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General Principles of Food Hygiene, Composition and Labelling

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PREFACE

Effective hygiene controls are vital to preventing food borne illness, food borne injury and food spoilage. The Canadian Food Inspection Agency's (CFIA) *General Principles of Food Hygiene, Composition and Labelling* (GPFHCL) is designed to serve as a guideline for Canadian food manufacturers and to assist them in establishing manufacturing practices that maintain food safety and meet regulatory requirements.

The CFIA has expanded the original *Code of Practice – General Principles of Food Hygiene* to address food compositional and labelling requirements. To reflect this change, the Code was renamed the *General Principles of Food Hygiene, Composition and Labelling* (GPFHCL). This expanded document includes the key controls necessary for manufacturers to control the safety, labelling and composition of food during manufacturing, processing, storage or distribution. It provides a sound foundation for the development of a system for ensuring food safety based on HACCP (Hazard Analysis Critical Control Point) principles. Although the GPFHCL is not meant to serve as a complete HACCP plan, it is a useful reference. Additional reference material can be found on the CFIA website.

The GPFHCL: An Assessment Tool

The GPFHCL is generic in nature, and the principles found within this document may be applied to all food processing or manufacturing establishments, regardless of their size or the food products they produce. In cases where manufacturers require further guidance, the CFIA may develop specific codes of practice for a variety of situations.

The CFIA's inspectors will utilize the GPFHCL to assist them in assessing whether an establishment complies with the requirements of the *Food and Drugs Act,* the *Food and Drug Regulations* and the *Consumer Packaging and Labelling Act* and *Regulations*. The GPFHCL is designed for establishments that are not specifically regulated under federal trade and commerce legislation such as the *Meat Inspection Act*, the *Fish Inspection Act* and the *Canada Agricultural Products Act*.

The GPFHCL is based on the *Recommended International Code of Practice – General Principles of Food Hygiene* adopted by the Codex Alimentarius Commission in 2003. This is consistent with the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement), which directs members to base their sanitary and phytosanitary measures on international standards, guidelines and recommendations.

Using the GPFHCL

Each section of the GPFHCL describes specific requirements. Each sub-section includes a principle statement (in a box) and, when necessary, a rationale, followed by the CFIA's assessment criteria.

Principle Statement
Principle statements are outcome-based generic statements of objectives similar to those found in the Codex Code. They are intended to capture the intent of the guideline while allowing flexibility in addressing specific products or processes.

Rationale
Rationales are included only when the principle statement needs explanation. They are included in several chapters (such as Control of Operation, Equipment, and Records) to explain the nature of the concern or potential hazard(s) and the need for control.

Assessment Criteria
Assessment criteria in the GPFHCL will describe the factors used in assessing a manufacturer's adherence to the objectives in the principle statement. The CFIA considers these factors during the course of its risk-based investigation or inspection activities in the non-federally registered sector.

The assessment criteria are intended to guide industry. The CFIA recognizes that there may be alternative means of meeting the intent of the principle statement other than those specified in the assessment criteria. These alternative means may include a specific process step that will be used to control an associated food safety risk or meet a regulatory requirement. Therefore, the CFIA has carefully worded the document to accommodate options or equivalents.

The CFIA also recognizes that manufacturers may require additional guidance to expand upon the hygiene, labelling and compositional requirements associated with specific products or manufacturing processes. This guidance will be further developed as needs are identified.

1.0 CONTROL OF OPERATION

1.1 PRODUCT FORMULATION AND COMPOSITION

1.1.1 Availability and Accuracy of the Product Formula

A current written formula is available for each product processed.

Rationale
A current written formula provides a basis for assessment of food additives, composition, labelling, nutritional requirements, food allergens and the scheduled process.

Assessment Criteria

- A written formula is available for each product.
- The formula contains all details of the formulation as follows:
  - identification of all ingredients (e.g. brand/supplier, concentration, type, common name, specific name of food colours) and components (ingredients of ingredients);
  - amounts of all ingredients, including food additives and added nutrients.
- Products are formulated to comply with food standards, when they exist.
- Products are formulated to ensure accurate nutrition declarations.
- The formula is current for the products being processed.

1.1.2 Identification of Critical Processing Factors in Product Formulation

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

Rationale
Inadequate identification of either critical ingredients and their specifications, or critical preparation/process steps, could result in an inadequate process, which could affect product safety or lead to inaccurate nutrient composition.

Assessment Criteria

- Ingredients critical to the product's composition and its nutritional profile, and to the safety of the process, are identified with their specifications and limits.
- Ingredients susceptible to property changes and nutrient losses are identified.

- Control factors that are critical to the safety and integrity of the product are identified (this includes microbiological, chemical or physical concerns, as well as concerns related to allergens, extraneous material, etc.). Their specifications and limits are identified (e.g. thermal process, pH and water activity for ready-to-eat fermented meats, salt content for brined mushrooms, sulphur content on dried fruit, etc.).

1.1.3 Compositional Requirements

The nutrient content of the food is controlled to meet declared label values and applicable requirements found in the *Food and Drugs Act* and the *Food and Drug Regulations.*

The addition of vitamins, mineral nutrients and amino acids to food products is controlled to meet the requirements of the *Food and Drugs Act* and the *Food and Drug Regulations.*

Foods for which nutrient content claims and health claims are made meet the compositional requirements of the *Food and Drug Regulations* [Division 24, B.01.503, B.01.601].

Products comply with food standards when they exist.

Rationale

Formulation controls are necessary to prevent hazards that could result from excesses, inadequacies and omissions of nutrients. Examples include fortified foods and foods for which there are nutrition and/or health claims (e.g. calorie-reduced, low sodium).

