Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Food Safety Enhancement Program Manual

Canada

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Glossary of Terms

Acceptable level of a food safety hazard – The level at which the finished product will not cause harm to the consumer when it is prepared and/or consumed according to its intended use.

Codex Alimentarius Commission – A subsidiary body of the Food and Agriculture Organization and the World Health Organization of the United Nations.

Control measures – Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Control Point (CCP) – A point or a step at which a control measure can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level.

Critical limit – A criterion that separates acceptability from unacceptability.

Deviation – A failure to meet required critical limits for a critical control point, or a failure to meet a standard identified in a prerequisite program or a process control.

Deviation procedure – A documented set of corrective actions that are implemented when a deviation occurs.

Establishment – A CFIA-registered company, plant or manufacturer that processes agri-food products (meat and poultry, dairy, processed fruits and vegetables, shell eggs, processed eggs, honey, and maple). Hatcheries are considered establishments.

Finished product – Product that will undergo no further processing or transformation by the establishment.
Note: A product that undergoes further processing or transformation by another establishment is a finished product, in the context of the first establishment and a raw material or an ingredient in the context of the second establishment.

Food Safety Enhancement Program (FSEP) – A CFIA program that specifies the minimum requirements for an effective food safety management system based on HACCP principles and encourages its development, implementation and maintenance in all federally registered establishments, excluding federally registered fish establishments.

Food safety – is a concept that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food safety recall – A food recall is an action by a manufacturer, to remove unsafe food products from the market to help protect the public.

Hazard Analysis Critical Control Point (HACCP) – A systematic approach to identifying and assessing hazards and risks associated with a food operation and defining the means of their control.

HACCP plan – A written document designed in order to control hazards associated with specific processes and/or products within an establishment.

HACCP system – A system that includes prerequisite programs, one or more HACCP plan(s), maintenance and reassessment procedures as defined by the Food Safety Enhancement Program (FSEP).

Hazard – An entity, a condition or a circumstance that has the potential to cause harm. Hazards can be biological, chemical or physical.

Incompatible operations – In respect of activities taking place in a food establishment – activities that cannot take place at the same time in the same area because it creates a potential risk of food products being contaminated.

Monitoring – The act, by company personnel of conducting a planned sequence of observations, tests or measurements to assess whether a CCP, a process control and/or a prerequisite program is under control. This includes recording the results of those observations.

Prerequisite Program (PP) – Steps or procedures that control the operational conditions within a food establishment and promote environmental conditions that are favourable for the production of safe food.

Preventative measure – A corrective action resulting from an investigation to determine the root cause of a deviation. A preventative measure includes subsequent steps required to prevent reoccurrence of the deviation.

Process Control (PC) - Where more than one step in an overall process may contribute to the reduction of a particular hazard, process controls are developed for the early steps of the process where the hazard cannot be fully controlled, but a subsequent step will result in the elimination or reduction of this particular hazard to an acceptable level. This final step would be determined to be a CCP.

Regulatory requirements – All pertinent acts, regulations and directives.

Responsible inspector – A CFIA-designated inspector who is responsible for inspecting a federally registered establishment.

Risk – An estimate of the likely occurrence of a hazard and the severity of possible adverse health effect.

Senior management – Management at the establishment with authority to ensure adherence to responsibilities outlined in section 2.2.1 of the FSEP Manual.

Standard – Criteria or specifications that can be judged or evaluated and that define the limit of acceptability associated with prerequisite programs and process controls.

Validation – Obtaining evidence that a control measure, if properly implemented, is capable of controlling the hazard to a specified outcome.

Verification – A company's use of methods, procedures, tests and other evaluations, in addition to monitoring, to determine its conformance to and the effectiveness of its HACCP system.

Section 1 – Food Safety Enhancement Program Description

1.1 Introduction

The objective of the Food Safety Enhancement Program (FSEP) of the Canadian Food Inspection Agency (CFIA) is to specify minimum requirements for an effective food safety management system. FSEP provides a mechanism for operators of establishments to demonstrate their ability to control food safety hazards in order to ensure that food is safe for the consumer. In addition, it enhances the establishment's ability to achieve and maintain compliance with the relevant regulatory requirements.

FSEP is based on the principles of the Hazard Analysis and Critical Control Point (HACCP) system developed by the Codex Alimentarius Commission. HACCP is an internationally recognized, science-based food safety system, designed to prevent, reduce or eliminate potential biological, chemical and physical food safety hazards.

A HACCP system is the responsibility of the establishment (see section 2). The food manufacturer has the most control over the product and thus can have the greatest impact on the safety of the food produced.

