Discussion Paper

CFIA Guidance Documents

Supporting Compliance with the Proposed *Safe Food for Canadians Regulations*

The purpose of this document is to:

(a) outline a proposed approach for written CFIA guidance that will support stakeholder understanding of the *Safe Food for Canadians Regulations* once they come into force; and
(b) facilitate further discussion and stakeholder feedback - in the interest of refining the type of CFIA guidance that will support compliance.

Context

The CFIA has made a commitment to provide information to stakeholders that will increase their understanding of the requirements of the *Safe Food for Canadians Regulations* once they come into force. As part of this commitment, the CFIA is preparing guidance documents with an aim to explain the regulatory requirements in a clear and simple manner. At present, the guidance is being drafted in two basic types:

Interpretive Guidance

The first type of guidance, referred to as 'interpretive guidance', is intended to explain the regulatory requirements and expected outcomes. This guidance describes why the requirements are important (i.e. the rationale) and how CFIA staff and industry will assess compliance (i.e. assessment criteria). The intended audience of these documents includes both regulated stakeholders and CFIA staff.

A series of interpretive guidance documents are being drafted for various parts of the regulations (e.g. (i) licensing; (ii) preventive control; (iii) traceability; and (iv) trade).

Model Systems

The second type of guidance, known as 'model systems', is intended to provide information about both new and historically accepted practices and procedures to help industry comply with the regulations once they come into force. The primary intended audience for this type of guidance is stakeholders, especially small and medium-sized enterprises. It will provide technical information that could be tailored to fit their particular business and/or product. The goal is to develop a series of model system documents that cover a range of regulatory requirements. Special attention will be given to create model systems for requirements that are more complex and/or technical in nature (e.g. sanitation, validation, hazard analysis, shelf life studies etc.).

Both types of guidance will be presented in a web-based, searchable format to accommodate ease of use. Options for a more interactive, easy-to-navigate website are being explored.

Preliminary examples of 'Interpretive Guidance' related to preventive control (Part 4 of Annex 3, and Annex 4 of *A New Regulatory Framework for Federal Food Inspection: Overview of Proposed Regulations* http://www.inspection.gc.ca/about-the-

cfia/accountability/consultations/federal-food-inspection/overview-of-proposed-regulations/eng/1400451508255/1400451811916 released on May 22, 2014) are provided below. This material is still under development and is expected to change over the coming year as work progresses on finalizing the *Safe Food for Canadians Regulations*; the CFIA's other transformation initiatives; and feedback from stakeholders. Examples of 'Model Systems' will be provided at a later date.

CFIA is seeking your feedback on the suitability of the overall organization, language style, and level/nature of detail included in these examples. Your input will help the CFIA create guidance documents that will allow for broad and consistent understanding and application of the requirements of the regulations.

Specifically, we would appreciate your views on the following:

- Considering the examples provided (the overall organization, language style, and level/nature of detail included), how helpful would these formats be in assisting you to comply with the proposed regulations?

- What improvements would you suggest for the CFIA's approach to providing guidance?

- Do you have any other views or suggestions to offer as the CFIA continues to prepare written guidance to support understanding of and compliance with the proposed regulations?

We would appreciate receiving your comments regarding above by October 31th, 2014.

Please forward your input to: cfia-Modernisation-acia@inspection.gc.ca

Examples of Interpretive Guidance – Preventive Control

Disclaimer

This draft Interpretive Guidance is based on suggested preliminary text for key provisions of the regulations and policy direction. It is provided solely as an example to help regulated parties understand CFIA's intended assessment of compliance on the subject matter and to provide an opportunity for feedback. It constitutes a work in progress and is subject to change and refinement as the regulatory process on the *Safe Food for Canadians Regulations* advances through its various stages towards implementation.

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Part 4: Preventive Control	
Element 0 Responsibility of Operator	
4.0	**Responsibility of Operator**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 26. Every operator must maintain and operate the establishment in accordance with this Part.
Compliance Rationale	The operator is responsible under the law to maintain and operate the establishment in accordance with this part of the and Regulations. The ultimate outcome is to produce safe food that meets regulatory requirements.
Assessment Criteria	The intent of this section is to link the "Operator" to "Every person" for example as it applies to Element 3: Hygiene and Competency CFIA may use various means to confirm that regulatory requirements are being met, including: • audits, • inspections, and • oversight of an establishment's facilities.

Part 4: Preventive Control	
Element 1 Products and Processes	
4.1.a	**Specifications and control of incoming ingredients, raw materials, agricultural inputs, packaging/labelling materials and rework**
Legal Authorities	**Note** *Annex 3: Preliminary Text for Key Provisions of the Proposed Regulations*, outlined in the *Regulatory Framework for Federal Food Inspection: Overview of Proposed Regulations* does not specifically address specifications and control of incoming ingredients, raw materials, agricultural inputs, packaging/labelling materials and rework in the context of Element 1 - Products and Processes. However, it is recognized that guidance on such topics is beneficial for both industry and CFIA inspection staff for compliance purposes and as part of good manufacturing practices and preventive controls. In specific situations, inspection staff may need to obtain information on specifications of incoming materials to help them determine the safety of a food commodity. Such information can be requested from regulated parties under the authority of section 27 of the Safe Foods for Canadian Act (SFCA). Section 27 provides: *An inspector may, for a purpose related to verifying compliance or preventing non-compliance with this Act, order a person to provide, on the date, at the time and place and in the manner specified by the inspector, any document, information or sample specified by the inspector.*
Compliance Rationale	Preventing food safety hazards begins with the control of incoming ingredients, raw materials and packaging materials, including labels. Inadequate control of these may lead to: • using ingredients or raw materials that do not meet the written specifications or formulation requirements for the food; • using ingredients intended for rework in error; • packaging materials imparting an undesirable chemical, physical, microbiological substance to the food, or not protecting the food sufficiently, when not used appropriately; • labels being applied or attached that do not meet specifications and regulatory requirements.
Assessment Criteria	It may be necessary to gather information and documentation on incoming ingredients, raw materials, agricultural inputs, packaging or labelling materials and rework for various reasons. Documentation may include specifications for incoming materials. When gathering information, it may be necessary to evaluate a system is in place to ensure that these specifications are met when the materials arrive at the establishment. **General** – The following information, if applicable, should be documented and maintained to demonstrate compliance: • Purchasing procedures are in place to ensure that incoming ingredients and raw materials as well as packaging and labelling materials are obtained from approved suppliers or sources. • A policy is in place, to govern the use of rework materials. • There are micro, chemical, and physical specifications for all incoming ingredients and raw materials and there is a system in place to confirm that these specifications are met at receiving. • There are specifications for all incoming packaging materials and labels, including physical dimensions, material specifications and performance specifications. Packaging material is suitable for the intended use. • Incoming materials comply with the *Food and Drugs Act* and the *Food and Drug Regulations* and the *Safe Food for Canadians Act* and *Safe Food for Canadians* Regulations as well as relevant foreign legislation if the food commodity is for export. • Nutrition information accompanies each shipment of incoming ingredients as per B.01.404(2), FDR. This information may be conveyed on a hard copy document which accompanies the delivery of the ingredient. In the case of ingredients that are shipped on a continual basis with no change to the formulation, documentation may be provided with the first shipment. The supplier advises of any change to the nutrition information as a result of formulation changes or other influences. **Control Processes** Incoming ingredients, raw materials and packaging and labelling materials may be controlled through one of the control processes outlined below or through an equivalent process. The degree of control exercised is appropriate to the level of risk that the ingredient, raw material or packaging and labeling material, poses to the safety or compositional integrity of the food.

A. Ingredients, raw materials and packaging and labelling materials that impact food safety

Option 1: Periodic evaluation of incoming items

- A Certificate of Analysis (CoA)/Letter of Guarantee is obtained for each lot. A representative sample is taken at a scheduled frequency (e.g., monthly) to verify the accuracy of the CoA.
- A documented history is maintained of adherence to specifications for suppliers and producers, such as analytical results. See PCP 1.7 Record Keeping Procedures (documentation)
- A new history of adherence to specifications is established when a suppliers or producer changes, when a new supplier or producer is used, or when a new ingredient, raw material or packaging material is purchased from an existing supplier or producer.

Option 2: Lot inspection

- Each incoming lot is sampled according to a statistically valid and pre-determined sampling plan and then analyzed and assessed for adherence to specifications. If a statically valid sampling is not available, then the following *Codex Alimentarius* standard may be used as guide: CODEX CAC/GL 50-2004

Option 3: Supplier verification

Suppliers are verified through the following control processes or equivalent processes:

- conduct supplier audits to validate the status of the supplier verification plan.
- review supplier's documentation to demonstrate an adequate knowledge of the supplier's processes as they relate to the items being supplied. Review may include process flow charts, on-site evaluations and identifying critical control points, specifications, control limits, monitoring plans and frequencies, corrective actions and verification procedures. This is done prior to the implementation of periodic monitoring plan; and
- analyze an appropriate number of consecutive lots to establish an historical database and confirm adherence to specifications.
- take a representative sample at a scheduled frequency (e.g. annually) and analyze it to verify adherence to specifications.

B. Ingredients, raw materials and packaging materials that are not likely to impact the safety of the food but may have an impact on compliance with other regulatory requirements

- take a representative sample at a scheduled frequency (e.g. annually) to verify adherence to specifications. Alternately obtain a Certificate of Analysis or supporting documentation. If a statistically valid sampling is not available, then the following *Codex Alimentarius* standard may be used as guide: CODEX CAC/GL 50-2004.
- maintain a documented history of adherence to specifications for each supplier, such as analytical results.
- establish a new history of adherence to specifications when a supplier changes, when an ingredient is purchased from a new supplier or when a new ingredient is purchased from an existing supplier.

Part 4: Preventive Control	
Element 1 Products and Processes	
4.1.b	**Formulations and Specifications**
Legal Authorities	**Note** *Annex 3: Preliminary Text for Key Provisions of the Proposed Regulations*, outlined in the *Regulatory Framework for Federal Food Inspection: Overview of Proposed Regulations*, does not specifically address formulations and specifications in the context of Element 1 - Products and Processes. However, it is recognized that guidance on such topics is beneficial for both industry and CFIA inspection staff for compliance purposes and as part of good manufacturing practices and preventive controls. In specific situations, inspection staff may need to obtain information on formulations and specifications to help them determine the safety of a food commodity. Such information can be requested from regulated parties under the authority of section 27 of the Safe Foods for Canadian Act (SFCA). Section 27 provides: An inspector may, for a purpose related to verifying compliance or preventing non-compliance with this Act, order a person to provide, on the date, at the time and place and in the manner specified by the inspector, any document, information or sample specified by the inspector.
Compliance Rationale	Formulae and specifications for foods being prepared contribute to the control of the manufacturing process and assist food businesses in producing foods that comply with regulations. • Formulae and specifications provide a basis for the control of food additives, composition labelling, nutritional requirements, food allergens, the process and compliance with regulatory requirements. • They help manage deviations in the process and reduce the risk of non-compliant food which can pose a food safety hazard. • Specifications also allow CFIA to verify that the food was prepared to comply with regulatory requirements. • Formulations must also include any reworked food used in production. Reworked food may contain allergens, ingredients or additives that could render the food as non-compliant. Strict conditions for the use of reworked food help manage the risk of food adulteration or contamination.
Assessment Criteria	The following controls may be used to demonstrate the formulation used to manufacture a food as well as the specifications for finished foods : • formulations and specifications identify all ingredients and their proportions, directions sequencing for the mixing and combining of ingredients, including reworked food, if used in preparing each food; • micro, chemical, and physical specifications are developed for all finished foods; • all ingredients, nutrients, food additives and chemicals, are permitted by the SFCA/R and the FDA/R and regulatory usage limits are met. Calculations may be used to demonstrate that ingredients, food additives and nutrients are used within levels as specified in the Food and Drug Regulations (or foreign country requirements if the product is for export); • the food is prepared according to the formula; • the finished food meets predefined specifications.

Part 4: Preventive Control	
Element 1 Products and Processes	
4.1.3	**Treatments to prevent, eliminate or reduce hazards that may be present in the food** **Commercial Sterility**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 27. Every operator must ensure that the food is treated using (a) the treatment set out in section 28, as applicable; (b) the treatment set out in Part X [Standards of Identity], as applicable; and (c) any other thermal treatment, drying treatment, chilling treatment, chemical preservation treatment and any other similar treatment as may be necessary to prevent, eliminate or reduce any biological, chemical or physical hazard that may be present in the food and that presents a risk of contamination of the food. 28. (1) Every operator who packages a low-acid food in a hermetically sealed package must thermally treat the low-acid food until commercial sterility is achieved. (2) Subsection (1) does not apply to a low-acid food packaged in a hermetically sealed package if the low-acid food is kept refrigerated or frozen and the statements “Keep Refrigerated” and “Garder au froid”, or “Keep Frozen” and “Garder congelé”, as the case may be, are shown on the principal display panel; (3) A low-acid food packaged in a hermetically sealed package must not be thermally treated unless (a) the thermal treatment meets the requirements of the scheduled process; and (b) if batch thermal treating is employed, a temperature-sensitive indicator that visually indicates whether or not the package has been thermally treated is shown on or attached directly or indirectly to the package. (4) Every operator who packages a low-acid food in a hermetically sealed package and thermally treats it to achieve commercial sterility must prepare, keep and maintain documents that describe, for each of those low-acid foods, (a) the scheduled process, together with the name of the person responsible for the development of the scheduled process; and (b) the formulation of the food. (5) The documents referred to in subsection (4) must be kept and maintained for three years after the day on which the scheduled process is last used. (6) Every operator who packages a low-acid food in a hermetically sealed package and thermally treats it to achieve commercial sterility must prepare, keep and maintain documents that describe the low-acid food history, including (a) the production volume and identification of the food; (b) the equipment used and the time, temperature and, if applicable, the pressure of the thermal treatment used; (c) the maintenance of and modifications to the equipment used including instruments for controlling, measuring and recording temperature, pressure, pH, time, concentration and density; (d) any deviations from the scheduled process and any corrective action taken; (e) the incubation results; and (f) if applicable, the cooling water treatments that are used. (7) The documents referred to in subsection (6) must be kept and maintained for three years after the day on which the thermal treatment is used.
Compliance Rationale	**Treatments to prevent, eliminate or reduce hazards that may be present in the food commodity** A properly designed and controlled process to treat food helps to mitigate risks inherent to food preparation. It also demonstrates an understanding of: • all processing steps specific to the food being produced and the associated hazards at each step • food-specific process control measures as well as critical limits appropriate to the food and the associated microbial contamination of food preparation surfaces; • specific processing equipment in use, the food under consideration and its associated ingredients, container size and format (pouch, plastic bag, bottle); and • the importance of consistency in process delivery.

