on 100% inspection of incoming lots. The manufacturer conducts a series of events prior to receipt of the material that ensures the material meets the required specification.

Verification - examination of the accuracy, correctness or effectiveness of validated process or process controls through testing, investigation or comparison with a standard.