Inaccurate nutrition information, nutrient content claims or health claims may pose a health risk to those under dietary management for chronic diseases (such as diabetes, heart disease, high blood pressure, cancer and osteoporosis) or for those who are making food choices based on the nutrient content of the food.

Inadequate control of food composition could also result in product misrepresentation and fraud. Consumers expect that the declared ingredients, compositional standards, nutrition information and claims accurately reflect the food’s composition.

Assessment Criteria

- The manufacturer has control over the formulation to ensure that all nutrient content declarations and regulatory requirements, including compositional requirements, are met.

Added nutrients

- Vitamins and mineral nutrients are added to foods in accordance with the *Food and Drug Regulations* (e.g. nutrients are permitted in the specific foods and added at the appropriate levels).
- The manufacturer has specifications for nutrients.
- The manufacturer receives the following documentation:
  - nutrition information for each shipment of nutrient premix [B.01.404]; and
  - a Certificate of Analysis for each lot of nutrient. For nutrients used in foods that are the sole source of nutrition, each certificate is verified through analysis.
- 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*.

Nutritional composition requirements

- Foods for which there are nutritional composition requirements (e.g. meal replacements, nutritional supplements, flour) meet these requirements.
- Final products meet the composition requirements for any nutrient content claim or health claim made on the label or in any advertisements.
- The nutrient content of the product is accurately reflected on the label and in compliance with the *Food and Drug Regulations* (i.e. the list of ingredients and the Nutrition Facts table).
- Label values have a high probability of being accurate and are rounded in compliance with the *Food and Drug Regulations* [Column 4 of the tables to section B.01.401 and B.01.402].
- Individual lots have a high probability of meeting the CFIA's *Nutrition Labelling Compliance Test* throughout the period the label is in use.
- The manufacturer verifies, as often as necessary, that the Nutrition Facts table is accurate and within tolerance.

Food standards

- Product formulations are designed to ensure that standardized food products meet the regulated standards of identity and composition.
- Controls are in place to ensure that the health, safety and fraud provisions of standards are consistently met.

NOTE: The following documents provide further guidance on composition and labelling. They are available on the CFIA website.

i. The *Evaluation Standard for Nutrition Labelling* addresses, in detail, the requirements of the Nutrition Facts table and the factors involved in determining nutrient content and producing a product with a consistent nutrient profile. This document may be found within the *Nutrition Labelling Toolkit*.

ii. The *Guide to Food Labelling and Advertising* provides detailed guidance on the requirements for nutrient content and diet-related health claims.

iii. The *Nutrition Labelling Compliance Test* constitutes the CFIA methodology for assessing the accuracy of nutrition labelling and claims.

1.1.4 Food Additives

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

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

Assessment Criteria

- The manufacturer ensures that all food additives that are used are permitted for use in the particular food and meet the requirements of the *Food and Drug Regulations* [Division 16] and other applicable regulations.
- The manufacturer has specifications for all food additives.
- Where there are no specifications in the *Food and Drugs Act* and the *Food and Drug Regulations*, the manufacturer requires that all food additives meet the United States Pharmacopeia *Food Chemical Codex* (FCC) specifications or equivalent (e.g. specification sheets or Letters of Guarantee).
- 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*.

1.2 LABELLING AND NET QUANTITY

1.2.1 Labelling

The manufacturer has controls in place to ensure that the labels are complete and accurate, and meet the requirements of the *Food and Drugs Act,* the *Food and Drug Regulations* and the *Consumer Packaging and Labelling Act* and *Regulations*.

Rationale
Mandatory information on food labels allows consumers to make informed choices by:

- providing basic product information (e.g. the product's common name, its list of ingredients, its net quantity, its durable life date (if applicable) and country of origin, as well as the name and address of the manufacturer, dealer or importer); and
- providing health, safety and nutrition information (e.g. instructions for safe storage and handling, nutrition information in the Nutrition Facts table and specific information on products for special dietary use).

Inaccurate labels may be considered false and misleading and in violation of section 5.1 of the *Food and Drugs Act*.

NOTE: Mandatory information is determined, in part, by the regulatory requirements specific to the commodity in question.

Assessment Criteria

- The manufacturer has procedures in place to ensure that all mandatory information is properly declared on food labels in accordance with Canadian food labelling legislation, and that all label claims are accurate and not misleading. The following are examples of such procedures.
    - Personnel responsible for the label development, design and sign off, whether company employees or consultants, have a good understanding of Canadian food legislation and labelling requirements and are kept current with respect to regulatory changes.
    - Labels are reviewed both for compliance with Canadian legislation (e.g. presence of mandatory labelling), and for accuracy and correctness of information. This assessment includes mandatory information, quality claims (e.g. natural, fresh), compositional claims (e.g. no preservatives.), nutrition claims, method of production claims (e.g. organic, grain fed) and standards of identity.
    - New labels and changes to current labels (e.g. changes to artwork, text and layout) are reviewed for compliance with Canadian legislation.

- Incoming labels from labelling and/or printing companies are reviewed against signed-off proofs.
- Corrective labels applied to products to bring them into compliance are reviewed against signed-off proofs.
- Changes in packaging are assessed for their impact on product labelling (e.g. changes in the size of the principal display surface, the available display surface or the location of the principal display panel).
- All pamphlets, posters, handouts and other Canadian advertising materials developed and/or distributed by the manufacturer are reviewed and verified for accuracy and compliance with Canadian legislation (see Chapter 3 of the *Guide to Food Labelling and Advertising*).
- Foods containing ingredients that are on Canada's list of priority allergens are labelled so that consumers are aware of their presence.

NOTE: The CFIA website provides extensive information and guidance to the food industry regarding food allergens, including additional information on each of Canada's priority allergens, guidance on the *Labelling of Foods Causing Allergies and Sensitivities* and *A Tool for Managing Allergen Risk in Food Products*.