	Documentation is required to: • allow training to be developed and delivered; • provide a scientifically based standard to audit against; • provide consistency in production; • to support compliance with procedures; • achieve continuous improvement; • help detect deficiencies in design and implementation; and • provide evidence that process design included scientific rigor and evidence-based analysis. Documentation specific to the process design and control is kept up-to-date to demonstrate continued control of the process. The process design is normally updated when: • formulation or compositional changes; • operational procedures change; • equipment is replaced or upgraded; • corrective measures are implemented to address emerging issues; • new regulations or requirements are put in place; or when • new scientific developments occur. Evidence, in the form of validation, demonstrates that the properly implemented control measure or combination of control measures is capable of controlling the hazard to the specified outcome. **Process Control - Commercial sterility** (1)Achieving commercial sterility of low acid foods is important to ensure that food in hermetically sealed packages is free from viable forms of microorganisms, including spores, capable of growing in the food at temperatures at which the food is normally held during distribution and storage. (2) Low acid foods packaged in a hermetically sealed package and labelled `Keep Refrigerated` or `Keep Frozen` are exempt from being heat treated to the extent where commercial sterility is achieved because the refrigerated or frozen states prevents or retards the growth of microorganisms. (3) (a) The scheduled process developed for the low acid food packaged in a hermetically sealed package must be followed because inadequate processing could result in the survival of microorganisms such as spores of *Clostridium botulinum.* (b) Effective controls, such as the use of heat sensitive indicators, prevent unprocessed product from by-passing the retort, prevent co-mingling of processed and unprocessed containers and ensures product is directed to the correct retort. Ineffective control could result in unprocessed or under processed food. (4) and (6) Written documentation including the scheduled process, application of the process to the product, the person responsible for the development of the scheduled process and the control over consistent product formulation are required to demonstrate that the process has been developed by a qualified person and the manufacturer has an understanding of and have implemented the process parameters. The process and finished product has to be monitored to ensure that the food has been adequately processed (5) and (7) The documented scheduled process and product formulation as well as records of the thermal treatment are kept for 3 years, because 3 years is generally beyond the life cycle of the product. These documents may be needed in the case of a trace-back. Critical factors are designed to both prioritize and to ensure the safety, compositional integrity and labeling requirements of the food at every step in the process and in the finished food.
Assessment Criteria	**Treatments to prevent, eliminate or reduce hazards that may be present in the food commodity** Critical factors are identified and validated for each food. Documentation on the validation approach(es) used may be based on: • CFIA model systems; • Internationally recognized control measures (e.g. Codex, OIE, ISO) or existing scientific data found in

credible references or peer reviewed publications;

- previous validation studies or historical knowledge of the performance of the control measure;
- control measures accepted by foreign countries with which Canada has established equivalency or comparability;
- scientifically valid experimental data to demonstrate the adequacy of the control measures, either by;
    - outsourcing to a laboratory or academic institutions to conduct validation studies, or;
    - pilot or in-plant validation studies under controlled conditions (collecting and analyzing one's own scientific data); and
- mathematical modelling.

Procedures set out in CODEX, Guidelines for validation of food safety control measures, CAC/GL 69-2008 could be followed. CFIA's Validation of Control Measures Model System was adapted from this document.

The critical processing factors for each food produced is documented and includes:

- all processing steps ;
- critical limits for each process step (e.g. time and temperature minima for cooking, water potability, limits on food additives for processing aids and other processing activities); and
- all processing equipment related to the process and specific to the product, container size and format being manufactured.

When developing a process design remember that one process on its own may not be sufficient as a control measure. A multiple hurdles approach may be necessary depending on the food or relevant pathogens or other hazards

Flow Diagrams

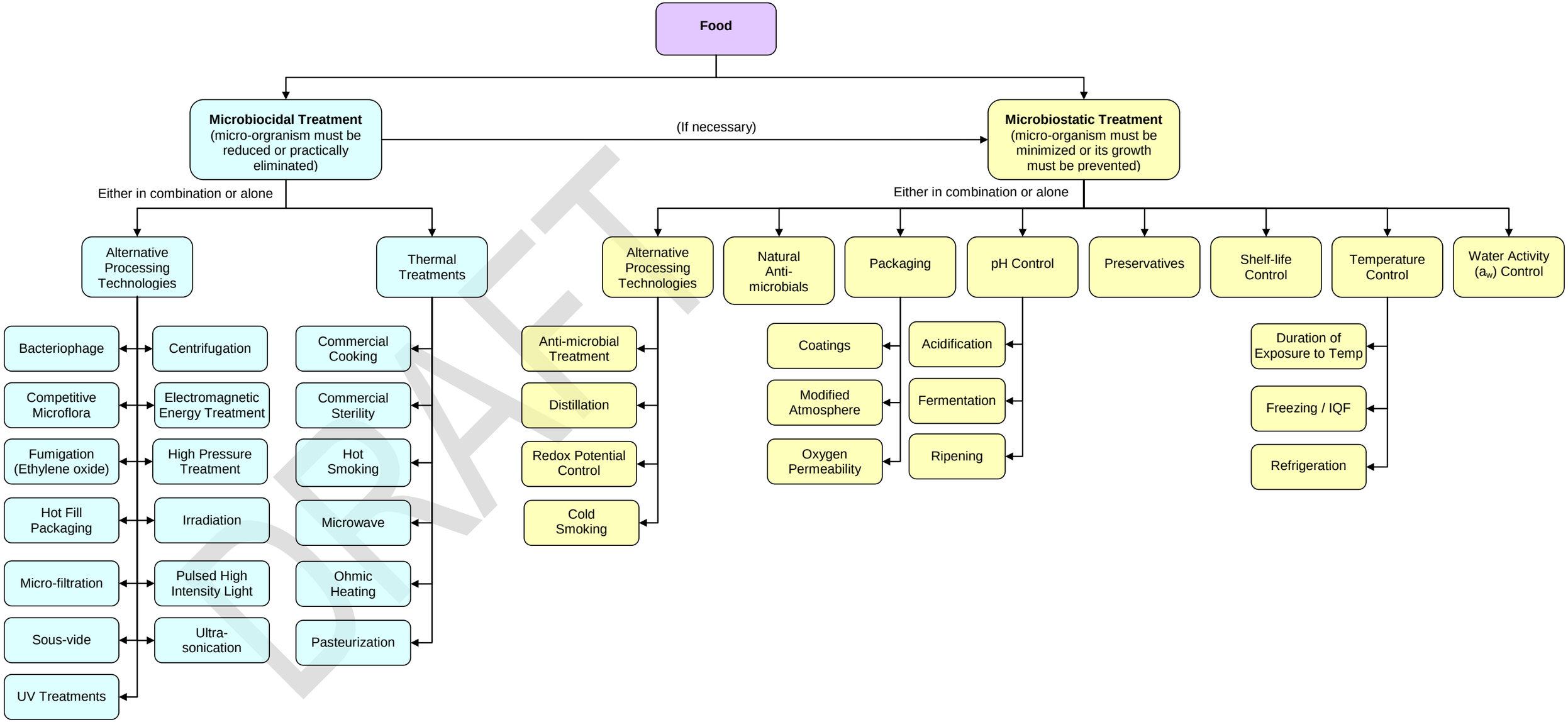
The following flow diagrams are provided to give examples of different processes that are currently or have been historically used in food processing situations. These diagrams are not intended to be all inclusive; they are flexible and allow for innovation in the future. When used in conjunction with a model system they can provide guidance to the level of documented detail that is expected to meet this element of the Preventive Controls.

- Examples of Microbiocidal and Microbiostatic Treatments Designed to Control Biological Hazards in Food
- Examples of Processes Designed for the Prevention, Control and/or Removal of Chemical Hazards in Food
- Examples of Processes Designed for the Detection and/or Separation of Physical Hazards in Food

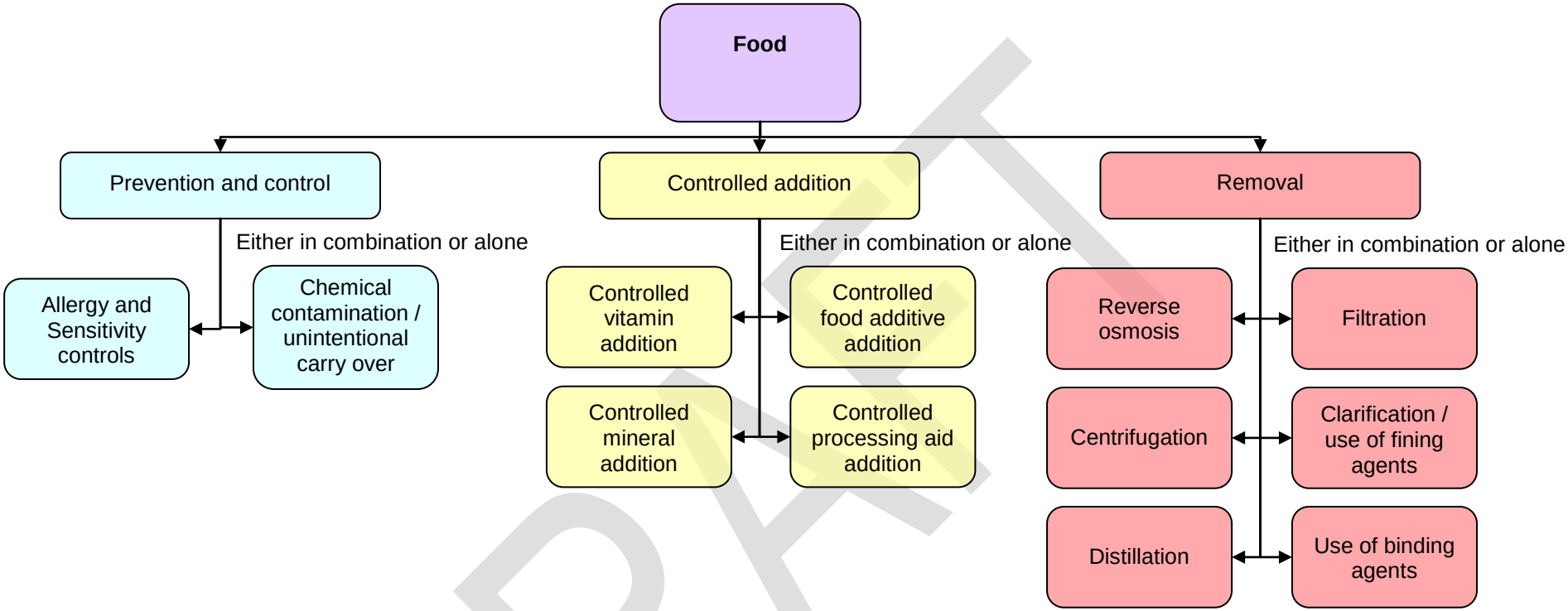
Note

Other process specific requirements may be set out in the Food and Drug Regulations.
See lexicon for descriptions and definitions for processes identified in the flow diagrams.

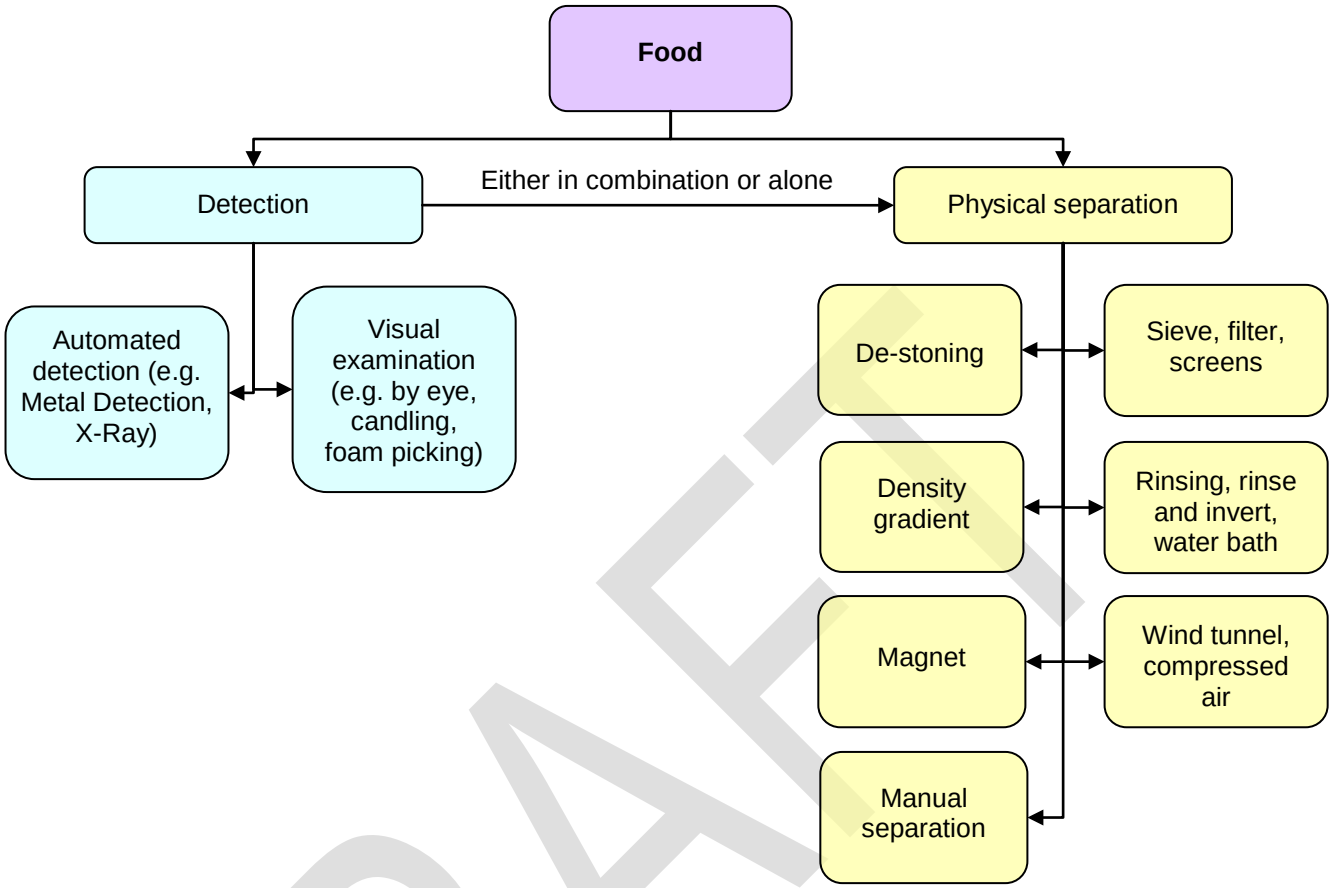
Examples of Microbiocidal and Microbiostatic Treatments Designed to Control Biological Hazards in Food



Examples of Processes Designed for the Prevention, Control and/or Removal of Chemical Hazards in Food



Examples of Processes Designed for the Detection and/or Separation of Physical Hazards in Food



Part 4: Preventive Control	
Element 2 Sanitation, Pest Control, Sanitizers and Chemical Agents	
4.2.1	**Cleaning and Sanitation**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 29. Every operator must ensure (a) that the establishment, and any equipment, facility and conveyance in it, is maintained in a clean and sanitary condition to prevent the contamination of the food; and (b) that the cleaning and sanitation of the establishment, and of any equipment, facility and conveyance in it, are conducted in a manner that does not present a risk of contamination of the food. 30. Every operator must ensure that any conveyance that is used to transport the food and that is admitted to or leaves the establishment is clean and sanitary.
Compliance Rationale	The establishment, equipment, facilities and conveyances used in the establishment, are maintained in a clean and sanitary condition in order to prevent contamination of the food. Improper or inadequate cleaning and sanitation activities can lead to the contamination of food, ingredients, packaging materials and food contact surfaces. Examples include: - chemical residues because of poor rinsing procedures , - bacteria or allergenic substance residues that are not effectively removed from food contact surfaces Performing cleaning activities must be done in a manner that does not present a risk of contamination of the food, through chemical or biological cross-contamination, or otherwise. For example, contaminants may be released into the air as a result of spraying a non-food contact surface, such as the floor, while operations are underway. In this scenario, nearby ingredients, packaging materials and food contact surfaces may all be affected and at risk of cross-contamination of the food Conveyances, e.g. trailer, bulk tank, truck, pallets, fishing vessels, or packages, e.g. bulk containers, shipping containers, tray packs that are used to transport food and that are admitted to or leave the establishment that are not properly cleaned and sanitized may lead to a number of potential contamination hazards to the food including: • physical contaminants from dust and foreign material left in the conveyance • chemical contaminants due to trace chemicals or allergens from previous loads • chemical contamination from exhaust from improper equipment such as forklifts used indoors • microbiological contaminants from previous loads.
Assessment Criteria	• the cleaning and sanitation program is carried out in a manner that does not present a risk of contamination of the food, food contact surfaces or packaging materials during or subsequent to cleaning and sanitizing; • the effectiveness of the cleaning and sanitation program is monitored and verified by, for instance, routine visual inspection of establishment and equipment, chemical residue or microbiological testing of the finished food and the environment; • operations begin only after cleaning and sanitation requirements have been met. Contact surfaces are free from the accumulation of dust, dirt, food residue, grease and other debris. Verification tools include visual inspection, adenosine triphosphate (ATP) swabs, etc.; • the cleaning and sanitation program for purposes of meeting the requirments of a preventive control plan includes procedures for cleaning and sanitizing all equipment and utensils, (where appropriate) and the establishment, including production and storage areas, waste and inedible/food waste facilities in a clean and sanitary condition so as to prevent food contamination, and to conduct such cleaning and sanitation in a manner that does not present a risk of food contamination. The cleaning and sanitation program would normally specify the: • person or persons responsible for conducting the sanitation activities; • frequency of the activities; • chemicals and concentrations to be used and their intended use. Note this does not apply to non-chemical sanitation methods such as dry cleaning of dry blend operations; • cleaning and sanitizing equipment to be used and their intended use; • instructions for proper handling and application of chemicals, such as the duration of application or contact time, in accordance with the manufacturer's instructions; • chemical solution temperatures and pressure requirements, where applicable;

- special sanitation and housekeeping procedures required during production, such as the removal of product residues during breaks in production;
- methods used to prevent the contamination of food and packaging materials prior to, during, and following cleaning and sanitizing;
- procedures for cleaning and sanitizing clean-out-of-place (e.g. hand-cleaned) equipment, clean-in-place equipment and establishment that includes
    - identifying areas, lines, equipment and/or utensils to be cleaned and sanitized,
    - a listing of cleaning, chemical and disinfecting products,
    - disassembly and reassembly instructions as required for cleaning and inspection,
    - specifying areas on equipment requiring special attention, and
    - methods of cleaning, sanitizing and rinsing; and
- environmental sampling procedures, if any.