FSEP specifies the requirements for an effective HACCP system that combines the following key elements to ensure the production of safe food:

- Prerequisite programs (see 3.1)
- HACCP plans (may include process controls, linked to a critical control point, if applicable) (see 3.2)
- Validation of critical control points (see 3.3)
- Maintenance and reassessment procedures (see 3.4)

FSEP outlines the process for HACCP recognition by the CFIA (see section 4). The recognition process applies to the following federally registered commodity groups: dairy, processed fruits and vegetables, shell eggs, processed eggs, honey, maple, and hatcheries. For establishments registered under the Meat Inspection Regulations in which a HACCP system in accordance with the FSEP Manual requirements is mandatory, please refer to the Meat Hygiene Manual of Procedures – Chapter 2 (Guidelines for the Applicant/Operator to the Registration of an Establishment and Licensing of an Operator).

FSEP details the changes to a recognized HACCP system that must be communicated to the CFIA (see section 5).

And finally, FSEP provides the necessary information for industry about the CFIA verification of FSEP voluntarily recognized establishments (see section 6). For establishments registered under the Meat Inspection Regulations, please refer to the Meat Hygiene Manual of Procedures – Chapter 18 (Compliance Verification System).

FSEP is consistent with the CFIA's Quality Management Program (QMP) for fish and seafood products and with HACCP initiatives being developed by provincial governments.

1.2 Types of food safety hazards controlled by a HACCP system

For the purposes of HACCP, hazards refer to agents in or conditions of food that can cause illness, injury or death of a person. These hazards fall into three categories: biological, chemical and physical.

Biological Hazards (B)
Biological hazards are those caused by micro-organisms (bacteria, virus, parasites and moulds) and are often associated with the failure of a process step. (E.g., Pathogen survival due to improper time/temperature applications during pasteurization)

Chemical Hazards (C)
Chemical hazards include those caused by substances/molecules that:

- Are naturally derived from plants or animals (e.g., poisonous mushrooms);
- Are intentionally added to the food during growth or during food processing. These substances are considered safe at established levels but are dangerous above these levels (e.g., sodium nitrite, pesticides);
- Contaminate the food accidentally (e.g., cleaning chemicals);
- Cause some individuals to experience an immune system response (food allergens).

Physical hazards (P)
Physical hazards include substances not normally found in food that can cause physical injury to the person consuming the food (e.g., wood slivers, glass fragments, metal shavings, bone pieces).

1.3 Benefits of HACCP

Although the adoption of HACCP systems worldwide is due primarily to the added food safety protection provided to consumers, there are other benefits to the food industry that can be realized by implementing a successful HACCP system.

a. Formally incorporates food safety principles as integral steps of production processes
HACCP recognition status cannot be completed without a firm commitment by senior management to formally support food safety control measures throughout the production process. The implementation and maintenance of those control measures play a critical role in raising awareness of front line production management and staff of the presence and importance of specific food safety procedures within their process.

b. Increased employees' ownership of the production of safe food
As a sign of this commitment, it is the responsibility of senior management to foster the idea within the facility that food safety is the responsibility of everyone. Through the process of developing and implementing a HACCP system, employees become more aware of food safety and their role in contributing to food safety. This increased knowledge leads to ownership of and pride in the production of a safe food product.

c. Increased buyer and consumer confidence
Establishments that have implemented a HACCP system provide buyers and consumers with a greater degree of confidence that the facility is producing a safe food product.

Establishments can demonstrate by showing documents and records that food safety is under control.

d. Maintaining or increasing market access
Market forces continue to drive HACCP implementation throughout the food industry. In many cases, buyer demands and foreign governments require HACCP implementation to maintain market share and/or gain access to previously inaccessible markets. As HACCP systems are accepted worldwide, FSEP helps the Canadian industry to maintain and expand its international markets.

e. Reduced waste
The preventative nature of HACCP allows a company to control costs by minimizing the amount of product requiring rejection or recall, and by focusing resources on areas that have been identified as critical in the manufacture of a safe food product. With the regular monitoring inherent in a HACCP system, establishments become aware of problems earlier and the costs of waste are reduced.

Section 2 – Responsibilities

2.1 CFIA responsibilities

Under FSEP, the responsibilities of CFIA are to:

- Recognize federally registered establishments' HACCP systems.
- Verify the implementation, effectiveness and maintenance of the HACCP system in federally registered establishments.
- Verify compliance to regulations, policies and directives in federally registered establishments.
- Provide competent staff for the recognition and verification of establishments' HACCP system.
- Ensure consistency of the recognition processes and consistency of the verification of compliance in all federally registered establishments.
- Provide the resources to enable the timely recognition of HACCP systems.
- Consider any copies of the establishment HACCP system documentation that are obtained by an inspector on grounds that they contain information relevant to the administration or enforcement of applicable Acts and Regulations as Agency original records with mandatory confidentiality and maintenance requirements as stated under the Library and Archives of Canada Act.