1.2.2 Net Quantity

Controls are in place to ensure that net quantity declarations are accurate and comply with the *Consumer Packaging and Labelling Act* and *Regulations* and the *Weights and Measures Act* and *Regulations*, where applicable.

Rationale
Companies that do not declare accurate net quantities for their products have an unfair competitive advantage within their market sector and do not contribute to the fair and effective operation of the marketplace.

The net quantity declaration provides important information that consumers use in making their purchasing decisions. Since the declaration helps consumers to know how much food is in a container, it enables them to compare prices. Consumers rely on net quantity declarations, trusting manufacturers to provide the quantity declared on a product's label.

Canada has adopted an international measurement standard, the *Average System of Net Quantity Determination*, as its method of determining the accuracy of net quantity declarations. The Average System is set out in section 39 of the

Consumer Packaging and Labelling Regulations and section 52 of the *Weights and Measures Regulations*.

Assessment Criteria

- The manufacturer has controls in place to ensure that the product's net quantity, as stated on the label, is in compliance with section 39 of the *Consumer Packaging and Labelling Regulations* and section 52 of the *Weights and Measures Regulations*.
- Production procedures that directly affect net quantity are identified and described. Measures are in place to ensure that these procedures are performed in controlled conditions in order to minimize the possibility of net quantity errors. Examples of the process control elements to be considered include:
  - sequence of operations;
  - equipment type;
  - work environment;
  - procedure control points and monitoring methods used at these control points;
  - name(s) of person(s) in charge of operations;
  - documentation;
  - data recording methods;
  - acceptance numbers; and
  - description of corrective action to be taken in cases of nonconformity.
- Inspection and testing during production permits the identification of causes of nonconformity before the final control stage and increases the overall effectiveness of the process by preventing the continued production of non-compliant products.
- Working procedures and instructions critical to compliance with the requirements set out in the *Consumer Packaging and Labelling Regulations* and the *Weights and Measures Regulations*, known as the *Average System of Net Quantity Determination*, are documented. These working procedures and instructions have been approved by the designated person in charge. Examples of information to be considered include:
  - equipment used;
  - equipment checks to be performed;
  - number of weighings;
  - frequency of weighings;

- place of sampling;
- acceptance numbers (tolerance, average);
- name(s) of person(s) in charge;
- description of corrective action to be taken in cases of non-compliance;
- data recording methods;
- density of checked product (for products declared by volume);
- environmental conditions (e.g. hot filled products, product temperature requirements of certified volumetric standards); and
- availability of Certificates of Analysis.

NOTE: Control of scales, gravimetric and volumetric standards, and other measuring equipment is covered in Section 2.1 - General Equipment.

1.3 PROCESS DESIGN

1.3.1 Process Design

The manufacturer demonstrates that foods do not develop any safety hazards (biological, physical or chemical) and labelling inaccuracies are prevented.

Rationale
Written verification is necessary to demonstrate that each process adequately ensures uniform composition and a safe product. An inadequate process could result in unsatisfactory incorporation of ingredients and nutrients, or in the lack of control of pathogenic organisms, toxins and other hazards.

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 (CCPs) for each product, including the critical limits for each CCP, are identified, tested and evaluated in the development of the process. Note that 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 Section 7.2.1 - Process Design Records, for further information.

1.4 INCOMING MATERIAL CONTROL

1.4.1 Ingredients

The manufacturer controls incoming ingredients so that foods are not exposed to safety hazards (biological, physical and chemical) and remain both safe and correctly labelled.

Rationale
Prevention of health hazards and fraud begins with control of incoming materials. Inadequate incoming product controls, such as a lack of appropriate product testing and sorting or a failure to verify labels, could result in the sale of contaminated product, misrepresented product or product that does not meet grade, composition or quality standards.

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 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 the *Food and Drug Regulations.*
- Nutrition information accompanies each shipment of incoming ingredients.

NOTE: i. The nutrition information may be conveyed on a hard copy document which accompanies the delivery of the food.

ii. In the case of foods that are shipped to a purchaser on a continual basis with no change to the formulation, documentation may be provided to the purchaser with the first shipment. The purchaser is advised of any change to the nutrition information as a result of formulation changes or other influences.

Control of Incoming Products: Options 1 - 4
The manufacturer controls incoming ingredients through one of the four control processes outlined below. The first three options apply to ingredients that may be critical to safety (further processing is not likely to eliminate a hazard.) The fourth option applies only to ingredients that do not pose a safety risk.

NOTE: Section 1.1.3 and Section 1.1.4 provide guidance for assessing specifications for food additives and nutrients.

Option 1: Periodic Evaluation of Incoming Products

- The manufacturer obtains a Certificate of Analysis for each lot.
- A representative sample is taken at a scheduled frequency (e.g. monthly) and analyzed to verify the accuracy of the Certificate of Analysis.
- The manufacturer maintains a documented history of adherence to specifications for each supplier, such as analytical results.
- A new history of adherence to specifications is established when a manufacturer changes suppliers, purchases ingredients from a new supplier or purchases a new ingredient from an existing supplier.

Option 2: 100% Lots Inspected

- 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 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 are available upon request from each supplier.
- Prior to implementing a periodic monitoring program, the manufacturer analyzes an appropriate number of consecutive lots to establish an historical database 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 (to be utilized only when food safety risks are unlikely)

- Where incoming ingredients are not likely to impact the safety of the food, the manufacturer conducts periodic monitoring to verify adherence to specifications (e.g. annually) or obtains a Certificate of Analysis.

Non-Conforming Ingredients

- When ingredients fail 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 (see Section 1.10 - Deviations and Corrective Action).

1.4.2 Incoming Packaging Material Control

The manufacturer controls incoming packaging materials to meet the requirements of the *Food and Drugs Act* and the *Food and Drug Regulations* and to prevent the introduction of biological, physical or chemical hazards.