- Conveyance used to transport foods to and from an establishment must be clean and sanitary.
    - In the case of conveyances under the direct control of the establishment, the establishment is responsible for cleaning and sanitizing activities.
        - Effectiveness may be confirmed by a visual inspection of the transport before it is loaded
    - For conveyances which are not owned by the establishment, cleanliness must still be controlled. Control may be demonstrated by:
        - Visual inspection of the :
            - loaded conveyance upon arrival and before it is unloaded
            - conveyance before it is loaded
        - The trucking company or operator may provide documentation that confirms cleaning and sanitizing has taken place e.g., a wash tag.

Part 4: Preventive Control	
Element 2 Sanitation, Pest Control, Sanitizers and Chemical Agents	
4.2.2	**Pest Control**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 31. (1) Every operator must ensure (a) that measures are taken to prevent entry into the establishment of any insects, rodents and other vermin that present a risk of contamination of the food; and (b) that no other animal is present in the establishment, unless it is a food commodity that is to be manufactured, prepared, stored, packaged or labelled in the establishment. (2) The measures taken for the purposes of complying with paragraphs (1)(a) and (b) must not present a risk of contamination of the food.
Compliance Rationale	Pests (insects, rodents and other vermin) can: • contaminate ingredients, packaging materials, food and food contact surfaces; and, • lead to microbiological and or extraneous matter contamination from droppings (e.g. feces, urine, hair/fur/feathers, etc.), as well as larvae and dead insects or animals. Pest control measures include: • preventing the attraction and entry of pests; • detecting and eliminating pests; • preventing the contamination of food by pests or pest control products. Dogs, cats and other animals within a food establishment can contaminate ingredients, packaging materials, food and food contact surfaces. Exception applies to animals necessary for the food commodity. Pest control products and devices, animals necessary for the food commodity and the elimination or removal of other animals, must be managed so they do not become a source of contamination for food. • Trapping devices are maintained to prevent accumulation of decaying vermin. • Pesticide treated baits that may migrate into food are controlled.
Assessment Criteria	Pest control activities apply to the interior and exterior of the establishment and its equipment. • Regular pest control activities are performed and include controls and procedures to: o prevent pests from entering the establishment; o discourage pests from harbouring in and around the establishment; and o ensure that pest control measures do not contaminate food, packaging materials or the processing environment. • Pest control activities include but are not limited to: o listing chemicals used, as well as the concentration, the location where applied, method and frequency of application; o describing the type and location of pest control devices used, pests detected and frequency of servicing; o conducting fumigation when necessary to control pests in and on equipment or in the establishment, and in a way that does not contaminate the environment, food, packaging materials or equipment; o ensuring pest control products are secured, segregated and handled by competent personnel only; o ensuring rodenticides are not used in food processing or storage areas; o using and servicing pest control devices in a manner that does not contaminate ingredients, packaging materials, food and food contact surfaces. • A person at the establishment is assigned responsibility for overseeing or conducting the pest control activities when the establishment undertakes these activities itself. • When the pest control activities are contracted to a third party, a person at the establishment is assigned responsibility for overseeing the activities of the third party. • Policies and procedures regarding animals are in place and ensure that animals, other than those intended for food, are excluded from the establishment

Part 4: Preventive Control	
Element 2 Sanitation, Pest Control and Sanitizers and Chemical Agents	
4.2.3	**Sanitizers and Chemical Agents**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 32. Every operator must ensure that any sanitizer and any chemical agent other than a food (a) is properly identified; (b) is appropriate for the purpose for which it is used and does not present a risk of contamination of the food; and (c) is handled and used in a manner that does not present a risk of contamination of the food and, if applicable, in accordance with the manufacturer's instructions.
Compliance Rationale	There is a greater risk of sanitizers, detergents and chemicals being misused when they are not properly identified. Misuse can cause the food or the food preparation environment to be contaminated. Increased risks of contamination arise from improper chemical concentrations, applications, or rinsing procedures. • chemical residue from poor rinsing, improper concentrations of no-rinse chemicals, and bacteria or allergenic substance residues that have not been effectively removed from food contact surfaces are all examples of chemical or biological contamination. Cleaners and sanitizers suitable to the processing conditions of the establishment are used. Products differ in their effectiveness depending on: o ambient temperature; o cleaning water characteristics - hard vs soft water; o the level and type of processing debris present; and o method of use, e.g., the application method, concentration and contact time. Using cleaners, sanitizers and other chemicals without following manufacturers' instructions may result in a combination of chemical contamination, biological contamination and unacceptable food residues. Not following manufacturers' instructions may result in: o improper concentrations of chemicals being used; o inappropriate temperatures being used; o incorrect contact times; o improper rinsing of equipment after cleaning; o lubricants designed for non-food contact areas being used in food contact areas; o boiler additives being used inappropriately; or o improper use of pest control products.
Assessment Criteria	**<u>Note</u>** The terms: • 'chemicals agents', applies to all non-food chemicals, including cleaning chemicals, detergents, lubricants, oils, pest control products, etc. • 'sanitizers' may or may not be of a chemical nature. For example, a sanitizer may refer to hot water or steam. Sanitizers and chemical agents are: a) properly identified • Form of identification - may be a label, color coding, an attached tag, permanent markings on the container, etc. • Information provided – may include the name of the product and other pertinent information, some of which may be dictated by other legislation. Product may be in an original container, which is identified by the manufacturer's label. Product may have been transferred or sub-divided to smaller or different containers, these containers are identified. b) appropriate for the purpose and intended use and does not present a risk of contamination of the food. c) handled and used in a manner that does not present a risk of the food (such as mixing chemicals in clean, correctly identified containers), and according to the manufacturer's instructions. Note: it is a good manufacturing practice to properly store chemical agents so that they maintain their effectiveness. Chemical agents when used must be appropriate for their use.

Part 4: Preventive Control	
Element 3 Hygiene and Competency	
4.3.1	**Clothing, Footwear and Coverings**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 33. Every person who enters or is in an area of an establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled must wear clothing, footwear and coverings, including gloves, hairnets, beard-nets and smocks, that are sound, clean and in sanitary condition and that are appropriate to the food and the activity being conducted.
Compliance Rationale	Clothing plays an important role in food safety; in particular the clothing persons wear in any area of an establishment where a food is being manufactured, prepared, stored, packaged or labeled. ~~W~~earing suitable clothing, footwear and coverings that are clean and appropriate to the operation, helps prevent the contamination of food in the establishment.
Assessment Criteria	Examples of suitable clothing, footwear and coverings include, but are not limited to: • coveralls, smocks, lab coats, aprons, hard hats, bump helmets • disposable footwear, rubber boots, toe rubbers • hairnets, beard-nets, protective headgear, hand coverings, gloves, sleeves Protective clothing, footwear, and coverings appropriate to the operation are: • worn only within the area of the establishment for which their use is designated, except where it can be shown that they are not required due to the nature of the work being conducted e.g., forklift operator repeatedly leaving and entering a processing area, etc.; • not a source of contamination to the food or things such as: o the environment in which the food is being processed or packaged o packaging materials o not a potential allergen - latex from latex gloves Reusable protective clothing, footwear, and coverings are: • made of materials which are able to be cleaned and disinfected. • maintained in a clean and sanitary condition and in good repair. • when worn, - maintained in a clean and sanitary condition and in good repair as appropriate to the operation, - e.g., garments are clean at the start of the shift and changed during the shift, as required. Protective clothing, footwear, and coverings intended for one-time use are not reused. Where appropriate to the operation, clothing and footwear worn outside of the establishment are not worn in any area of the establishment unless procedures are in place to ensure that they do not contaminate the food, or other things in the establishment such as packaging materials, equipment, etc.

Part 4: Preventive Control	
Element 3 Hygiene and Competency	
4.3.2	**Personal cleanliness** **Spitting, gum chewing and other acts** **Foreign objects and substances**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 34. Every person who enters or is in an area of an establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled must maintain personal cleanliness to prevent the contamination of the food, including by cleaning and, if appropriate, sanitizing, their hands (a) immediately upon entering the area; (b) immediately before beginning or resuming the activity being conducted; (c) immediately after using lavatories; and (d) at a frequency appropriate to the food and the activity being conducted. 35. Every person who enters or is in an area of an establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled must refrain from spitting, chewing gum, using tobacco products, consuming food, having unnecessary contact with the food and doing any other act that presents a risk of contamination of the food. 36. Every person who enters or is in an area of an establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled must refrain from wearing any object and using any substance that presents a risk of contamination of the food.
Compliance Rationale	**Personal cleanliness** • Contamination of food can result from contact with persons (e.g., personnel, management, visitors and contractors) who do not maintain personal cleanliness, e.g. bathing, groomed hair, clean fingernails. • Where direct contact with a food or food contact surface (e.g., packaging material or equipment) is unavoidable, inadequate hand sanitization may lead to food becoming contaminated. **Spitting, gum chewing and other acts** • Contamination of food can result from persons (e.g., personnel, management, visitors and contractors) who do not refrain from unhygienic behaviors.(e.g., chewing gum, eating, spitting, using tobacco, unnecessary contact with the food) while in the establishment. **Foreign objects and substances** • Unsecured personal objects (e.g., jewelry) or substances such as chipping nail polish may contaminate the food.
Assessment Criteria	**Personal cleanliness** • All persons entering an establishment exhibit good personal hygienic practices such as cleaned skin, hair, fingernails, etc. • All persons wash and dry their hands upon entering an area of the establishment where a food is prepared or packaged. The same applies to any activity that poses a potential risk of contamination such as before starting work, after using toilet facilities, after handling any contaminated item, after breaks and as often as hands become soiled. • Persons who are required to come in direct contact with a food, or with things that come in contact with a food, wash and sanitize their hands or use equivalent means (e.g., hand wipes, hand dips, sprays). • Hands are washed effectively (e.g., using suitable water temperature, single service soap and hand-drying devices, etc.). • When provided, disinfectant hand dips and footbaths fixtures are used as intended. • A notice or sign prohibiting unhygienic practices or stating requirements for acceptable hygienic practices are

posted. These should be presented in a manner than can be understood by persons entering the establishment. Examples of hygiene practice and behaviour signage include: hand-washing and sanitizing; use of hand dips, and footbaths.

Spitting, gum chewing and other acts

- All persons, in any area of the establishment, refrain from any behaviour that could result in the contamination of a food, such as, but not limited to:
    - using tobacco;
    - chewing gum;
    - eating;
    - sneezing, spitting or coughing;
    - unnecessary contact with the food or other things such as food contact surfaces, packaging materials and utensils

- If a food comes in contact with a non-food contact surface, a person follows the procedures which have been put in place, and which direct the appropriate course of action in respect to the control or disposal of that food.

- If drinking water stations are provided in food processing areas, good hygienic practices are followed for those stations, e.g., water is consumed from designated stations only.

- A notice or sign prohibiting unhygienic behaviour or stating requirements for acceptable hygienic behaviours are posted. These should be presented in a manner that can be understood by persons entering the establishment e.g., smoking not permitted.

Foreign objects and substances

- Clothing and effects such as purses and jackets are stored in designated locations away from processing areas.

- Persons remove objects such as jewellery, pins, adornments, nail polish. Objects that cannot be removed e.g., religious apparel, wedding bands, medical alerts are secured and covered.

Part 4: Preventive Control	
Element 3 Hygiene and Competency	
4.3.3	**Health**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 37. (1) Every person who works in an area of the establishment where a food that is to be exported or to be sent or conveyed from one province to another is manufactured, prepared, stored, packaged or labelled who has a disease or illness, symptoms of a disease or illness or an open or infected lesion must report the disease or illness, the symptoms or the lesion to the operator. (2) Every operator must ensure that no person who is suffering from or is a known carrier of a communicable disease or who has an open or infected lesion is present in an area of the establishment where the food is manufactured, prepared, stored, packaged or labelled if the person's condition presents a risk of contamination of the food.
Compliance Rationale	Persons working in a food establishment may be a potential source of contamination if they: • are suffering from or who are carriers of a communicable disease likely to be transmitted through food, or who • have open cuts, wounds or infected skin lesions It is important that diseases and illnesses are reported to a responsible person so that the person with the disease or illness may be excluded from areas where food may be contaminated.
Assessment Criteria	• Persons working in an establishment are aware that they must report a disease or illness, as well as symptoms of a disease or illness, and an open or infected lesion, to a responsible person in the establishment. In this regard, a mechanism is in place for such persons to report their condition to a responsible person in the establishment. • Persons known to be suffering from, or carriers of, a communicable disease e.g., Salmonellosis, Campylobacter, Shigellosis, Amebic dysentery, etc., likely to be transmitted through food are prevented from entering certain areas of the establishment where food contamination can occur. • Persons with open cuts or wounds are prevented from participating in the manufacture, preparation, or packaging of a food unless the injury is completely protected by a secure waterproof covering e.g., gloves suitable for a food operation.

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Element 3 Hygiene and Competency	
4.3.4	**Competencies and Qualifications**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 38. Every operator must ensure that any person involved in the manufacturing, preparation, storage, packaging or labelling of the food has the appropriate competencies and qualifications to carry out their duties.
Compliance Rationale	The competence and qualifications of persons undertaking or supervising the preparation, manufacturing and packaging of food is important. These persons: • play an important role in protecting the safety of food; • support awareness and understanding of potential hazards and their responsibility in reducing contamination in the food; • help comply with regulatory requirements e.g., food safety, grades, standards, labelling, etc.
Assessment Criteria	Persons are competent and qualified in basic food production procedures to carry out their duties. This includes but is not limited to an understanding of generic practices such as: • methods for proper hand washing and sanitizing, including proper use of hand and footbaths; • correct use of protective clothing, hair coverings, gloves, footwear; • hygienic behaviour and practices; • health and hygiene policies e.g., protocols for reporting symptoms, disease or illness transmissible through food, as well as actions to be taken upon the detection of an open or infected lesion; • food safety and food hygiene matters; • employee traffic and process flow policies; • procedures for the control of cross-contamination and allergens; • procedures for visitors and contractors e.g., restricted access, hygienic practices; and • food security and controls e.g., detection of product tampering. Persons are competent and qualified, as appropriate to the complexity of the establishment and the manufacturing process, in the procedures for which they are responsible such that they understand the importance of process controls, critical factors and their limits, corrective actions when deviations or deficiencies occur and recordkeeping. Examples of specific competencies and qualifications may include: • use of proper procedures for monitoring and verification; • correct use of equipment, instruments and utensils and process technology, e.g., retort, pasteurization; • appropriate maintenance, calibration, and corrective action e.g., in-house or contract repair of equipment, instruments and utensils e.g., scales, metering devices, pasteurizers; • ability to interpret or analyse results; • proper application of principles and methods required for effective cleaning and sanitizing of equipment; • applying effective methods for pest control, including proper handling of hazardous chemicals; and • knowledge of current Canadian food legislation and policies related to food safety, grades, standards, or other regulatory requirements e.g., labelling.