2.2 Establishment responsibilities

2.2.1 Establishment senior management commitment

Under FSEP, the responsibilities of the establishment's senior management are to:

- Ensure that the establishment complies with all regulatory and CFIA program requirements.
- Ensure that the establishment's HACCP system complies with all requirements of the FSEP manual.
- Ensure that food safety is fully embedded in every level of their business.
- Demonstrate a commitment to their HACCP system by:
    - Providing the necessary resources and the time required for the development, implementation and effective maintenance of the HACCP system and for the training of appropriate staff in their area(s) 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 and program requirements and support the implementation and effectiveness of the HACCP system;
    - Designating personnel that have 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 HACCP system, including any regulatory and CFIA program requirements related to food safety, and the importance of reporting problems to the identified person(s);

  - Allowing designated management personnel to enforce compliance of the food safety procedures identified in the establishment's HACCP system for any person entering or working within the facility;
  - Allowing the continuous improvement of the HACCP system to ensure its effectiveness through the validation of control measures, by making changes to the system as a result of corrective actions or reassessment activities, and through the use of HACCP team meetings;
  - Providing sufficient time for HACCP team meetings.
- Ensure all information and documentation is accessible to the CFIA staff during recognition processes and subsequent verification activities.

A letter of commitment shall be included in the HACCP System documentation. The letter of commitment shall be signed and dated by a representative of senior management at the establishment with authority to ensure adherence to responsibilities described in this section. The letter shall be signed on an annual basis and when that senior manager is replaced. The letter must:

- Confirm senior management's full support for developing, implementing and maintaining an effective HACCP system;
- Confirm the establishment's commitment to produce food in compliance with all regulatory and CFIA program requirements.

2.2.2 HACCP team leader

Senior Management shall appoint a HACCP team leader who, irrespective of other responsibilities, shall have the responsibility and authority:

- To ensure that the HACCP system is developed, implemented, maintained and reassessed;
- To be the main HACCP related contact with CFIA staff.

Note: It is recommended that the HACCP team leader be on the premises on a regular basis. Where the HACCP team leader is not at the establishment on a regular basis, an on-site liaison person must be identified to take on these responsibilities and authorities.

2.2.3 HACCP team

The HACCP team consists of assigned personnel that have adequate knowledge and or experience. Representing various areas within an establishment such as production, sanitation, quality control, food microbiology and equipment maintenance, they are responsible for assisting the HACCP team leader in developing, implementing and maintaining the HACCP system.

The number of people on the HACCP team may vary based on the complexity of the process and the number of employees at the establishment. In small plants with a limited number of staff, the HACCP team may be made up of a few people that have a good understanding of the facility and its products, as well as HACCP.

The HACCP team should meet on a regular basis to discuss, among other points:

- Changes in the HACCP System
- Deficiencies in the HACCP System
- Root causes

- Action plans
- CFIA concerns

It is recommended that representatives from senior management participate periodically in HACCP team meetings to be aware of the HACCP system performance within their facility.

2.2.4 Competency

The HACCP team leader should, at a minimum, be knowledgeable of:

- Food safety hazards common to the establishment's products and processes
- Applicable regulatory and CFIA program requirements
- FSEP requirements
- HACCP principles

The HACCP team should be knowledgeable of:

- The HACCP principles
- The technology or equipment used on processing lines
- The equipment preventative maintenance
- The practical aspects of food operations
- The flow of processes
- The sanitation techniques
- The applied aspects of food safety hazards as they relate to the process

Designated employees involved in the delivery of procedures developed in response to the requirements of the prerequisite programs, CCPs, process controls and reassessment activities must, at a minimum, be knowledgeable of their roles and responsibilities within the HACCP system.

It is important to note that the ultimate responsibility for a food safety system resides with the establishment operator and their employees. They cannot rely solely on the expertise of external consultants.

2.2.5 HACCP system performance reporting

A documented procedure shall be established which defines how the HACCP system performance is communicated to the senior manager who has signed the letter of commitment (see 2.2.1).

The procedure shall include as a minimum:

- The name or title of personnel responsible to communicate the HACCP system performance and CFIA verification results;
- The frequency of communication;
- The method used to communicate the information;
- The method used to demonstrate to the CFIA that the communication took place.

The main objectives of the communication process are to:

- Make establishment senior management aware of the overall HACCP system performance within their facility;

- Convey the information required for senior management to provide support and supply resources to the HACCP team to ensure issues are corrected.