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 the product or may permit physical, chemical or biological contamination of the product.

Assessment Criteria

- The manufacturer demonstrates that the packaging material is suitable for the intended use. 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, including physical dimensions, material specifications and performance specifications.

NOTE: Additional requirements for evaluation of incoming packaging materials will depend on the type of product, the process and the sensitivity of the product.

Control of Incoming Packaging Material

See Options 1 - 4 of Section 1.4.1 - Control of Incoming Products.

See Section 7.2.2 - Incoming Material Control Records.

1.5 PACKAGING MATERIAL CONTROL

1.5.1 Packaging Material

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

Rationale
Inadequate control of packaging may result in the use of damaged, defective or contaminated packaging material, which may lead to contamination of the product.

Assessment Criteria

- The manufacturer has an effective system in place to prevent the use of contaminated, damaged or defective packaging material. This can be accomplished using a variety of controls to minimize damage, to prevent contamination and to ensure cleanliness. Examples are listed below.
    - The manufacturer has controls in place to minimize damage and verifies the effectiveness of these controls through periodic audits. Controls might include:
        - receiving controls (e.g. driver handling, unloading, identification of damage problems and corrective action);
        - storage controls (e.g. stacking restrictions related to heights and spacing, protection from damage and contamination);
        - depalletizing and conveying controls (e.g. careful loading, removal of damaged packaging, effectiveness of damage control, synchronization of line speeds, transfer points);
        - visual examination (i.e. prior to use, packaging is examined for damage and contamination); and
        - careful handling/transfer (i.e. to minimize damage and contamination by careful handling at conveyors, transfer points, etc.)
    - The manufacturer has controls in place to prevent contamination of clean packaging (i.e. packaging is used for its intended purpose only).
    - Where appropriate, the manufacturer has in place an effective sanitation program.

1.6 PRODUCT PREPARATION AND BLENDING

1.6.1 Control of Preparation, Composition and Blending

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, nutrient content, product claims and net quantity.

Rationale
Inadequate control of critical factors associated with product preparation and blending could result in inadequate processing, the formation of toxins or the presence of undeclared allergens. The product may violate permissible levels of food additives, or may fail to meet compositional standards and/or the product's nutrient content declaration may be inaccurate.

Assessment Criteria

- The manufacturer has controls in place to prevent hazards associated with the preparation or blending of the product. Critical areas are outlined below.

Microbial control during preparation and blending

- 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 by-products of microbial growth. Critical factors which may require control include the following:
    - size control: dicing, grinding, slicing;
    - temperature treatment control: heating, blanching (textural changes), defrosting, cooling;
    - moisture control: rehydration, concentration (e.g. viscosity, brix);
    - proportion control: weighing, volumetric control (e.g. metering);
    - pH/acidity control: pH measurement, titratable acidity; and
    - control of preservatives, such as nitrite.

Allergens

- The manufacturer has controls in place to prevent the presence of undeclared allergens. Manufacturers may require controls to prevent the following:
    - misdirection of ingredients;
    - use of rework;
    - contamination by undeclared ingredients;
    - ingredient carryover;
    - ingredient substitutions; and
    - carryover from equipment (e.g. product changeovers).

Food additives

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

Nutrient addition

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

Composition

- The manufacturer has controls in place to ensure that the composition of the product accurately reflects the formulation. Manufacturers may require controls to prevent the following:
  - misdirection of ingredients;
  - use of rework;
  - ingredient carryover;
  - ingredient substitutions; and
  - carryover from equipment (e.g. product changeovers).

See Section 7.2.3 - Product Preparation and Blending Records.

1.6.2 Cleaning and 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 biological, physical and chemical hazards (where appropriate).

Biological hazards

- The manufacturer may utilize the following:
  - inspection controls: visual, sensory, etc. (e.g. removal of decomposed product);
  - control by washing (e.g. reduction of the microbial load).

Physical hazards

- The manufacturer may utilize the following:
  - metal contamination controls (e.g. magnets, metal detectors);
  - other extraneous matter controls (e.g. sifting, sorting/cleaning by gravity, air or water).

Chemical hazards

- The manufacturer may control natural toxins by sorting. Examples include sorting by colour (e.g. glycoalkaloids in potatoes).

1.7 PRODUCT CODING CONTROL

1.7.1 Product Coding

Each prepackaged food, where required, 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 and provides information on shelf life. Controls are also necessary to prevent damage that could compromise the container as the coding is being applied.

NOTE: Mandatory coding requirements vary, depending on the specific legislation that applies to the commodity. It is suggested that manufacturers consult with inspection authorities in order to confirm specific requirements applicable to products.

Assessment Criteria

- The manufacturer ensures that, where required or applicable, prepackaged food has been permanently marked with a legible code or lot identification.

- The coding system allows for the identification of the establishment where the food was processed, and the day, month and year in which the food was produced.
- The exact meaning of all code marks used is 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.

1.8 PROCESS CONTROL

1.8.1 Processing Controls

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

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

Assessment Criteria

- The manufacturer evaluates the process and identifies all critical factors.
- The manufacturer ensures that 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 Section 7.2.4 - Process Control Records.

1.9 LABELLING CONTROL

1.9.1 Prevention of Mislabelling

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 could pose a potential health hazard to segments of the population who may be allergic to certain foods or who are monitoring their diet to treat certain diseases in which nutrition plays a role.

Assessment Criteria

- The manufacturer has controls in place to prevent the mislabelling of products. Typical controls are listed below.
    - Product types are effectively separated 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.
    - Identifying marks and/or colours are utilized 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.
    - During storage, care is taken to prevent mixing of individual labels or bundles of labels (e.g. labels are stored in separate boxes; no labels are loose; unused labels are returned to the correct boxes).
    - Procedures are in place to ensure the product being supplied or added to the labelling operation corresponds to the labels in use.