Part 4: Preventive Control	
Element 4 Equipment and Conveyances to be used in an Establishment	
4.4.1	**Equipment and Conveyance Design, Construction, Operation and Maintenance**
Legal Authorities	*Safe Food for Canadian Regulations (based on current suggested preliminary text)* 39. (1) Every operator must ensure that any equipment or conveyance used in the manufacturing, preparation, storage, packaging or labelling of the food (a) is appropriate to the food and the activity being conducted; (b) is designed of, constructed of and maintained using, materials that are appropriate for the purpose for which they are used and, if the materials present a risk of contamination of the food, that are (i) corrosion-resistant, (ii) durable, (iii) capable of withstanding repeated cleaning and, if appropriate, sanitizing, unless the equipment is of single-use, and (iv) free of any noxious constituent; (c) is designed, constructed, maintained and, if applicable, installed (i) to not impart any substance that presents a risk of contamination to the food, (ii) as appropriate, with instruments to control, measure and record parameters including temperature, pressure, pH, time, concentration and density, (iii) to function as intended, and (iv) to be accessible for cleaning and, if necessary, easily disassembled for cleaning, sanitizing, maintenance and inspection; (d) is of sound construction and in good repair; (e) has food contact surfaces, if any, that are (i) smooth, (ii) free from pitting, crevices and loose scale, (iii) unaffected by the food, and (iv) non-absorbent; (f) is used as designed and constructed; and (g) is used, maintained and, if necessary, calibrated (i) in accordance with the manufacturer's instructions, and (ii) in a manner that does not present a risk of contamination of the food. (2) Any equipment used to handle contaminated materials, waste or anything that is inedible, including fish offal, inedible egg, inedible processed egg and inedible meat products, must (a) be used only for that purpose; (b) be identified as such; and (c) satisfy the requirements of paragraphs (1)(a) to (g).
Compliance Rationale	For the purpose of this section equipment includes such things as utensils, containers, and devices used for controlling, measuring and recording. It also includes such things such as forklifts and hand lifts which are used to transport materials within the establishment. • Equipment that is well designed, constructed and installed minimizes the potential for biological, chemical and physical hazards. • Poorly designed equipment may result in the accumulation of food residues that may contain allergenic components or micro-organisms that can cause cross-contamination. • Pits, cracks and crevices can provide areas for residues to accumulate and micro organisms to grow. • Poor design and installation can result in parts or areas that cannot be properly cleaned, sanitized and inspected. • Equipment that is designed and installed in such a way that does not allow for adequate maintenance and inspection can result in hazards not being detected. • When the equipment is easy to disassemble and reassemble, it is conducive to proper cleaning and maintenance of the equipment. • Equipment used for cleaning and sanitizing that is capable of delivering the requirements of the sanitation plan will facilitate a sanitary environment (e.g., temperature indicators, racks, reels, hoses, CIP system). • Improper design, construction, installation and validation of instruments and control devices may result in inadequate processing, food additives, nutrition, composition, or net quantity violations. • Inadequate exhaustion of equipment to the outside can result in excessive condensation.

	• Improper hook up to drainage systems can result in a collection of water or other liquids or flooding. • Equipment, instruments, utensils and food contact surfaces that are not suitable for the activities being performed can impart hazards such as damage or contamination of the food commodities or packaging materials. • Poor or missing identification of equipment, instruments and utensils, including containers used to handle inedible or contaminated materials, or using such equipment to handle food commodities could result in contamination. Processing equipment, utensils, containers, controlling devices and instruments including measuring, timing and recording devices must be properly maintained and calibrated. This is to ensure that they function as designed and that no potential physical or chemical hazard result, e.g., inappropriate repairs, flaking paint or rust, excessive lubrication. Sanitation equipment must be properly maintained and calibrated to deliver appropriate temperature and chemical concentrations, and to ensure proper cleaning of processing equipment. The improper calibration of controlling devices may lead to a loss of process control including: • inadequate processing of food e.g., time temperatures not being met; and • failure to meet other regulatory requirements e.g., incorrect container filling (net quantity), nutritional inaccuracies or composition violations. Maintenance or calibration taking place during production may result in contamination of the food from the following: • nuts and bolts dropped into food; • vacuum cleaner exhaust used to clean up, after maintenance, contaminates the air and food contact surfaces; and • paint dripping into food, or odors present in the air.
Assessment Criteria	**<u>Equipment and Conveyances to be used in an Establishment</u>** All equipment, utensils, containers, conveyances and controlling and measuring devices used in food preparation and storage are: • designed, constructed and installed: o to be accessible for cleaning, sanitizing, maintenance and inspection and is easily disassembled for those purposes, o to prevent contamination during operations, o where necessary, is exhausted to the outside to prevent excessive condensation, and o to permit proper drainage from the equipment and where appropriate, connected directly to drains; • used only for the intended purpose; • functioning as intended and capable of delivering the requirements of the process (time, temperature), the sanitation plan, and contributing to specifications being met, e.g., net quantity, composition, labelling, etc.; • smooth, non-corrosive, non-absorbent, non-toxic, free from pitting, cracks and crevices where there are food contact surfaces; • unaffected by the food e.g., effect of salt or food acids on some materials • made of cleanable materials that can withstand repeated cleaning and sanitation; • fit for purpose and do not contaminate the food in terms of coatings, paints and other materials used for food contact surfaces or equipment where there is a possibility of contact with food; • using the appropriate strength and type of magnets, if applicable, and these installed in a manner to effectively remove ferrous metal before or after certain operations (e.g., dicing, slicing or filling). Water, ice and steam handling equipment is designed, constructed and installed in a manner that will not jeopardize the potability of water. Traps are provided as necessary to ensure that condensation is removed and foreign materials are eliminated. Cleaning and sanitizing equipment is designed for its intended use, and performs as intended. Equipment used to handle inedible or contaminated materials or waste are identified and used only for that purpose. Identification can include labelling, tagging, color coding, etc.

Instrumentation

Instruments that control critical safety factors are designed, installed and constructed to ensure that they function as intended. It is recommended that they are located to be easily and accurately read by the operators. The following are some examples of instrumentation that may be required to control factors critical to the process.

Measuring, timing and recording devices (thermometers, pressure gauges, recorders)

- One unit of measurement is used consistently throughout the processing system
- Scales are within the operating range, and are easily readable.
- Controls are in place to verify that process time requirements are met.

Metal detectors

- Metal detection equipment is designed, constructed and installed according to manufacturers' instructions, to ensure that metals are effectively detected. Depending on the food commodity, the equipment manufacturer's manual may describe adjustments that can be made to maintain the level of effectiveness of metal detection, selection of target metal and size, timing of the reject mechanism and suitability for environmental conditions.

Scales and metering devices

- The sensitivity is appropriate to the use.
- Scales are designed and installed to withstand the environmental conditions or are adequately protected from drafts, rust, corrosion.

Other instrumentation

- Other specialized instrumentation may be necessary to control critical factors (e.g., pH meters, refractometers etc.). These must be appropriate for the intended use.

Maintenance and calibration is carried out to ensure that:

- all equipment performs consistently as intended to, and prevents contamination of the food;
- instruments that control critical factors function as intended. These include measuring, timing and recording devices e.g., thermometers, pressure gauges, recorders, metal detectors, scales or metering devices;
- the performance of the following activities do not pose a risk to the food or the food production environment:
    - dismantling of equipment
    - lubrication or other equipment servicing
    - changing filters and gaskets
    - painting
    - calibration

Maintenance activities may include:

1. listing all equipment, utensils, containers, conveyances, controlling devices and instruments that require regular maintenance.
2. identifying the maintenance procedures and frequencies (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).
3. naming the competent individual responsible for conducting the maintenance of the equipment, conveyances and instrumentation.

Calibration activities may include:

1. listing equipment and instruments that are used for monitoring, controlling and measuring devices, and that require regular calibration to ensure accuracy.
2. identifying the calibration procedures and frequencies (upon installation and on an ongoing basis as often as established by the equipment or instrument manufacturer) for equipment that is used for monitoring or controlling devices or instruments.
3. naming the competent individual responsible for calibrating the equipment and instruments or overseeing the calibration if it is performed by a third party service.

Part 4: Preventive Control	
Element 5 Design Construction and Maintenance of Establishments	
4.5.1	**Design, Construction and Maintenance of Establishment Exterior**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 40. Every operator must ensure that (a) the land that forms part of the establishment (i) is free of debris and refuse, (ii) provides or permits good drainage, and (iii) is maintained in a manner to prevent harbourage of insects, rodents and other vermin; and (b) the establishment is not in proximity to anything that presents a risk of contamination of the food, including any source of pollution or any place that harbours insects, rodents or other vermin, unless measures are taken to eliminate any risk of contamination of the food as a result of the proximity.
Compliance Rationale	Outside sources of contamination (e.g., dust, foul odours, smoke, pest infestation, airborne microbial and chemical contaminants, flood waters and mud) potentially can impact an establishment and contaminate the interior environment and food commodity.
Assessment Criteria	***Design, construction and maintenance of establishment exterior*** • The surrounding property is o maintained to minimize sources of contamination such as debris, dirt, dust, fumes and pest harbourage areas, and o drained, appropriate to the operation, to prevent water and mud contamination of the establishment • The building is not located in close proximity to any environmental contaminants; air intakes are appropriately located and filtered; the roof, walls and foundation are maintained to prevent leakage.

Part 4: Preventive Control	
Element 5 Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 41. Every operator must ensure that the interior of the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled is (a) designed, constructed and maintained (i) to be of sanitary design so as to prevent accumulation of contaminants including dust, dirt, micro-organisms and food particles and to permit effective maintenance, cleaning and, if appropriate, sanitizing, (ii) to be of adequate size and layout to accommodate the activity being conducted and the equipment used in the activity, (iii) of materials that are (A) appropriate for the purpose for which they are used and appropriate to the food and the activity being conducted, (B) durable, (C) capable of withstanding repeated cleaning and, if appropriate, sanitizing, and (D) free of any noxious constituent, (iv) to prevent the entry of insects, rodents or other vermin, (v) to have floors, walls, ceilings, windows and doors, if any, that are smooth, non-absorbent and impervious to moisture, and (vi) to have floors, if any, that provide or permit good drainage; and (b) of sound construction and in good repair.
Compliance Rationale	Structure which are properly constructed and maintained support cleaning and sanitation and help prevent the entry of pests and contaminants. Structures and materials that can be effectively cleaned minimize the development of unsanitary conditions (e.g., presence of bacteria, mold). Structures which are properly constructed and maintained support cleaning and sanitation and help prevent the entry of pests and contaminants. Ceilings and overhead structures, stairs and elevators that are well designed will minimize the build-up of dirt, condensation and the shedding of particles that may contaminate a food commodity or packaging materials. Floors that are designed to permit liquids to drain to trapped outlets help prevent water pooling. Standing water can become stagnant and therefore a source of contamination. Doors and windows are constructed of materials that are durable, impervious, smooth, cleanable, free of any noxious constituents as appropriate to the operation and maintained in good repair help to prevent contamination of a food or packaging material and to facilitate sanitation. Windows that are sealed or equipped with close-fitting screens and doors that are tight fitting will help prevent entry of contaminants and pests. Windows constructed of, or protected with, unbreakable materials will help prevent foreign material, including glass, contamination of food, ingredients, packaging materials and food contact surfaces. Door locations such as employee entry to the establishment and flow to work rooms influence operational flows and ingredient/production flows; adequate separation or control between incompatible operations promotes the prevention of contamination (see 5.2.1 flow separation). As appropriate to the operation, doors are self-closing to facilitate process separation and to help prevent doors from being left open.
Assessment Criteria	Note: Conveyances referred to in this section including those such as fishing vessels where food is manufactured, prepared, stored, packaged or labeled are considered to be establishments. • Floors, walls and ceilings are: constructed of materials that are durable, impervious, smooth, and cleanable;

	appropriate to the operation; maintained in good repair, and; facilitate sanitation. • Where appropriate, wall, floor and ceiling joints are sealed and angles are coved to prevent contamination and facilitate cleaning. • The design, construction and maintenance of ceilings, overhead structures, stairs and elevators prevents the build-up of dirt, condensation and the shedding of particles and facilitates sanitation. • In food preparation areas floors are designed, constructed and maintained to permit drainage and prevent water pooling. • Drains must be trapped and be of adequate size, number and location to help prevent the pooling of water or other processing wastes and not pose a contamination risk to food commodities or packaging materials. • Doors and windows in rooms or areas where food is manufactured, stored, packaged, received or shipped are constructed of materials that are durable, impervious, smooth, cleanable,and free of any noxious constituents; appropriate to the operation; maintained in good repair, and; facilitate sanitation. • Doors are located so as to limit access to the processing area and provide a physical separation between the outdoors, raw receiving and production areas (see 5.2.3 flow separation). • Doors leading to processing areas are close fitting, properly sealed and, as appropriate to the operation, are self-closing/opening and such doors are kept closed during processing. • Air curtains, plastic separators etc. if used, are appropriate for their intended use are maintained in good repair and facilitate sanitation. • Windows are properly sealed or equipped with close fitting screens. • Windows that in the case of breakage, could result in the contamination of food, are constructed of alternative materials or are adequately protected.

Part 4: Preventive Control	
Element 5 Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
4.5.2.1	**Process Flow Separation**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 42. Every operator must ensure that the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled is designed, constructed and maintained to effectively control the movement of persons, equipment, conveyances and food commodities within — and into and out of — the facility or conveyance so that the movement does not present a risk of contamination of the food. 43. Every operator must ensure that measures are taken to effectively control the movement of persons, equipment, conveyances and food commodities within — and into and out of — the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled, so that the measures and the movement do not present a risk of contamination of the food. 44. Every operator must ensure that incompatible activities or foods are separated by physical or other effective means. 45. The operator must ensure that measures are taken to keep the food separate from (a) any food that does not comply with these Regulations; (b) anything that has been or is to be manufactured, prepared, stored, packaged or labelled that is not for human consumption; and (c) any food that is to be sold solely within a province.
Compliance Rationale	Appropriate design of operational flow will help prevent contamination / cross contamination of food commodities and other items e.g., • employee entry to the establishment and flow to work rooms, change rooms, storages etc. • ingredient/production flows • animal food/feed and not for human consumption , inedible product or food waste and garbage flows • adequate separation or control between incompatible operations (e.g. separation of time or space between the handling of raw ingredients and the handling of cooked or final food commodities; living quarters and areas where animals are kept are completely separated and do not open directly to any processing areas) Appropriate design of operational flow will help prevent products destined for intra provincial trade, which are not subject to the SFCA/R, from being mixed with food commodities subject to the SFCA/R. Uncontrolled access to the establishment and/or any area within the establishment, may lead to food safety risks including tampering.
Assessment Criteria	Note: two types of conveyances are referenced here. The conveyance which is considered an establishment and conveyances used in or at the establishment to move materials. Access to the establishment and/or areas within the establishment is controlled by one of the following or equivalent: • Limiting access to individuals to specific areas of the establishment where there is a risk of contamination of the food commodity • Allowing access to specific areas of the establishment provided that procedures are in place to mitigate the risk (e.g., changing clothing and footwear) Where there is potential for cross-contamination, incompatible items or activities are separated by physical or other effective means such as: o separate rooms which are constructed using walls, doors and windows suitable to the operation. o anteroom between incompatible rooms/areas o separate processing lines o sequencing or scheduling of processing o regulated flow of employees o regulated flow in the process from the arrival of the raw material at the premises to the finished food commodities

Part 4: Preventive Control	
Element 5 Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
4.5.2.2	**Lighting**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 46. (1) Every operator must ensure that the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled is equipped with natural or artificial lighting that does not affect the food and is appropriate to the activity being conducted. (2) Every operator must ensure that any light fixtures in the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled (a) are capable of withstanding repeated cleaning and, if appropriate, sanitizing; and (b) do not present a risk of contamination of the food in the event of breakage.
Compliance Rationale	Appropriate and sufficient lighting allows personnel to perform designated duties, increases efficiency in determining defects, allows easier monitoring of sanitation and visible contaminants and helps prevent the production of natural toxins, where there is a risk for this. If the light source alters or changes the appearance of the natural colour of the food, it may result in an incorrect assessment of the food. Inadequate or overexposure to lighting may result in the deterioration of nutrients, affect the quality of food commodities or result in the production of natural toxins. Excessive lighting may affect the efficiency of chorine used in sanitation. Properly designed light fixtures facilitate cleaning and sanitation to help prevent contamination of work surfaces, food commodities and packaging materials. Broken light bulbs or lighting fixtures over exposed food, ingredients, packaging materials or food contact surfaces, may result in a physical foreign material hazard. Safety covers contribute to the prevention of breakage and the containment of any material resulting from a breakage.
Assessment Criteria	Lighting is appropriate such that the intended production or inspection activities can be effectively conducted. In general, the following intensity levels, measured using a light meter at the work surface level or approximately 1 m from the floor, have been historically acceptable: - 540 lux (50 foot candles) in inspection areas - 220 lux (20 foot candles) in work areas - 110 lux (10 foot candles) in other areas Lighting is appropriate such that the appearance of the natural colour of the food is not altered. Light bulbs and fixtures located in areas where there is exposed food, ingredients, packaging materials or food contact surfaces are of a safety type or are equipped with safety covers. They are appropriately designed to facilitate cleaning

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Element 5 Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
4.5.2.3	**Air Quality and Ventilation**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 47. Every operator must ensure that the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled is equipped with a ventilation system that is designed, constructed and maintained to (a) provide natural or mechanical ventilation with sufficient air exchange (i) to provide only clean air to areas of the facility or conveyance where air presents a risk of contamination of the food, (ii) to prevent accumulation of steam, condensation or dust that presents a risk of contamination of the food, and (iii) to remove unclean air and odours that could affect the food; (b) be accessible and, if necessary, disassembled, for cleaning, maintenance and inspection; (c) to be capable of withstanding repeated cleaning; and (d) function as intended.
Compliance Rationale	• Proper location of air intakes and the use of effective filters (pore size and cleanliness) are essential to prevent the introduction of air contaminated with insects, dust, smoke, objectionable odour, etc. • Adequate ventilation minimizes airborne contamination of food (e.g., from aerosols or condensation droplets) and minimizes condensation, which could contaminate food. • A clean and well maintained ventilation system that functions properly prevents excessive heat, steam, condensation and dust build up in the facility, removes contaminated air and prevents the ventilation system itself from becoming a source of contamination. • The flow of contaminated air through an establishment can be a source of bacterial contaminants for microbiologically sensitive food processing areas. • The use of food grade air or gases contributes to the prevention of airborne contamination to food or packaging materials. • Proper ventilation in animal holding areas is necessary to ensure animal comfort.
Assessment Criteria	• Ventilation openings are equipped with close fitting screens or filters as appropriate to prevent the intake of contaminated air. • Ventilation provides sufficient air exchange to prevent unacceptable accumulations of heat, steam, condensation or dust and remove contaminated air. • HVAC (heating, ventilation and air conditioning) systems are designed and constructed so that air flow into clean areas is not contaminated. Systems are adequately maintained and cleaned. • Holding areas that are used for food animals awaiting slaughter are provided with adequate ventilation • Airflow is directed from more microbiologically sensitive areas (e.g., ready-to-eat processing rooms and aseptic rooms) to less microbiologically sensitive areas (e.g., raw ingredient handling areas). • Where required, ambient air, compressed air or gases utilized in processing equipment that: o contact food commodities or packaging materials are sourced and treated, as appropriate to the operation, to minimize contamination of food commodities and packaging. o do not contact food commodities or packaging materials but rather are used to operate valves or equipment pneumatically are treated so as to not damage equipment or contaminate food or packaging materials.

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Element 5 – Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
4.5.2.4	**Humidity and Temperature Control**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 48. (1) Every operator must ensure that the temperature and humidity levels in the facility or conveyance where the food is manufactured, prepared, stored, packaged or labelled are appropriate to the food and to the activity being conducted. (2) If the facility or conveyance is equipped with a heating, cooling or humidity control system, the system must be designed, constructed and maintained (a) to have the appropriate instruments for indicating and recording the temperature and humidity levels; (b) to be accessible and, if necessary, disassembled for cleaning, maintenance and inspection; (c) to be capable of withstanding repeated cleaning; and (d) to function as intended.
Compliance Rationale	The lack of temperature and humidity control in processing rooms where temperature / humidity sensitive food commodities are prepared/packaged may result in the deterioration of the food commodity resulting in food safety / quality issues. The lack of temperature and humidity control for sensitive ingredients and food commodities during storage in coolers or freezers or during the process of receiving/shipping may result in the deterioration of food resulting in food safety / quality issues. Storage of packaging materials and food commodities under humid conditions may result in damaged packaging materials and containers.
Assessment Criteria	Note: in this section conveyances refer to such things as fishing vessels which are considered to be establishments. Note: This IG addresses the facility, design construction and maintenance for temperature and humidity control not the activities related to receiving/shipping, and storage of the food commodity and the control of temperature and humidity during these activities. The temperature in a room or area of an establishment where a food commodity is prepared, packaged, or labeled is appropriate to prevent deterioration of the food commodity. Furthermore, temperature control can also limit bacterial growth in the food commodity as well as on food contact surfaces. Historically, a room temperature of not more than 10°C has been found to be adequate for food commodities requiring reduced temperatures for preparation, packaging, and labelling. Receiving/shipping and storage areas are designed, constructed and maintained to allow for the control of the temperature and humidity to prevent deterioration and spoilage or affect the safety of the food commodity. Moreover this prevents deterioration of packaging materials and containers (e.g., rusting, corrosion) • Refrigerated areas are capable of maintaining stored ingredients and food commodities refrigeration temperatures (i.e., less than 4°C (39°F) but not frozen, FDR B.27.001) • Freezer areas are capable of maintaining frozen ingredients and food commodities in a frozen state. Generally, for long term storage, freezer storages are maintained at a temperature of -18°C (0°F) or colder. • Areas other than those listed above are maintained at temperatures and humidity levels that minimize microbiological, physical and chemical deterioration (e.g., thermophilic spoilage) of items stored therein.

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Element 5 Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
4.5.2.5	**Waste Management and Disposal**
Legal Authorities	*Safe Food for Canadians Regulations (based on suggested current preliminary text)* 49. Every operator must (a) provide effective means for the removal and disposal of contaminated materials and waste, including a drainage, sewage and plumbing system that is designed, constructed and maintained to (i) adequately remove or dispose of all contaminated materials and waste in a manner that does not present a risk of contamination of the food, (ii) be capable of withstanding repeated cleaning, and (iii) function as intended; (b) remove and dispose of contaminated materials and waste at a frequency that is sufficient to prevent the accumulation of contaminated materials and waste which presents a risk of contamination of the food; and (c) when removing and disposing of the contaminated materials and waste, do so in manner that does not present a risk of contamination of the food.
Compliance Rationale	The sanitary handling and disposal of sewage, waste, inedible or food waste products and the maintenance of waste containers and facilities will prevent the accumulation of materials and the potential contamination of food handling areas, as well as minimize the attraction of pests and prevent objectionable odours. Improperly storing garbage, waste and in-edible items may contaminate ingredients, food, packaging materials or the environment. An effective waste removal and disposal system will reduce pest harbourage and the risk of cross-contamination of food, ingredients, packaging material, food contact surfaces or the safe water supply (for example, drain back-ups leading to flooding). Cleanable and properly identified containers and utensils used for waste will prevent misuse that may result in cross-contamination. The presence of mechanisms to prevent backflow (for example, trapping, venting) will help prevent sewer gases, pests, micro-organisms or other contaminants from entering the establishment through the plumbing system.
Assessment Criteria	Sewage, effluent and waste storage and disposal systems are designed, constructed and maintained in a manner to prevent conditions which may result in contamination of food, preparation areas or water Disposal of sewage, effluent and solid wastes is done in a sanitary manner which does not expose the establishment or food products to potential contamination. Inedible and waste materials do not accumulate in processing areas to the point where it presents a risk of contamination of the food or the environment. Waste storage facilities, utensils and containers are identified, of suitable capacity and cleaned to avoid attracting pests. • Solid waste containers within the establishment are: o sufficient in number and accessible; o constructed of suitable non-absorbent materials o designed to minimize both the attraction of pests, and the potential for airborne contamination; o identified as to their contents; and o emptied when full or at least daily o cleaned and sanitized as often as necessary. • Garbage storage rooms are emptied, cleaned and sanitized so as to be maintained in a clean and sanitary manner. • Solid waste containers located outside the premises are: o equipped with covers and closed when not in use;

	• Solid waste containers are maintained in a manner that does not attract pests; cleaned regularly and emptied when full or at least frequently enough to minimize the contamination potential. Continuous handling systems that carry waste on conveyors or in flumes to waste containers are constructed in a manner so that they pose no threat of contamination to the processing areas or to food being processed and: o be equipped with tight-fitting covers; o if located inside the processing areas, be constructed of non-absorbent and non-corrodible materials and kept in a sound condition for ease of cleaning and disinfection; o if located outside the processing areas, be kept in a sound condition for ease of cleaning and disinfection and be constructed of a suitable non-absorbent metal; and o if delivering materials to the interior of the bin, be located over or surrounded by a concrete pad Where applicable, denaturing procedures and chemical(s) used do not contaminate food, the food production environment or waste materials being directed for use as animal feed. Waste containers containing materials considered inedible but destined for animal feed are identified as such and handled and stored in a sanitary manner. 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. Drainage and sewage systems are adequate for the volume and type of effluent being produced during normal processing and cleaning operations, are equipped with appropriate traps and vents and backflow is prevented.

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Element 5 Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
4.5.2.6.1	**Hand washing stations, sanitizing stations, lavatories, water drinking stations, break rooms and change rooms**
Legal Authorities	*Safe Food for Canadians Regulations (based on current preliminary suggested text)* 50. (1) Every operator must provide and maintain hand washing stations, sanitizing stations, lavatories, water drinking stations, break rooms and change rooms, as appropriate to the food and activity being conducted, that (a) are appropriately equipped and appropriate in number and size for the number of persons using them; (b) are located so that they are readily accessible to the persons using them; and (c) are capable of withstanding repeated cleaning and, if appropriate, sanitizing. (2) Hand washing stations must have (a) water at a temperature and pressure that is conducive to effective cleaning of hands; (b) suitable materials for cleaning and, if appropriate, sanitizing, hands; and (c) means for hygienic drying of hands. (3) Lavatories must not open into any area of the establishment where the food is manufactured, prepared, stored, packaged or labelled.
Compliance Rationale	Adequate (i.e., sufficient number and size), clean and conveniently located washrooms, hand-washing and sanitizing stations, change rooms and lunchroom facilities support personal hygiene and reduce the risk of contaminants. • handwashing stations that are easily accessible facilitates hand washing. • providing an acceptable area for employees to change into and store street clothes and work clothes helps prevent exterior contaminants from entering the processing areas. • lunch rooms provide employees with a designated area to eat and drink that is segregated from processing areas Hand-washing and sanitizing stations can become a source of contaminants if they are not properly located, designed, constructed or maintained. Sanitizing stations (hand and boot dips) are used to control the potential for cross-contamination from operational equipment and employees.
Assessment Criteria	Employee facilities are located, designed, constructed and maintained to permit effective employee hygiene and to help prevent contamination of a food commodity or food processing areas. • washrooms are provided with a sufficient number of toilets and sinks to accommodate the number of employees using the facilities during the same period. • as appropriate to the operation, washrooms have hot and cold or warm potable running water, soap dispensers, soap, sanitary hand drying equipment or supplies and a cleanable waste receptacle. • washrooms, lunchrooms and change-rooms are appropriately located, constructed and maintained in a clean condition. • it is recommended that hand-washing notices are posted in appropriate areas • the location of hand-washing and sanitizing stations in processing areas do not contribute to or cause contamination of food. • handwashing stations are provided in processing areas and in other areas as appropriate. They have hot and cold (or mixed as warm) potable running water, sinks, soap dispensers, soap, sanitary hand drying equipment or supplies and cleanable waste receptacles. They are conveniently located, have trapped waste pipes to drains and are properly maintained. • sanitizing stations (e.g. for hands and footwear) are provided in locations that are appropriate to the operation, are properly maintained, are provided with potable water at temperatures and, where applicable, chemical concentrations appropriate for their intended use. • rooms designated for eating and drinking are segregated from processing areas. • water drinking stations, if located in an area of the establishment where the food commodity is prepared, operate in a hands-free manner, are directly drained, easily accessible, protected from contamination, and are not a potential source of food contamination. • change rooms or lockers, which are segregated from the processing area, are provided for the storage of personal effects.

	• facilities are provided for storing clean protective clothing (e.g. aprons, gloves, boots, jackets, smocks, lab coats) in a sanitary manner.

Part 4: Preventive Control	
Element 5 Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
4.5.2.6.2	**Areas for Cleaning and Sanitizing of Equipment and Conveyances**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 51. Every operator must have adequate areas and means for the cleaning and sanitizing of equipment and conveyances.
Compliance Rationale	Facilities for cleaning and sanitizing equipment/utensils, containers, conveyances and clothing may become a source of contamination if they are not properly located, designed and used.
Assessment Criteria	Facilities for cleaning and sanitizing, equipment/utensils, protective clothing, containers and conveyances are appropriate to the manufacturing process. Cleaning and sanitizing 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/materials used. • are separated from food storage, processing and packaging areas. • are adequate for effective cleaning and sanitizing of: o crates and transport containers used for the conveyance of animals to the establishment. o cases/totes used to transport finished food commodities and which have been returned for future use o pallets o equipment/utensils including waste containers o food commodity containers (new or recycled) prior to filling. See 1.2.1 In-process Packaging Control. For example, cleaning racks for protective clothing are located such that the clothing can be cleaned under sanitary conditions and the operation does not contaminate food commodities, packaging material or the surrounding environment.

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Element 5 Design, Construction and Maintenance of Establishments	
4.5.2	**Interior of the Facility or Conveyance**
4.5.2.7	**Inspection Areas**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 52. On the request of an inspector, an operator must provide an area for inspections that is appropriately equipped and sized and that is readily accessible to the inspector.
Compliance Rationale	Appropriately designed, constructed and maintained inspection stations/areas for CFIA staff are necessary to allow CFIA staff to perform their inspection tasks properly and safely as well as allow for the proper identification and evaluation of defects.
Assessment Criteria	**Inspection areas** In cases where food commodity grading or inspection is requested or is required for certification purposes the license holder provides to CFIA staff a room or area where the inspection can be performed in which: • the temperature is appropriate • there is adequate lighting for a proper inspection • there is an electrical outlet to facilitate the use of electronic equipment • there is a grading/inspection table, if needed • there is garbage/waste disposal • it is recommended that the work area is located free from vehicular traffic or other hazards