1.10 DEVIATIONS AND CORRECTIVE ACTION

1.10.1 Deviation Control

When critical limits are exceeded or defects occur that could affect product safety, composition or net quantity, procedures are in place to identify, isolate and evaluate the affected product.

Rationale
Deviations from critical limits and procedures, or the occurrence of defects, may affect the safety, authenticity and quality of the product. Inadequate deviation procedures or non-adherence to procedures could result in the sale of unsafe product, misrepresented product or product of inferior quality.

Assessment Criteria

- The manufacturer has a pre-determined and documented deviation procedure to identify deviations in either the product and/or the procedures, and isolate defective products.

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. firmly attached tags contain the following information: hold number, product, the amount, the date held, the reason for the hold and 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).
- Evaluation is adequate to detect potential health hazards, or to identify misrepresentation or product that does not meet quality or grade requirements. For example,
    - 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 the product is in compliance with appropriate legislation.
- Disposition of affected product (e.g. sorting of suspect lots, disposal) is conducted in an appropriate manner by adequately trained personnel.

1.10.2 Corrective Action

Corrective action taken following any deviation is effective to rectify and to prevent recurrence of the deviation.

Rationale

Corrective action procedures are necessary to determine the cause of the problem and to take action to prevent recurrence. It is essential to follow-up any corrective action with monitoring and reassessment to ensure that the correction has been effective. Appropriate corrective action will address the root cause of any deviations of critical control points, thereby minimizing health risks and product misrepresentation.

Assessment Criteria

- As part of the deviation procedure, the manufacturer documents corrective actions, including:
  - an investigation to determine the cause of the deviation;
  - effective measures taken to prevent recurrence of the deviation; and
  - verification by the manufacturer of the effectiveness of the corrective action taken.

See Section 7.2.5 - Deviations and Corrective Action Records.

1.11 VERIFICATION OF PRODUCT SAFETY

1.11.1 Verification Procedures

The manufacturer uses supplementary methods of evaluation to verify the effectiveness of controls affecting product safety, composition, representation, quality and compliance with Canadian legislation.

Rationale
The purpose of verification is to assess the effectiveness of existing controls 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 the product and process, since the methods must be appropriate to the specific hazards and risks that may be encountered.

Examples of verification methods
- Verification methods may include the following:
  - sampling and analysis of in-process and finished product for the appropriate chemical, microbiological or physical hazards and for composition and nutrient profile;
  - 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; and
- 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 Section 7.2.6 - Verification Records.

2.0 EQUIPMENT

2.1 GENERAL EQUIPMENT

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 results that are required;
  - it is accessible for cleaning, sanitizing, maintenance and inspection;
  - contamination of the product during operation is prevented (e.g. location of lubricant reservoirs);
  - it is exhausted to the outside to prevent excessive condensation (e.g. filler bowls, blanchers, retorts), where necessary; and
  - proper drainage is permitted and where appropriate, equipment is connected directly to drains.

NOTE: Equipment design, construction and installation is not considered deficient if the potential hazards can be controlled by other procedures.

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 able to withstand repeated cleaning and sanitation.
- When coatings, paints, chemicals, lubricants and other materials are used for food contact surfaces or utilized on equipment where there is a possibility of contact with food, either:
  - the substances are listed in the *Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Products*, published by the CFIA, or

- the manufacturer has a “letter of no objection” from Health Canada.

NOTE: The Reference Listing is on the CFIA website.

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 the product.

Assessment Criteria

- The manufacturer has an effective written preventive maintenance and calibration program to ensure that equipment that may impact on food safety and net quantity functions as intended. This includes:
  - a list of equipment requiring regular maintenance; and
  - the maintenance procedures and frequencies (e.g. equipment inspection instructions; a schedule of adjustments and part replacements based on the equipment manufacturer’s manual or equivalent, or based on operating conditions that could affect the condition of the equipment).
- The manufacturer establishes written protocols, including calibration methods and frequencies, for equipment monitoring and/or controlling devices that may impact on food safety.
- Equipment is maintained in a manner that ensures that there is no potential for the development of physical or chemical hazards (e.g. hazards resulting from inappropriate repairs, flaking paint and rust, excessive lubrication).
- Maintenance and calibration of equipment is done by appropriately trained personnel.
- The preventive maintenance program and written protocol are adhered to.

See Section 7.3.1 - Equipment Maintenance and Calibration Records.

2.1.4 Instrumentation Maintenance and Calibration Program

Instrumentation is designed, constructed, installed, calibrated and maintained such that the equipment is capable of delivering the required process, thereby ensuring product safety and net quantity accuracy.

Rationale
Improper design, installation, calibration or maintenance of instruments can lead to inadequate processing of the product or to improper use of food additives, nutritional inaccuracies or composition violations.

Assessment Criteria

- Instruments that control factors that are 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 (i.e. Celsius or Fahrenheit).
- Temperature measuring devices are calibrated against a known standard just prior to installation, and thereafter, 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, bimetal thermometers).

Mercury in glass (MIG) thermometers

- Mercury in glass thermometers are calibrated against a known standard just prior to installation, and thereafter, a minimum of once per year (or more frequently as necessary to ensure the thermometer's accuracy). If there is a deviation of more than 0.5°C (1°F) from the standard thermometer, corrective action is taken based on the directives found in this document (see Section 1.10.2 - Corrective Action).
- Thermometer scales are within the operating range, are easily readable to 0.5°C (1°F), and do not contain more than 4°C/cm (17°F/in).

Temperature recorders

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

Timing devices

- Timing devices and recorders are verified upon installation, and thereafter once per year (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.
- Any official timing device is located so that it can be easily and accurately read by the operators.