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Element 5 Design, Construction and Maintenance of Establishments	
4.5.3	**Water, Ice and Steam**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 53. (1) Every operator must ensure that (a) the establishment has a supply of potable water that is protected against contamination and that meets the standards set out in the *Guidelines for Canadian Drinking Water Quality – Summary Table*, prepared by the Federal-Provincial-Territorial Committee on Drinking Water of the Federal-Provincial-Territorial Committee on Health and the Environment and published by the Department of Health, as amended from time to time; (b) any water that may come into contact with the food is potable water, unless the use of water other than potable water does not present a risk of contamination of the food; (c) any steam or ice that may come into contact with the food is generated from potable water, unless the use of water other than potable water does not present a risk of contamination of the food; and (d) there are no cross-connections between systems for potable water and any other system, unless measures are taken to effectively eliminate any risk of contamination of the food as a result of the cross-connections. (2) Every operator must provide, as appropriate to the food and activity being conducted, (a) water at adequate quantity, temperature, pH and pressure; (b) steam at adequate quantity and pressure; and (c) ice at adequate quantity. (3) Every operator who treats water, steam or ice must do so in a manner that does not present a risk of contamination of the food.
Compliance Rationale	• Water, ice and steam can be a source of biological or chemical contaminants. Because they can be used for a variety of purposes (e.g., sanitation, recycling, hand washing, as an ingredient or processing aid) it is important to perform water sampling and testing for both microbiological and chemical content to confirm acceptability for its intended use. • Treated water can be a source of contaminants if the chemical treatment or treatment process is incorrectly performed and/or monitored. • Filtration systems can become a source of contamination if bacteria are allowed to grow on the organic materials that have accumulated on filters. • An adequate supply of potable water with appropriate facilities for its storage and distribution will help prevent contamination of water. • If water and steam are not supplied at the necessary volume, pressure and temperature, the ability to properly complete certain activities can be compromised (e.g., hand washing, sanitation, product rinsing) • Collecting and testing water samples from different outlet(s) will aide in determining that the establishment's water supply is not source of contamination.
Assessment Criteria	Note: for the purpose of this part – protection of potable water used in processing includes protection during storage, if any. Water, ice and steam that come in contact with food commodities or food contact surfaces : • is suitable for the process being undertaken o meets applicable standards: potability as defined in Health Canada's Guidelines for Canadian Drinking Water Quality – summary table (http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/2012-sum_guide-res_recom/index-eng.php) Ice and steam are manufactured from potable water. Ice, when purchased, meets purchasing specifications. Safety of water (source and in-plant), ice and steam is confirmed using recognized laboratory methods at a frequency adequate to confirm its potability. Microbiological and chemical analysis is performed. • where municipal sources are used, municipal test results may be accepted. • where the supply of potable water is derived from a private well, adequate protection is afforded to the well

	head to help prevent contamination of the water supply The volume, temperature and pressure of the potable water/steam are adequate for all operational and cleanup demands. Where filters are used they are of the appropriate size and maintained in a sanitary manner. Where applicable, water treatment procedures provide that: • any chemically treated water including boiler feed water treatment (e.g., corrosion inhibitors, water conditioning and chlorination) that has direct product impact or is used on product contact surfaces meets the appropriate regulatory requirement and is potable; • other treatment methods (ozonation, UV treatment etc.) if used, are controlled in a manner intended to deliver the desired outcome and to prevent contamination. Re-circulated water (water re-used in a closed loop for the same processing operation) is treated, monitored and maintained as appropriate to the intended purpose and has a separate distribution system which is clearly identified. Reclaimed water (water that was originally a constituent of a food, has been removed from a food by a process step, and that is intended to be subsequently re-used in a food processing operation such as condensate water [water recovered from hoods and coils] and filtrate water [water collected after concentration by osmosis] is safe and suitable for its intended purpose. This water may be treated and maintained as appropriate for the intended use within the establishment. There is no cross-contamination between safe and unsafe water supplies. Hoses, taps or other similar sources of possible contamination are designed to help prevent back-flow or back siphonage. The use of untreated water/seawater (e.g., holding live fish) is acceptable, provided that the water does not contaminate the product and there is no cross-connection to any approved system, Clean water as opposed to potable water may be used in slaughter facilities if it can be demonstrated its use does not pose a risk to animal welfare, animal health, or the safety of products derived from the animals after slaughter. Water used solely for fire protection, boilers or auxiliary services does not have to meet the same criteria for potability but there must be no connection between the system for that water and the system for potable /clean water Where non-potable water is used, the line(s) must be clearly identified. Water and ice storage facilities are adequately designed, constructed and maintained in a manner to prevent conditions that may result in contamination.

Part 4: Preventive Control	
Element 6 Receiving, Transportation and Storage	
4.6. 1	**Conveyances that Contain Food**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 54. It is prohibited for an operator to admit to the establishment any conveyance that contains the food, or to allow such a conveyance to leave the establishment, unless the conveyance is (a) designed, constructed and maintained (i) of materials that are (A) appropriate for the purpose for which they are used and appropriate to the food and the activity being conducted, (B) durable, (C) capable of withstanding repeated cleaning and, if appropriate, sanitizing, (D) free of any noxious constituent, (ii) to not impart any substance that presents a risk of contamination of the food, (iii) with the appropriate instruments for indicating and recording the temperature and humidity levels, and (iv) to establish and maintain the temperature and humidity at a level that is appropriate to the food; (b) of sound construction and in good repair; (c) capable of protecting the food from a risk of contamination; and (d) not being used and has not been used for the transport of animals, pest control products as defined in the *Pest Control Products Act* or any other material or substance that presents a risk of contamination of the food.
Compliance Rationale	The licence holder addresses the risks associated with conveyances, specifically those that impact food safety and quality. Packaging materials and foods, including water and ingredients, may become contaminated or may not reach their destination in a suitable condition if effective control measures are not taken during loading, unloading and storage Conveyances admitted to or leaving an establishment, e.g. trailer, bulk tank, truck, pallets, fishing vessels, ships, or packages, e.g. bulk containers, shipping containers, tray packs that are not properly constructed, maintained can lead to a number of hazards including: • physical contaminants from dust and foreign material; • chemical contaminants from unsuitable surfaces or trace chemicals or allergens from previous loads or exhaust from improper equipment such as forklifts used indoors • microbiological contaminants from previous loads. The safety and quality of foods requiring temperature and humidity control can be compromised if left at ambient temperatures for prolonged periods. Adequate temperature and humidity control during transportation will minimize microbial growth, toxin formation and food spoilage. Transporting food and non-compatible food or materials together in one conveyance or package can cause the food to become contaminated. Examples include non-food chemicals with food or onions with dairy products. Certain types of conveyances such as pump trucks can puncture holes in packages. This can allow microorganisms or physical contaminants to be introduced into the food.

Assessment Criteria	Note: • This section does not apply to conveyances such as fishing vessels which have processing and packaging facilities and which therefore are considered to be an establishment. • This section also does not apply to conveyances such as forklifts and hand-lifts or other transportation vehicles which are used to transport food or other things within the establishment (on-site). These are considered to be equipment. Conveyances admitted to or leaving an establishment and used to transport packaging materials and foods, including water and ingredients are: • designed, constructed, maintained, cleaned and used to prevent contamination, damage and deterioration of the food or packaging materials. Where third party conveyance companies are used, the licence holder is responsible to ensure that the conveyances meet these requirements; • not used to transport materials or substances that might contaminate or adulterate the food or packaging materials unless appropriate measures were taken to clean the conveyance. In addition, these measures must be validated prior to loading or unloading using, for example, cleaning certificate, wash ticket, letter of guarantee, or a record of previous material ; • loaded, arranged and unloaded to prevent damage and contamination of the food and packaging materials and prevents outside contaminants from entering the establishment. • equipped, where applicable, to prevent temperature abuse conditions; o Ingredients and foods requiring refrigeration are transported at a temperature appropriate to the commodity. o Frozen ingredients and foods are transported at temperatures that do not permit thawing, o Finished foods are not transported under extreme temperature conditions to minimize microbiological, physical and chemical deterioration (e.g. thermophilic spoilage). ▪ equipped, where applicable, to prevent humidity abuse conditions; o Foods and packaging materials that require humidity control are transported under appropriate conditions to maintain their safety, quality and integrity and to prevent deterioration such as rusting, corrosion or damage to packaging materials and packages.

Part 4: Preventive Control	
Element 6 Receiving, Transportation and Storage	
4.6.2	**Loading and unloading of food** **Return of food to the establishment**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 55. Every operator must ensure that the loading and unloading of the food onto or from a conveyance at the establishment is done in a manner that does not present a risk of contamination of the food. 56. Every operator must ensure that any food that is admitted to the establishment and that presents a risk of injury to human health, is returned under section 17 or does not meet the requirements of the Act or these Regulations must be identified as such and moved to a designated area within the establishment and must not present a risk of contamination to any other food.
Compliance Rationale	Forklifts and other unloading devices can puncture holes in ingredient or food containers or damage packaging materials. This can allow microorganisms or chemical and physical contaminants to be introduced into the food. Foods and ingredients requiring refrigeration or freezing may deteriorate or spoil if they are not moved from the receiving dock to the appropriate storage quickly or are left out at ambient temperatures for prolonged periods. Receiving materials in areas of the establishment other than the processing area can lead to contamination of the environment in the processing area and the food. Raw or contaminated ingredients, as well as non-food chemicals need to be managed at receiving to prevent cross-contamination with ingredients, food and packaging materials. Where loading docks are used, it is important that carriers are properly sealed to the building. Alternately, other means are used when loading or unloading to prevent outside contaminants/pests from entering the establishment. It is advisable to control all materials coming into the establishment, as part of good manufacturing practices. • Ingredients that do not meet specifications can result in foods being manufactured that are unsafe or do not meet other regulatory standards. • Packaging materials that do not meet specifications may not adequately protect the food or may lead to the food being contaminated. • Labels that do not meet specifications, including regulatory requirements may result in food being improperly labelled. • Returned or recalled food which is not managed or disposed of properly may result in cross-contamination of ingredients, finished foods or the processing environment. • Inappropriate cleaning chemicals, paints, lubricants for example, may result in chemical contamination of the food or the environment.
Assessment Criteria	The process of receiving and shipping of incoming ingredients, foods, raw materials, agricultural inputs, packaging and labelling materials and rework, construction materials and non-food chemicals is managed to prevent damage, spoilage and contamination of the food in the establishment**.** These materials are: • loaded, unloaded and handled to prevent damage and their condition is assessed at receiving; • managed at receiving to prevent contamination from non food chemicals, raw or contaminated ingredients; • received into areas and shipped from areas of the establishment other than processing areas and are moved from receiving docks to appropriate storage areas; • Foods which require refrigeration or freezing are assessed at receiving to ensure conditions are satisfactory, are moved from receiving docks to appropriate storage and are not left out at ambient temperatures for prolonged periods; and, • non-food chemicals are received separately from foods, ingredients and packaging materials and are moved to storage areas to prevent contamination of food, packaging materials and food contact surfaces. In respect to returns, this section applies to the return of: • Recalled foods

	• Exported foods which are being returned to Canada • Returned foods that do not meet regulatory requirements Recalled, returned, defective or suspect foods or materials, if readmitted to the establishment, are clearly identified and moved to a designated area for re-inspection, assessment and appropriate disposal. Returns that meet regulatory requirements are not required to be identified and placed in a designated area. The operator must assess the returning product to ensure it meets regulatory requirements. As part of a food safety investigation, an inspector may request documents to prove that the incoming materials were assessed at receiving.

Part 4: Preventive Control Plan	
Element 6 Receiving, Transportation and Storage Requirements	
4.6.3	**Storage at the Establishment**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 57. (1) Every operator who stores the food must do so in a manner that does not present a risk of contamination of that or any other food, including by keeping the food separate from anything that presents a risk of contamination. (2) Every operator who stores packaging material, labels, sanitizers, chemical agents, equipment or conveyances must do so in manner that does not present a risk of contamination of the food.
Compliance Rationale	• Storing ingredients, food containers, packaging materials and finished foods in a controlled manner will prevent contamination or cross-contamination from microorganisms, chemicals and foreign matter. Controlled storage will also prevent foods from deteriorating. • During storage, foods can deteriorate resulting in issues with food safety or food quality from the lack of temperature and humidity control for sensitive ingredients. • Storing packaging materials and foods under humid conditions may cause packaging materials and containers to become damaged. • Returned or recalled foods are identified, controlled and segregated to eliminate the risk of contamination to stored ingredients, packaging materials, and finished foods. • Food intended to be used as rework may contaminate stored ingredients or in-process food if it is not clearly identified and stored in a designated area. • When not properly rotated ingredients, packaging materials and finished foods can reach their expiry date increasing risk to the consumer. • Improperly identifying and storing non-food chemical agents may contaminate the environment, ingredients, packaging materials or finished foods. . • Water used as an ingredient and ice, if improperly stored, may become contaminated. This can lead to the contamination of food and the environment. • Improperly stored equipment may harbour pests; hinder proper cleaning and sanitation of the establishment and impede employee traffic patterns.
Assessment Criteria	Incoming Materials Storage • Ingredients that require refrigeration are stored at appropriate temperatures. • Frozen foods are stored at temperatures that do not permit thawing. • Ingredients and packaging materials are handled and stored in a manner to prevent damage and/or contamination. • Foods and packaging materials that are sensitive to humidity are stored under appropriate conditions to prevent deterioration and spoilage and to ensure that the safety and quality of the food are not compromised. Foods for Rework Storage • Finished or partially finished foods being used as rework are: o stored in a designated area; o and maintained at an appropriate temperature and level of humidity. In-Process Storage Foods that are stored for a period of time during the manufacturing process are: • kept at an appropriate temperature and level of humidity to prevent deterioration and spoilage and to ensure that the safety and quality of the food are not compromised; and • protected from contamination during storage periods. Finished Food Storage

	• Finished foods are stored and handled under environmental conditions to minimize deterioration (e.g., rusting, corrosion or damage to packaging materials and containers) and to prevent contamination or damage which may affect the safety or quality of the food. Stock Rotation • Rotation of ingredients and packaging material where appropriate is controlled to prevent deterioration and spoilage and to ensure that the safety/quality of the food are not compromised. • Stock rotation of finished foods is controlled to minimize deterioration, prevent spoilage or ensure that the safety and quality of the food are not compromised, e.g. rusting of containers, container corrosion resulting in leakage, food exceeding shelf life. Water and Ice Storage Water and ice which will be used as an ingredient or packaged and sold as such, when stored, are: • protected from contamination and treated, where applicable, to prevent microbial growth; and • stored at an appropriate temperature to prevent microbial growth and in the case of ice, thawing. Chemical Agents (Non Food Chemical) Storage Chemical Agents: • are stored in a separate room or area, which is dry, well ventilated and designated to eliminate any possibility for cross-contamination of food, packaging materials or food contact surfaces. • are stored in a manner that prevents food, food contact surfaces or packaging materials from becoming contaminated, where required for ongoing use in food handling areas; Personal Items and Clothing Storage • These are stored in designated locations so that they are easily accessible and do not contaminate food. Equipment and Utensils Storage • Portable equipment and equipment that is not in use is properly stored so that it does not present a risk of contamination to food in the establishment (e.g. not causing congestion, harboring pests or posing an obstacle to proper cleaning). • Instruments and utensils are stored in designated locations.

Part 4: Preventive Control	
Element 7 Investigation and Notification, Complaints and Recall	
4.7.1	**Investigation and Notification**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 58. (1) Every operator, and every licence holder authorized to import a food, who learns that the food might present a risk of injury to human health or might not meet the requirements of the Act or these Regulations must investigate the matter as soon as feasible. (2) If the results of the investigation indicate that the food presents a risk of injury to human health, the operator or licence holder must notify the Minister without delay.
Compliance Rationale	Quickly and effectively identifying, investigating and controlling food that might present a risk of injury to human health or might not meet legislative requirements are crucial to protecting consumers from preventable health risks and other issues of non-compliance to regulatory requirements. The Minister of Health, as the responsible Minister for federal laws relating to food safety, must be notified without delay when a food safety issue has been identified in order that the Minister can take appropriate action to protect consumers. The Agency oversees food safety compliance.
Assessment Criteria	For the purpose of this section: Investigation – as soon as feasible is applied as: • In the case of food safety issues – it is expected that appropriate investigations and action is taken before anything else • In the case of non-food safety issues – as soon as possible. Notification of the Minister: without delay (notification is provided immediately upon determination of food safety risk – no delay is permitted). "Learning" about possible food safety risks or possible non compliances may come from many sources: a) test results b) complaints c) notification from staff with suspicion of problems d) notification from suppliers e) news reports / internet reports Once the operator is made aware that the food might present a risk of injury to human health or might not meet the requirements of the Act or these Regulations, they are obliged to investigate the issue. If a risk to human health is identified the Minister must be immediately notified.

Part 4: Preventive Control	
Element 7 Investigation and Notification, Complaints and Recall	
4.7.2	**Complaints**
Legal Authorities	*Safe Food for Canadians Regulations(based on current suggested preliminary text)* 59. (1) Every operator, and every licence holder authorized to import a food, must prepare, keep and maintain a document that sets out a procedure for receiving, investigating and responding to complaints received in relation to the food. (2) If a complaint is received, the operator or licence holder must implement the procedure and prepare, keep and maintain a document that sets out the complaint information, the results of the investigation and the actions taken based on those results for a period of three years from the day on which the actions are completed.
Compliance Rationale	Complaints are important indicators of possible deficiencies in preventive controls and in the preventive control plan, its implementation or the distribution system. Deficiencies in the way complaints are handled could result in the failure to identify and eliminate food safety risks and other regulatory issues. Records of complaints must be kept for three years after the complaint has been actioned to demonstrate that the complaint was properly managed and the system is being properly maintained and improved.
Assessment Criteria	A comprehensive plan is in place for handling and investigating complaints. The product complaint procedure includes, but may not be limited to: • Instructions for the complaint handling and investigation process; • identifying a competent person or persons responsible for receiving, evaluating, categorizing and investigating complaints; • a means of categorizing complaints e.g. health and safety risks, labelling issues; • the procedure for examining the complainants sample specimen, retail product or other product of the same code by appropriate personnel; • instructions for immediately forwarding details of potentially serious complaints to appropriate personnel for action; • a process for investigating safety and contamination complaints by trained technical personnel; and, • the manner of ensuring that the investigation of a complaint is appropriate to the risk and known complaint trends. Product complaints are investigated based on the applicable complaints procedure to determine the root cause. If deemed necessary, corrective actions are taken for non-compliance, to address: • the implicated food, and • any changes to processes or procedures that are required to prevent recurrence Records pertaining to complaints, including the complaint information, results of the investigation and the actions taken based on those results, are maintained for a period of three years from the day on which the actions are completed.

Part 4: Preventive Control	
Element 7 Investigation and Notification, Complaints Procedure and Recall Procedure	
4.7.3	**Recall**
Legal Authorities	*Safe Food for Canadians Regulations (based on current suggested preliminary text)* 60. (1) Every operator, and every licence holder authorized to import a food, must prepare, keep and maintain a document that sets out a recall procedure to enable the effective recall of the food and must conduct a recall simulation based on the recall procedure at least once a year. (2) If the food is recalled, the operator or licence holder must without delay notify the Minister and implement the recall procedure and must prepare, keep and maintain, for a period of three years from the day on which the recall is initiated, a document that sets out the date of the recall and how the recall was carried out.
Compliance Rationale	CFIA needs to know when a recall has been initiated to allow for CFIA oversight including effectiveness checks. Non-compliant food must not be distributed. If distributed, it must be rapidly retrieved and controlled to protect consumers. Recall plans permit the complete control and rapid recall of any lot of an implicated food from distribution. Recall plans are tested yearly to verify the capability to rapidly identify and retrieve an implicated food. Records of when the recall was initiated and how the recall was conducted must be kept for three years from the date the recall was initiated to demonstrate that the recall was properly managed and the system is being properly maintained and improved. The Minister of Health as the responsible Minister for federal laws relating to food safety, must be notified without delay when a recall has been determined in order that the Minister can take appropriate action to protect consumers. The Agency oversees the issue of food safety compliance.
Assessment Criteria	A written recall plan has been developed and implemented and is maintained. To be effective, the plan includes but is not limited to: • Names of employees responsible for managing a recall (Recall Management Team) including: - position; - contact telephone numbers; and - responsibilities. • A system to track product notifications; - initial notification information; - . • A recall contact list for CFIA notification including: - title of the CFIA contact; - contact telephone number; - email address; - contact fax number. • Methods to trace the food including: • a procedure to maintain food identification throughout the process until final packaging, including: - tracing raw ingredients; - premixing of ingredients ahead of use; and - rework; • the use and explanation of the coding system. • A system to record distribution for the food including: - the level of distribution (e.g., local, national); - name of the account and address; - type of account (e.g., manufacturer, distributor, retailer); - food name and identifying code (if any);

- who to contact at the account;
- telephone number and other contact numbers consistent with the documented method of contact during the recall (e.g. fax number, e-mail address); and
- amount of food shipped to each account.

- Procedure(s) for developing, producing and maintaining records for the recalled food.
  - Records that are to be kept in case of recalls (e.g. list of records to be kept, and template for records to be kept).

- Step by step procedures for a recall, including:
  - assemble the recall management team;
  - notify the Minister through the CFIA without delay;
  - identify the reason for the recall and all food to be recalled;
  - detain and segregate all food in the establishment's control to be recalled;
  - prepare a press release, if required;
  - prepare the distribution list;
  - prepare and distribute the notice of recall;
  - verify the effectiveness of the recall;
  - control of the recalled food
  - determine and control disposal of the recalled food; and
  - identify and correct the cause of the recall.

- Methods to assess the effectiveness of the establishments recall notification process.

- Procedures and frequency for testing the recall plan (e.g. mock recall exercise, internal simulations).

The recall plan is periodically tested to verify its capability to rapidly identify and retrieve a food:

- At least once a year, test, conduct mock recall exercises or internal simulations to verify the capability of the procedure to rapidly identify and control a code lot of potentially affected food and reconcile the amount of food produced, in inventory and in distribution.
- Identify and correct any deficiencies in the recall plan.

When a recall takes place, the Minister is notified of the recall without delay; notification is provided immediately upon determination of recall – no delay is permitted.

Records pertaining to the date of the recall and how it was conducted are maintained for a period of three years from the date the recall was initiated.

Part 4: Preventive Control	
Requirements for a written Preventive Control Plan (PCP)	
4. PCP 1.1	**Design Elements of a PCP**
Legal Authorities	*Safe Food for Canadians Regulations* **<u>Note</u>: The following is <u>not</u> based on preliminary regulatory text. The regulatory wording is under development and reflects CFIA's current suggested policy direction based on general concepts. The Compliance Rationale and Assessment Criteria are accordingly intended only as an example of the type of guidance that may be provided in respect of requirements relating to a Preventive Control Plan.** A Preventive Control Plan (PCP) means in respect of a food or the manufacturing, preparing, storing, packaging, labelling, growing, harvesting and importing of a food, a written preventive control plan that effectively: • Identifies for Elements 0-7: ▪ all hazards that must be prevented, eliminated or reduced; ▪ critical control points and related control measures that are validated by evidence that demonstrates that the control points and related control measures effectively control the hazards identified ; ▪ critical limits; ▪ monitoring procedures; ▪ corrective action procedures; ▪ verification procedures; and ▪ record keeping procedures; and • Identifies for other specified requirements, the measures that will be taken to achieve compliance with the Act and Regulations. Every licence holder and every person who grows or harvests a fresh fruit or vegetable that is to be sent or conveyed from one province to another must: • prepare, keep and maintain a PCP; • implement the PCP; • prepare, keep and maintain documents that substantiate that the food has been imported, manufactured, prepared, stored, packaged, labelled, grown and harvested in accordance with the PCP; • prepare, keep and maintain documents that substantiate that the manner in which the food was imported, manufactured, prepared, stored, packaged, labelled, grown and harvested is in compliance with the Act and the Regulations; and • prepare, keep and maintain a written document that sets out a procedure for the maintenance and review of the PCP, and implement that procedure. Every person who prepares a food that is to be exported, every person who exports a food, and every person who grows or harvests fresh fruits and vegetables that is to be exported must prepare, keep, maintain and implement a PCP as described above if they request an export certificate.
Compliance Rationale	PCPs are an internationally accepted approach to prevent or mitigate hazards associated with food safety. PCPs also demonstrate that hazards and risks to food safety are eliminated or are being effectively controlled. Historically, industry has relied on end product testing as a means of demonstrating the safety and regulatory compliance of their food. PCPs aim to reduce this reliance, instead providing a more holistic approach to ensuring food safety. PCPs allow for a preventive foundation with fewer limitations than end product testing. These include representative sample size, limits of detection, accuracy of testing methods, precision, variability and reproducibility, as well as risk of sample contamination. In addition, the PCP covers the whole spectrum of food production (i.e., food safety, quality and composition) by incorporating both HACCP-based food safety principles and factors unrelated to food safety. Since each food operation is unique in terms of its hazards and risks, and how these are controlled, PCPs must be tailored to a specific operation. Food being produced for the export market must meet all requirements of the importing country. Therefore, the PCP must address all aspects of production including food safety, composition, additives, colorants, and labelling, for example. Keep in mind that these may be different from Canadian requirements.

	Food being imported into Canada must meet all regulatory requirements for safety, nutrition, composition, labelling, packaging and quality, as applicable. Importers do not have direct control over the food production and would therefore need to develop specific strategies to address risks. Importers need to include elements of the preventive control plan that apply to their operation.
Assessment Criteria	A written PCP is required by: • Importers: licenced under paragraph 20(1)(a) of the Act, • Persons preparing food for interprovincial trade: licenced under 20(1)(b) of the Act • Person growing and harvesting a fresh fruit or vegetable that is to be sent or conveyed from one province to another or being exported with a certificate: There is no requirement for a licence. • Exporter (including those preparing food for export and brokers) if they require a certificate. Note: Exporters preparing food need a licence under 20(1)(b) of the Act and must meet regulatory requirements but no written PCP is required unless they require an export certificate or other document from CFIA. An effective written PCP, suitable to the operation, is developed, implemented and maintained. • Develop – a written PCP must be developed taking into consideration all processes, items and the environment in which food is prepared. The PCP must include, in addition to food safety, all other regulatory requirements that apply to the product. These may include net quantity, standards of identity, and bilingual labelling, for example. • Implement – once developed, the PCP must be implemented as designed and prior to production for the market or import/export. • Evaluate – the PCP must be evaluated to ensure it is effective in controlling all identified hazards and that it meets all regulatory requirements. • Maintain – once developed, implemented and evaluated, the PCP must be reviewed at a frequency appropriate to the operation and revised as necessary. PCPs must also be reviewed following any changes made to or in the operation. (see also PCP 7 – Management Review) The operation and products must comply with all regulatory requirements. Depending on the type of operation, the PCP would therefore include some or all of the following elements: Element 1. Products and Processes Element 2. Sanitation, Pest Control, Sanitizers and Chemical Agents Element 3. Hygiene and Competency Element 4. Equipment and Conveyances to be used in an Establishment Element 5. Design, Construction and Maintenance of Establishments Element 6. Receiving, Transportation and Storage Element 7. Investigation and Notification, Complaints and Recall Imports Importers are required to comply with regulatory requirements that govern imported food commodities. They must demonstrate how compliance is achieved in their PCP. Elements 0-7 must be considered and those applicable to the operation must be addressed. Please refer also to Trade IG – Import (under development). Exports Exporters are required to comply with applicable foreign country requirements that govern food commodities to be exported. In addition, there may be minimal Canadian regulatory requirements that exporters must also meet. When export certificates or document are required, the exporter must demonstrate how compliance is achieved in their PCP. Elements 0-7 must be considered and those applicable to the operation must be addressed. Please also refer to Trade IG – Exports (under development). Commitment to the PCP may be demonstrated by: • providing the necessary resources and the time required to effectively develop, implement and maintain the PCP, and by verifying the competencies of appropriate staff in their area of responsibility; • providing the financial resources to ensure that the construction of the premises, its internal fittings, the installation of the equipment, the maintenance of the premises and equipment, as well as the supplies required to perform the above, meet all applicable regulatory requirements and support the implementation and effectiveness of the PCP; • designating personnel that have competencies, defined responsibilities and the authority to initiate, implement and record corrective actions; • communicating to employees the importance of meeting the requirements of the establishment's PCP and

	reporting problems to the identified person; • allowing designated management personnel to enforce compliance of the procedures identified in the establishment's PCP for any person entering or working within the establishment; • allowing the continuous improvement of the PCP to ensure its effectiveness by validating control measures, and by making changes to the system as a result of corrective actions or reassessment activities; • providing sufficient time for the individual who is responsible for the development and ongoing maintenance and review of the PCP to perform these duties; • ensuring all applicable information and documents related to the PCP are accessible to staff at the establishment and the CFIA; and • implementing procedures for managing documents.

Part 4: Preventive Control	
Requirements for a written Preventive Control Plan (PCP)	
4. PCP 1.2	**Food Safety Hazard Identification and Control**
Legal Authorities	*Safe Food for Canadians Regulations* **<u>Note</u>: The following is <u>not</u> based on preliminary regulatory text. The regulatory wording is under development and reflects CFIA's current suggested policy direction based on general concepts. The Compliance Rationale and Assessment Criteria are accordingly intended only as an example of the type of guidance that may be provided in respect of requirements relating to a Preventive Control Plan.** A Preventive Control Plan (PCP) means in respect of a food or the manufacturing, preparing, storing, packaging, labelling, growing, harvesting and importing of a food, a written preventive control plan that effectively: • Identifies for Elements 0-7: ▪ all hazards that must be prevented, eliminated or reduced; ▪ critical control points and related control measures that are validated by evidence that demonstrates that the control points and related control measures effectively control the hazards identified ; ▪ critical limits;
Compliance Rationale	Foods have inherent risks, as well as risks associated with preparing them. Consumer safety can be compromised if these are not identified and controlled properly. When developing a PCP, it is important to understand both the characteristics of the food being prepared, and the factors that may impact its safety. A hazard analysis identifies all of the potential hazards that are likely to occur. Another important step in developing a PCP is to determine and implement appropriate control measures for each identified hazard. It is also important to validate critical limits. This will ensure that the process is under control and the selected control measure(s) are capable of effectively controlling the hazards.
Assessment Criteria	Developing the PCP includes the following steps: 1. Identify, through the hazard analysis process, all potential food safety hazards (biological, chemical and physical) associated with incoming ingredients, raw materials, packaging and labelling materials and finished foods. Include each processing step involved in producing the food. 2. Specify the control measures for all hazards including critical limits. 3. Describe how control measures are validated to ensure they will achieve the critical limits and the pre-determined outcomes. A) Conducting a hazard analysis Typically the following approach is followed: • Describe the food and identify its intended use; • List ingredients and incoming materials, including all ingredients, any components of ingredients (with reference to other documents if needed), additives, processing aids and incoming materials that come in contact with the food or are used in preparing the food; • Construct a process flow diagram, then confirm and evaluate its accuracy to identify whether any food safety hazards might occur, be introduced or increase; and • Create a plant schematic, then confirm and evaluate its accuracy to identify potential points of cross-contamination. Each incoming ingredient, packaging material, processing step and potential area of cross-contamination is evaluated systematically to identify all hazards which are likely to be associated with the items. The evaluation process should take into consideration: • the knowledge and experience of employees on practical aspects of the establishment's operations; • documented production issues such production rework, returned items, complaints and recalls; and • external information including reference texts, scientific publications, and government guides such as the CFIA's Reference Database for Hazard Identification.

B) Determining critical control points and related control measures and establishing critical limits, including validation

For each hazard that is identified, conduct an analysis to determine:

- the likely occurrence of the hazard;
- the severity of possible adverse health effects associated with the hazard; and
- whether the identified hazard is:
    - controlled by PCP Element 1-6,
    - partially controlled by a process control,
    - controlled at a specific point in the process, or
    - controlled before the ingredient comes into the establishment or after the food leaves the control of the establishment, via consumer education, cooking, etc.

Establish critical limits or criteria for each identified hazard. Properly maintained, these parameters will confirm the safety of the food. Critical limits may either be quantitative (e.g., data which can be measured such as length, height, area, volume, weight, speed, time, temperature, humidity) or qualitative (e.g., subjective properties which can be observed but not measured such as colors, textures, odors, tastes, appearance, lack of holes in the carrier, or items being stored off the floor). Those critical limits based on subjective data, such as visual inspection of the food are described clearly so they may be easily understood and uniformly applied by those responsible for monitoring.

Where critical limits are prescribed by Canadian regulations, at a minimum, these are met. The establishment may require higher standards than the existing minimum regulatory requirements and set them out in its PCP. In this case these requirements are met as part of the obligation to comply with the PCP. Where critical limits are not prescribed in Canadian legislation, the selected critical limits are validated to demonstrate that they are capable, on a consistent basis, of achieving the intended level of hazard control.

Validation is performed:

- at the time the control program is designed and the critical limit is selected;
- prior to the start of production, when equipment is commissioned; or
- when any change occurs that may impact process parameters.

Depending on the critical limit being validated, the validation approach may use:

- CFIA model systems;
- internationally recognized control measures (e.g. Codex, OIE, ISO) or existing scientific data found in credible references or peer reviewed publications;
- previous validation studies or historical knowledge of how the control measure has performed;
- control measures accepted by foreign countries with which Canada has established equivalency or comparability;
- mathematical modelling
- scientifically valid experimental data to demonstrate the adequacy of the control measures; such as
    - outsourcing to a laboratory or to academia to conduct validation studies;
    - pilot or in-plant validation studies under controlled conditions (collecting and analyzing one's own scientific data).