Pressure gauges

- Each pressure gauge is calibrated at least annually (or more frequently as necessary to ensure 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 are 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 (e.g. adequately cleaned, metal particles removed).

Metal detectors

- Metal detection equipment is designed, constructed, installed, calibrated and maintained in accordance with 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).
- Scales and meters are calibrated in accordance with the equipment manufacturer's manual to ensure accuracy at all times.

Other instrumentation

- Other specialized instrumentation necessary for the control of critical factors is in place and calibrated as necessary (e.g. pH meters, refractometers).

NOTE: The manufacturer initiates corrective action as per Section 1.10 - Deviations and Corrective Action, whenever products could have been affected and found not to meet specifications.

3.0 PREMISES

3.1 BUILDING EXTERIOR

3.1.1 Outside Property and Buildings

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

Assessment Criteria

Grounds, roadways and drainage

- The surrounding land is maintained to minimize 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, dust proofed 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. the exterior has no unprotected openings; air intakes are appropriately located; the roof, walls and foundation are maintained to prevent leakage).

3.2 BUILDING INTERIOR

3.2.1 Design, Construction and Maintenance

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

Assessment Criteria

Floors, walls, ceilings

- Floors, walls and ceilings are constructed of materials that are durable, impervious, smooth, cleanable and suitable for the production conditions in the area.
- 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

- Activities are adequately separated by physical or other effective means where cross-contamination may result.
- Buildings and facilities are designed to prevent contamination (i.e. there is 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. Note that inspection areas are defined as any points where food products or packaging materials are visually inspected or where instruments are monitored (e.g. empty container evaluation, product sorting and inspection).
- 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.
- 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 the event 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 heat, 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.
- 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 their removal from the establishment. These facilities are designed to prevent contamination.
- Containers used for waste are clearly identified, leak proof and, where appropriate, covered.
- Waste is removed and containers are cleaned and sanitized at an appropriate frequency to minimize the potential of contamination.

3.3 SANITARY FACILITIES

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 hand-washing 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 change rooms are maintained in a clean condition.
- Hand-washing 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 that are 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 AND STEAM QUALITY

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. 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 CFIA, or the manufacturer has a "letter of no objection" from Health Canada.

- 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 that is clearly identified.
- Ice that is used as an ingredient or that is 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 Section 1.4.1 - Incoming Material Control – Ingredients.

3.4.2 Steam

The potability of steam that is 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 CFIA, or the manufacturer has a "letter of no objection" from Health Canada.
- 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 Section 7.4.1 - Water, Ice and Steam Quality Records.

4.0 SANITATION AND PEST CONTROL

4.1 SANITATION

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 the responsible person, the frequency of the activity, the chemicals and concentrations used, the temperature requirements, and the procedures for cleaning and sanitizing. Cleaning and sanitizing procedures are discussed below.
    - For Cleaned Out of Place (C.O.P.) equipment, written procedures will:
        - identify equipment and utensils;
        - outline disassembly/reassembly instructions as required for cleaning and inspection;
        - identify areas on equipment requiring special attention; and
        - outline the method of cleaning, sanitizing and rinsing.
    - For Cleaned in Place (C.I.P.) equipment, written procedures will:
        - identify lines and/or equipment;
        - outline C.I.P set-up instructions;
        - describe the method of cleaning, sanitizing and rinsing; and
        - outline 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, the method of cleaning, the 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 Products*, published by the CFIA, or the manufacturer has a "letter of no objection" from Health Canada.
    - 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. no contamination from aerosols or 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 Section 7.5.1 - Sanitation Records.

4.2 PEST CONTROL

4.2.1 Pest Control Program

Effective pest control programs are in place to prevent entry of pests, to detect and eliminate pests and to 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 to whom 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 they were applied, and the 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 with the Pest Management Regulatory Agency under the *Pest Control Products Act and Regulations* and have been issued a Pest Control Product (PCP) Registration Number. Pesticides are used in accordance with the label instructions.
- 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 the *Food and Drug Regulations* is not exceeded (e.g. the number of fumigation treatments per lot is limited).
- Poisonous rodenticides are not used in food processing or storage areas.

- Birds and animals, other than those intended for slaughter, are excluded from establishments.

See Section 7.5.2 - Pest Control Records.

5.0 PERSONNEL

5.1 HYGIENE AND HEALTH REQUIREMENTS

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 who are entering food handling areas wash their hands before starting work, after handling contaminated materials, after breaks and after using toilet facilities. Where necessary to minimize microbiological contamination, employees may use disinfectant hand solutions.
- 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 that 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 that may fall into food, or otherwise contaminate food. Jewellery which cannot be removed, including wedding bands and medical bracelets, 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 and Injuries

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

Assessment Criteria

- The manufacturer has a policy, and enforces the policy, to prevent personnel from working in food handling areas if they are known to be suffering from a disease, or are known to be carriers of a disease, transmissible through food.
- 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; and
    - discharge from the ears, eyes or nose.
- 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

5.2.1 General Food Hygiene Training

Food handlers are trained in personal hygiene and hygienic handling of food, and they understand the precautions necessary to prevent the contamination of food.

Assessment Criteria

- The manufacturer has a written training program for employees that 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, if applicable.

5.2.2 Technical Training

To ensure food safety, accuracy of product representation and net quantity, personnel are trained such that they have adequate technical knowledge and understanding of the operation(s) or process(es) for which they are responsible.

Assessment Criteria

- Training is appropriate to the complexity of the manufacturing process and the tasks assigned. Examples are listed below.
    - 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, the labelling requirements and the records to be kept.
    - All employees, including maintenance and customer services employees, are trained to implement allergen controls.
    - Operators are trained to have current knowledge of equipment and process technology (e.g. apprenticeship training, training for retort operators or pasteurization operators).
    - Personnel responsible for the 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 the principles and methods and are competent in procedures to protect the safety of food.
    - Training is appropriate to ensure that personnel have a current understanding of Canadian food legislation (e.g. the manufacturer has trained personnel responsible for label development, design and sign-off).