Follow procedures set out in Codex, Guidelines for Validation of Food Safety Control Measures; CAC/GL 69-2008. The model system, Validation of Control Measures, was adapted from the Codex document. For additional details and guidance on the need for re-evaluation, see PCP 1.6 Reassessment and Management Review.

There are many changes that could lead to a need to revalidate a control measure or combination of control measures. These include, but are not limited to:

• System failure
    - monitoring or verification identifies failures when a reason cannot be found for a process deviation;
    - non-compliance with monitoring or verification criteria may indicate a need to change the parameters of the food safety control system (i.e., the selection and specification of the control measures); or
    - inadequate hazard analysis may cause the food safety control system to fail.

• Process changes, when:
    - a new control measure, technology or a piece of equipment is introduced to the food safety control system; or
    - changes are made in the product formulation or the control measures (e.g., time or temperature).

• New information obtained from scientific, regulatory or in-plant sources indicates:
    - higher concentrations of hazards than originally encountered and accounted for in the design;
    - response of the hazard to the control measure changes (i.e., adaptation);

	o the hazard is not being controlled to the level specified (e.g., new epidemiological findings or new validated and internationally accepted analytical technologies); or o a new food safety outcome.

Part 4: Preventive Control	
Requirements for a written Preventive Control Plan (PCP)	
4. PCP 1.3	**Monitoring Procedures**
Legal Authorities	*Safe Food for Canadians Regulations* **<u>Note</u>: The following is <u>not</u> based on preliminary regulatory text. The regulatory wording is under development and reflects CFIA's current suggested policy direction based on general concepts. The Compliance Rationale and Assessment Criteria are accordingly intended only as an example of the type of guidance that may be provided in respect of requirements relating to a Preventive Control Plan.** A Preventive Control Plan (PCP) means in respect of a food or the manufacturing, preparing, storing, packaging, labelling, growing, harvesting and importing of a food, a written preventive control plan that effectively: • Identifies for Elements 0-7: ▪ monitoring procedures;
Compliance Rationale	Monitoring allows issues to be detected as they arise and appropriate corrective actions to be initiated. This is the best way to avoid non-compliant food from being produced and marketed.
Assessment Criteria	Establishing Monitoring Procedures Monitoring procedures are documented (specifying any tests, measurements or observations) and confirm that food safety controls identified in the PCP are followed. Monitoring procedures include: • identifying a competent, responsible person or team to conduct the monitoring and evaluate the monitoring results; • establishing the frequency of monitoring; • establishing tests, methods or instructions for testing, measurements or observations to be performed (including instructions on keeping records). These are described in enough detail to ensure a consistent delivery between monitors; • defining the forms and procedures for recording the results of monitoring; and • defining a system to identify deviations when they occur.

Part 4: Preventive Control	
Requirements for a written Preventive Control Plan (PCP)	
4. PCP 1.4	**Corrective Actions**
Legal Authorities	*Safe Food for Canadians Regulations* **<u>Note</u>: The following is <u>not</u> based on preliminary regulatory text. The regulatory wording is under development and reflects CFIA's current suggested policy direction based on general concepts. The Compliance Rationale and Assessment Criteria are accordingly intended only as an example of the type of guidance that may be provided in respect of requirements relating to a Preventive Control Plan.** A Preventive Control Plan (PCP) means in respect of a food or the manufacturing, preparing, storing, packaging, labelling, growing, harvesting and importing of a food, a written preventive control plan that effectively: • Identifies for Elements 0-7: ▪ corrective action procedures;
Compliance Rationale	Defects in, or deviations from, critical limits and procedures may affect the safety of food or compliance with food safety regulations. Unsafe food could be sold to consumers if adequate corrective actions are not taken, or procedures are not followed. Appropriate procedures and timely corrective actions are necessary to determine the cause of the deviation, prevent recurrence and minimize health risks. Monitoring and reassessment ensure that actions taken were effective. Appropriate and timely corrective action will help address the root cause of deviations and minimize health risks.
Assessment Criteria	Establishing Corrective Action Procedures When critical limits are exceeded or defects occur which could affect the safety of the food, procedures are in place to identify, isolate, and evaluate the food and address the non-compliance. The PCP outlines steps or procedures to be taken following a deviation, and include: • controlling the food by: • immediately isolating and marking all food or production lots that may be affected, • preventing unsafe food from continuing to be produced, • evaluating the food to determine if it is safe to consume, sell, or to use in another food, and • bringing an affected food into compliance before it is distributed or sold, or disposing of it as appropriate; • identifying and following up, as required, when a non-compliant food has entered the marketplace or into the food supply chain as a precursor to another food; • determining the root cause of the deviation, and preventing recurrence; • recording deviations and taking corrective actions; and • re-evaluating whether the hazard should be incorporated into the PCP, when an unforeseen or previously unidentified deviation is identified. Unforeseen Circumstances In addition to the above, procedures are in place for unforeseen circumstances such as a fire in part of the establishment or a natural disaster. These include: • identifying, retaining, and assessing ingredients, packaging materials and non-compliant food; and • disposing of the ingredients, packaging materials and food as appropriate, according to the nature of the problem.

Part 4: Preventive Control	
Requirements for a written Preventive Control Plan (PCP)	
4. PCP 1.5	**Verification Procedures**
Legal Authorities	*Safe Food for Canadians Regulations* **<u>Note</u>: The following is <u>not</u> based on preliminary regulatory text. The regulatory wording is under development and reflects CFIA's current suggested policy direction based on general concepts. The Compliance Rationale and Assessment Criteria are accordingly intended only as an example of the type of guidance that may be provided in respect of requirements relating to a Preventive Control Plan.** A Preventive Control Plan (PCP) means in respect of a food or the manufacturing, preparing, storing, packaging, labelling, growing, harvesting and importing of a food, a written preventive control plan that effectively: • Identifies for Elements 0-7: ▪ verification procedures;
Compliance Rationale	The purpose of verification is to: • assess the effectiveness of existing food safety controls in preventing and controlling hazards, and ensure that non-compliant food is not produced; • confirm that existing controls are up to date and relevant to the hazards inherent to the operation; and to • identify areas where improvements to the PCP are required.
Assessment Criteria	Establishing Verification Procedures An evaluation (verification) is performed to verify the effectiveness of controls. Verification procedures confirm that monitoring and corrective actions are followed and that control measures are capable of consistently achieving the described outcome. The procedures could include: • naming a competent responsible person, or team, other than the person who conducts the monitoring • determining a frequency appropriate to the hazards associated with the food and process for the verification • describing the activities to be conducted. These might include but are not limited to: • directly observing monitoring activities: review of retort or pasteurization charts; • interviewing persons responsible for monitoring and corrective actions; • directly observing corrective actions taken; • reviewing records documenting the monitoring activities; • reviewing records documenting the actions taken in response to a deviation; • sampling and testing the environment or a food to confirm the safety of the food. In this instance, the procedures: • are described, • use sampling techniques that do not contaminate the samples, • use accepted test methodologies that provide accurate and meaningful results, e.g., - sampling and analysis for the appropriate chemical, microbiological or physical hazards, - incubation testing to confirm commercial sterility/hermetic seal, - visual/mechanical/electronic screening (e.g., dud detection, x-ray, metal detection), - organoleptic evaluation • verifying net quantity; • reviewing labels. • recording the results of the verification • specifying procedures to follow when deviations are identified. This may occur when monitoring or corrective actions are not conducted according to the written PCP, or the PCP is not effective in maintaining control of the food safety standards or regulatory requirements.

Part 4: Preventive Control	
Requirements for a written Preventive Control Plan (PCP)	
4. PCP 1.6	**Reassessment and Management Review**
Legal Authorities	*Safe Food for Canadians Regulations* **Note: The following is not based on preliminary regulatory text. The regulatory wording is under development and reflects CFIA's current suggested policy direction based on general concepts. The Compliance Rationale and Assessment Criteria are accordingly intended only as an example of the type of guidance that may be provided in respect of requirements relating to a Preventive Control Plan.** Every licence holder and every person who grows or harvests a fresh fruit or vegetable that is to be sent or conveyed from one province to another must: • prepare, keep and maintain a PCP; • prepare, keep and maintain documents that substantiate that the food has been imported, manufactured, prepared, stored, packaged, labelled, grown and harvested in accordance with the PCP; • prepare, keep and maintain documents that substantiate that the manner in which the food was imported, manufactured, prepared, stored, packaged, labelled, grown and harvested is in compliance with the Act and the Regulations; and • prepare, keep and maintain a written document that sets out a procedure for the maintenance and review of the PCP, and implement that procedure. Every person who prepares a food that is to be exported, every person who exports a food, and every person who grows or harvests fresh fruits and vegetables that is to be exported must prepare, keep, maintain and implement a PCP as described above if they request an export certificate.
Compliance Rationale	The process of managing a PCP continually generates new information that can be used to actively improve operations and maximize food safety. It also confirms that the PCP is current and relevant. Management commitment is generally accepted as a significant factor to food safety. There are additional benefits of maintaining a PCP: • PCP documents are approved before being issued or re-issued. • Changes are identified when a situation affecting the hazard analysis occurs. This demonstrates that the plan is being maintained effectively. • Revised versions of forms and documents are identified. • Relevant versions of applicable documents are available at points of use. • Obsolete documents are not used unintentionally.
Assessment Criteria	Reassessment and Management Review The PCP and the records associated with it are reviewed by an identified, competent, person within the establishment. This person is responsible for assessing the ongoing effectiveness of the PCP in producing safe food. Management is involved in the oversight and review of the reassessment process. Reassessing the plan involves: • identifying the team member who will conduct the review and are responsible for updating the PCP; and • determining the frequency of the review. The complete plan should be reviewed annually, at a minimum. Portions of the plan is reviewed whenever changes or situations occur that could affect the PCP. The PCP may need to be updated or reassessed prior to its annual review when any of the following potential triggers occur. These triggers include but are not limited to: • new regulatory requirements; • new foods being produced; • a new food line that could potentially cause cross-contamination; • new ingredients or incoming materials coming in contact with the food or being used to prepare the food; • non–compliant situations identified through monitoring and verification activities;

- non-compliance identified through CFIA verifications or third party audits;
- complaints from consumers or clients;
- food being recalled;
- unsatisfactory laboratory results;
- loss of control of critical limits indicated by trend analysis;
- new process step;
- new technology or equipment that may impact the level of a hazard;
- new or ongoing construction, or a change in the production flow or employee traffic patterns that could cause cross-contamination;
- new control measure for an identified hazard;
- changes in product formulation or preparation;
- changes in applying a critical limit; or
- changes in production volume that may impact on the flow, sanitation schedule, or employee training, for example.

In addition, as part of the reassessment, it is necessary to conduct a review of the written preventive control plan, a record review and an on-site assessment of all elements and sub-elements of the PCP including:

Element 1.	Products and Processes
Element 2.	Sanitation, Pest Control, Sanitizers and Chemical Agents
Element 3.	Hygiene and Competency
Element 4.	Equipment and Conveyances to be used in an Establishment
Element 5.	Design, Construction and Maintenance of Establishments
Element 6.	Receiving, Transportation and Storage
Element 7.	Investigation and Notification, Complaints and Recall

The reassessment will also:

- determine that the elements:
  - are up to date,
  - identify and control all hazards, resulting in the desired outcomes,
  - conform to food safety regulatory requirements, and
  - are conducted according to the written plans.

• confirm whether the PCP has achieved the outcomes. If not, interim measures, are implemented as required to control any hazards which may have resulted from an identified deficiency.

• identify changes that need to be implemented for continuous improvement. Changes are verified to ensure they are implemented effectively. Revised versions of the PCP, including records, are made available.

Part 4: Preventive Control	
Requirements for a written Preventive Control Plan (PCP)	
4. PCP 1.7	**Record Keep Procedures (Documentation)**
Legal Authorities	*Safe Food for Canadians Regulations* **<u>Note</u>: The following is <u>not</u> based on preliminary regulatory text. The regulatory wording is under development and reflects CFIA's current suggested policy direction based on general concepts. The Compliance Rationale and Assessment Criteria are accordingly intended only as an example of the type of guidance that may be provided in respect of requirements relating to a Preventive Control Plan.** A Preventive Control Plan (PCP) means in respect of a food or the manufacturing, preparing, storing, packaging, labelling, growing, harvesting and importing of a food, a written preventive control plan that effectively: • Identifies for Elements 0-7: ▪ critical control points and related control measures that are validated by evidence that demonstrates that the control points and related control measures effectively control the hazards identified ; ▪ record keeping procedures; and Every licence holder and every person who grows or harvests a fresh fruit or vegetable that is to be sent or conveyed from one province to another must: • prepare, keep and maintain a PCP; • prepare, keep and maintain documents that substantiate that the food has been imported, manufactured, prepared, stored, packaged, labelled, grown and harvested in accordance with the PCP; • prepare, keep and maintain documents that substantiate that the manner in which the food was imported, manufactured, prepared, stored, packaged, labelled, grown and harvested is in compliance with the Act and the Regulations; and • prepare, keep and maintain a written document that sets out a procedure for the maintenance and review of the PCP, and implement that procedure. Every person who prepares a food that is to be exported, every person who exports a food, and every person who grows or harvests fresh fruits and vegetables that is to be exported must prepare, keep, maintain and implement a PCP as described above if they request an export certificate.
Compliance Rationale	Records provide an accurate history of the food and its manufacturing process. Records provide a means to track and review deviations, identify the root cause of an issue, help improve a process, and identify trends indicating that a process is moving toward deviation. Records provide a means to demonstrate compliance to the Act and Regulations. For example, records: • Confirm that sanitation is being performed as prescribed in the PCP, is effective and the pest control program is properly implemented. • Confirm the building is being maintained to prevent contamination using appropriate materials. • Confirm that equipment is being maintained and calibrated as per the written maintenance and calibration program. • Confirm that the food has been manufactured in a manner to meet regulatory requirements. • Provide data for on-going oversight and trend analysis throughout a production process and not only when deviations occur. • May identify where competencies require development and assist in the development of those competencies. • Facilitate internal verification and verifications by the CFIA or other competent authorities • Of complaints and their handling are important for trend analysis/tracking. • Provide evidence of reported illnesses and, as required, medical assessment or medical related exclusions from certain areas in the establishment.
Assessment Criteria	Establishing record keeping procedures (documentation) The PCP outlines all records associated with each element of the plan and where and how long they will be retained,

	including: • validation of critical limits/criteria • monitoring • deviations and corrective actions • verification • reassessment and management review Records (written or electronic) are kept as follows: • 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. Electronic signatures are acceptable provided security controls are in place to manage accessibility by authorized persons. • critical processing records are signed/verified by a competent designated individual 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 available at the facility and are made available to the CFIA upon request. All records associated with the preventive control plan shall be prepared, kept, maintained and provided, in English or French, and be available in Canada for a period of three years.

Part 4: Preventive Control	
Requirements for a written Preventive Control Plan (PCP)	
4. PCP 1.8	**Other Regulatory Requirements, Controls and Records**
Legal Authorities	*Safe Food for Canadians Regulations* **<u>Note</u>: The following is <u>not</u> based on preliminary regulatory text. The regulatory wording is under development and reflects CFIA's current suggested policy direction based on general concepts. The Compliance Rationale and Assessment Criteria are accordingly intended only as an example of the type of guidance that may be provided in respect of requirements relating to a Preventive Control Plan.** A Preventive Control Plan (PCP) means in respect of a food or the manufacturing, preparing, storing, packaging, labelling, growing, harvesting and importing of a food, a written preventive control plan that effectively: • Identifies for other specified requirements, the measures that will be taken to achieve compliance with the Act and Regulations.
Compliance Rationale	In addition to food safety requirements, the PCP identifies control measures which are in place to achieve compliance to non-food safety regulatory requirements such as composition, labelling and net quantity. The goal is to ensure that the label is not deceptive and does not create an erroneous impression and that the food meets all non-food safety regulatory requirements.
Assessment Criteria	In addition to food safety controls the PCP includes procedures to ensure that the information on the label and advertisements of all food is complete, truthful, not misleading and accurately represents the composition of the food and the content of the package. The PCP : 1) Identifies all non-food safety regulatory requirements for the food, including but not limited to: • composition of the food • net quantity, • quality / grade, • general labeling requirements • nutrition labeling • label declarations e.g., claims etc.