6.0 TRANSPORTATION AND STORAGE

6.1 TRANSPORTATION

6.1.1 Food Carriers

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

Assessment Criteria

- The manufacturer verifies that carriers are suitable for the transportation of food. For example:
  - carriers are inspected by the manufacturer prior to loading and upon receipt of products to ensure that they are free from contamination and suitable for the transportation of food;
  - the manufacturer can demonstrate that the carrier has an adequate cleaning and sanitizing program in place (e.g. a written cleaning and sanitizing procedure is available for bulk carriers).
- 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 food loads in the same shipment or to subsequent food loads (after an acceptable clean out). 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, visual inspections, analysis as appropriate).
- Carriers are loaded, arranged and unloaded in a manner that prevents damage and/or contamination of the food.
- Bulk tanks are designed and constructed to permit complete drainage and 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 of the product and affect its safety.

Assessment Criteria

- Ingredients requiring refrigeration are transported at 4°C (39°F) or less, and the temperature is appropriately monitored. Frozen ingredients are transported at temperatures that do not permit thawing, and the temperature is appropriately monitored.
- Finished product is transported under conditions that minimize microbiological, physical and chemical deterioration (e.g. thermophilic spoilage).

6.2 STORAGE

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°C (39°F) 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 that prevents damage and/or contamination.
- Stock rotation of ingredients, and where appropriate, packaging materials 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 that prevents 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 product is stored and handled in a manner that prevents damage and contamination.

Assessment Criteria

- Finished product is stored and handled under conditions that 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 of containers, container corrosion resulting in leakage, products exceeding shelf life).
- Finished product requiring refrigeration is stored at 4°C (39°F) or less and is appropriately monitored. Frozen finished product is stored at a temperature that does not permit thawing.
- Defective, suspect or returned product is clearly identified and isolated in a designated area for appropriate disposition.
- Finished product is stored and handled in a manner that minimizes damage (e.g. forklift damage or damage due to uncontrolled stacking heights).

7.0 RECORDS

7.1 GENERAL RECORDS

7.1.1 General Record Requirements

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

Assessment Criteria

- Records are legible, permanent and accurately reflect the actual events, conditions or activities.
- Errors or changes are identified so that the original record remains 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.
- A qualified individual, designated by management, signs all critical records (e.g. records related to the adequacy of the thermal process and the achievement of a hermetic seal) prior to distribution of product. 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

7.2.1 Process Design Records

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

Rationale
Records are necessary to verify 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.

7.2.2 Incoming Material Control Records

The manufacturer keeps records that demonstrate the adequacy of incoming material control.

Rationale
Records are necessary to verify the manufacturer's control over biological, physical and/or chemical hazards.

Assessment Criteria

- The minimum record requirements for the four monitoring and/or certification options (periodic evaluations, 100% lot inspection, vendor certification and non-conforming incoming materials) are outlined below.

Periodic evaluations
- The manufacturer has records to:
    - document the history of adherence to specifications (i.e. analytical results);
    - state the results of spot checks (i.e. analytical results).

100% Lot inspection
- The manufacturer has analytical results for each incoming lot.

Vendor certification
- The manufacturer has records that:
    - 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);
    - demonstrate the capability of supplier's process (e.g. capability studies), with statistical process control charts available upon request;
    - provide an historical data base (e.g. analytical results on consecutive lots);
    - record results of periodic monitoring (e.g. analytical results); and
    - state the results of supplier audits (e.g. audit reports).

Non-conforming incoming materials
- The manufacturer has records to:
    - identify the material;
    - identify the deficiency; and

- specify the preventive and corrective action taken.

7.2.3 Product Preparation and Blending Records

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

Rationale
Records are necessary to verify that critical factors in preparation and blending are controlled.

Assessment Criteria

- Records are available upon request to demonstrate control of product preparation and blending, through adherence to critical limits specified in the formula (e.g. records for critical factors specified in the process, for fillings, and for nutrients in foods).

7.2.4 Process Control Records

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

Rationale
Records are necessary to verify the safety of the process and product 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.

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
Records are necessary to verify that the manufacturer has control of deviations and that corrective action has been effective.

Assessment Criteria

- The manufacturer supplies records of deviations and corrective action that contain the information specified below, at a minimum.

Deviation and hold

- Records contain the product and code, the date the product was produced, held or released, the reason for the hold, the amount of product held (e.g. back to the point where the process was last in control), the results of the evaluation or sort (e.g. the amount analyzed and an analysis report of the number and nature of defects).
- The records further contain information about the disposition of the held product (e.g. amount sorted; amounts destroyed; amounts reconditioned; amounts disposed of through employee sales, distress or salvage; and retail sales).
- Records include the signature of personnel responsible for the hold and evaluation, and the signed authorization for disposition.

Corrective action

- Records identify the cause of deviation, the corrective action taken to correct the deficiency and a follow-up/assessment to gauge the effectiveness of the corrective action.
- Records include the date that the corrective action was taken and verified, and the signature of the person responsible.

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

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

7.3 RECORDS ON EQUIPMENT

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

- Maintenance records for critical equipment typically include an identification of the equipment, the maintenance activity, the date of maintenance, the person responsible and the reason for the activity.
- Calibration records for critical equipment typically include an identification of the equipment, the date of calibration, the person responsible and the calibration results.

7.4 RECORDS ON PREMISES

7.4.1 Water, Ice and Steam Quality Records

Written records that adequately reflect control of water, ice 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, ice and steam supply as outlined below.

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	- analyst
- analyst	- analyst	- date
- date	- date	

7.5 RECORDS ON SANITATION AND PEST CONTROL

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; the person responsible; a list of the equipment, floors, etc. being cleaned; the

corrective action taken; and the microbiological test results, where appropriate.

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

7.6 RECORDS ON COMPLAINT HANDLING AND RECALLS

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 and of the subsequent investigation, including corrective action taken. Complaint records include the information listed below.

Consumer information
- The manufacturer's records contain, at a minimum:
  - the name, address and telephone number of the complainant, and the date the complaint was received;
  - details of the complaint and/or illness;
  - the product's name, code and size; and
  - the retail outlet where the product was purchased.

Investigation

- The manufacturer's records contain, at a minimum:
  - the name of the person responsible for the investigation;
  - the action taken (concerning the product and/or the process) as a result of the investigation;
  - the corrective action taken to prevent a recurrence; and
  - a follow-up/assessment of the effectiveness of the corrective action.

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 distribution records contain, at a minimum:
  - the product identification and size;
  - the lot number or code;
  - the quantity; and
  - customer names, addresses and phone numbers to the initial level of product distribution.

8.0 COMPLAINT HANDLING AND RECALLS

8.1 COMPLAINT HANDLING

8.1.1 Product Complaints

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

Rationale
Product complaints are important indicators of possible deficiencies in manufacturing controls and/or deficiencies in the distribution handling system. When the complaint handling system itself is deficient, it could result in failure to identify and eliminate risks.

Assessment Criteria

- The manufacturer has a system to handle and investigate product complaints, which identifies the person or persons responsible for receiving, evaluating, categorizing and/or investigating complaints.
- Complaints are accurately categorized according to safety, composition and other regulatory concerns.
- 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, the retail product or other product of the same code is conducted on complaints related to food safety.
- Complaints pertaining to composition, fraud and other regulatory concerns are investigated in an effective manner.
- 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 Section 7.6.1 - Complaint Records.

8.2 RECALLS

8.2.1 Recall 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 identifies the person or persons responsible (e.g. recall coordinators) and the roles and responsibilities of those who coordinate and implement a recall.
- The procedure specifies methods to identify, locate and control recalled product, and includes a requirement to investigate other products that may be affected by the hazard and should be included in the recall.
- The procedure requires that the recall be monitored to assess its effectiveness (e.g. an effectiveness check is conducted to the appropriate level of distribution specified in the recall notice).
- The CFIA is immediately notified in the region where the manufacturer is located. This notification includes the following:
    - the amount of product produced, the amount in inventory and the amount distributed;
    - the name, size, code or lot numbers of the recalled product;
    - the area in which the product was distributed (e.g. local, national, international); and
    - the reason for the recall.

See Section 7.6.2 - Distribution Records.

8.2.2 Recall Capability

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

Assessment Criteria

- The manufacturer demonstrates the capability to provide accurate information on a timely basis, in order to verify that all affected product can be rapidly identified and removed from the marketplace. For example:
    - the manufacturer conducts periodic testing (i.e. mock recall) to verify the capability of the procedure to rapidly identify and control a code lot of potentially affected product, and to reconcile the amount of product produced with the amount in inventory and the amount in distribution;
    - the manufacturer identifies and corrects any deficiencies in the recall procedure.

GLOSSARY

Allergen – 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 – in this document, certification refers to the guarantee a supplier (vendor) provides to a manufacturer, ensuring that the material meets the manufacturer's specifications (e.g. a Certificate of Analysis).

Control – means that an operation performs consistently within predetermined 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. 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 is prompt and appropriate to the seriousness of the deficiency.

Critical control point (CCP) – 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 – any property, characteristic, condition, aspect, or other parameter, a variation of which may affect the safety of the product or the process.

Critical limit – a value that 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 food products discussed in this document, deterioration can be used interchangeably with spoilage. However, non-food products such as packaging materials can also deteriorate. 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 predetermined and documented set of corrective actions that are implemented when a deviation occurs. The goal is to re-establish control of the process and to control the affected product.

Documentation – for the purposes of this text, documentation refers to written formulas, 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 – a container designed and intended to be secure against the entry of micro-organisms, including spores.

Incubation – tests in which the heat-processed product is kept at a specific temperature for a specified period of time in order to determine if an outgrowth of micro-organisms or other problems occur under these conditions.

Lot – 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 – 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.

Monitoring – a planned sequence of observations or measurements to assess whether a critical control point (or other activity) is under control.

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 purposes 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 processes or process controls through testing, investigation or comparison against a standard.

RESOURCES

Canadian Food Inspection Agency
http://www.inspection.gc.ca

Codex Alimentarius - Official Standards List
http://www.codexalimentarius.net/standard_list.asp

Consumer Packaging and Labelling Regulations
http://laws.justice.gc.ca/eng/C.R.C.-c.417/index.html

Evaluation Standard for Nutrition Labelling
http://www.inspection.gc.ca/english/fssa/labeti/nutrikit/sectjintroe.shtml

Food Allergens
http://www.inspection.gc.ca/english/fssa/labeti/allerg/allerge.shtml

Food and Drugs Act
http://laws.justice.gc.ca/eng/F-27/index.html

Food and Drug Regulations
http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/index.html

Guide to Food Labelling and Advertising
http://www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml

Guidelines for Canadian Drinking Water Quality
http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/index-eng.php

Nutrition Labelling Compliance Test
http://www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

Nutrition Labelling Toolkit
http://www.inspection.gc.ca/english/fssa/labeti/nutrikit/nutrikite.shtml

Pest Management Regulatory Agency's Public Registry - *Pesticide Product Information Database*
http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php

Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products
http://www.inspection.gc.ca/english/fssa/reference/refere.shtml

Weights and Measures Regulations
http://laws.justice.gc.ca/eng/C.R.C.-c.1605/index.html