2.2.6 Signing and dating the HACCP system documentation

The first page of the prerequisite programs, HACCP plan(s) and process control(s) shall be signed and dated by the HACCP team leader or senior management representative:

- Upon initial implementation;
- Upon any modification;
- At least annually, upon reassessment.

All pages of the prerequisite programs, HACCP plan(s), process control(s) and supporting documentation linked to the HACCP system (standard operating procedures, work instructions, etc) shall be dated:

- Upon initial implementation;
- Upon any modification.

The signature shall signify that the prerequisite programs, HACCP plan(s), process control(s) and supporting documentation have been approved by the HACCP team leader or senior management representative and will be implemented as specified.

The establishment's HACCP team leader or senior management representative may utilize a stamp in lieu of their signature. The stamp must have their actual signature and may also incorporate the date. Procedures must be in place to ensure control over access and use of the stamp(s).

2.2.7 Control of records

Records shall be maintained to provide evidence of conformity to requirements and evidence of the effective operation of the HACCP system.

Records maintained on computers are acceptable provided the establishment implements appropriate controls to ensure the integrity of the electronic data. Access to the electronic data bank and the electronic signature must be secure.

Unless otherwise specified in CFIA program requirements, records shall be retained for at least one year or for the shelf life of the product, whichever is greater.

Section 3 – HACCP System Documentation

The HACCP system documentation shall include:

- Prerequisite programs (see 3.1);
- HACCP plans (see 3.2);
- Validation documentation for critical control points (see 3.3);
- HACCP system maintenance and reassessment procedures (see 3.4).

3.1 Prerequisite programs

Prior to developing HACCP plans, the establishment shall develop and implement prerequisite programs to assist in controlling the likelihood of introducing food safety hazards to the product through the work environment and operational practices.

The prerequisite programs shall be documented, updated whenever there are changes associated with the prerequisite programs and reassessed at least annually.

The prerequisite program requirements outlined in this manual are generic in nature. Establishments must ensure that their prerequisite programs reflect the current work environment and operational practices within their establishment and comply with specific commodity policies, manuals, procedures and associated regulations.

An establishment may develop their prerequisite programs using a structure other than the one described in this section as long as the prerequisite program requirements are covered as well as the monitoring, deviation and record keeping components.

There are seven (7) prerequisite programs:

- A Premises
- B Transportation, Purchasing/Receiving/Shipping and Storage
- C Equipment
- D Personnel
- E Sanitation and Pest Control
- F Recall
- G Allergen Control

Each prerequisite program is divided into Elements, Sub-elements and Bullets which include the requirements.

A	Program (e.g., Premises)
A.2	Element (e.g., Building)
A .2.2	Sub-element (e.g., Lighting)
A. 2.2.1	Bullet (Lighting is appropriate such that food colour is not altered and the intended production or inspection activity can be effectively conducted.)

Each establishment must create a documented program that responds to each prerequisite program bullet requirement (see 3.1.1). The documented program shall include:

- Specific programs, procedures or policies as per prerequisite program bullet requirements;
- Monitoring procedure (see 3.1.2);
- Deviation procedure (see 3.1.3).

The record keeping shall meet the requirements defined in 3.1.4.

The establishment may have to develop more programs, standard operating procedures or tasks to meet applicable regulatory requirements and/or to facilitate the control of the prerequisite program requirements in their establishment. Any additional food safety related programs, procedures or tasks shall be referenced within the respective bullet.

NOTE: The individuals responsible for specific control measures within a prerequisite program, monitoring and deviation procedures may be identified by a position title or the term "designate". In this case, the establishment must be able to demonstrate that individuals have received adequate training.

3.1.1 Prerequisite programs requirements

The seven prerequisite programs include the following elements and sub-elements:

(A) Premises (see 3.1.1.1)

- A.1 Outside Property
  - A.1.1 Outside Property
- A.2 Building
  - A.2.1 Building Design, Construction and Maintenance
  - A.2.2 Lighting
  - A.2.3 Ventilation
  - A.2.4 Waste and Inedible/Food Waste Disposal
- A.3 Sanitary Facilities
  - A.3.1 Employees Facilities
  - A.3.2 Hand Washing Stations and Sanitizing Installations
- A.4 Water/Steam/Ice Quality, Protection and Supply
  - A.4.1 Water/Steam/Ice Quality, Protection and Supply

(B)Transportation, Purchasing/Receiving/Shipping and Storage (see 3.1.1.2)

- B.1 Transportation
  - B.1.1 Food Carriers
- B.2 Purchasing/Receiving/Shipping and Storage
  - B.2.1 Purchasing/Receiving/Shipping
  - B.2.2 Storage

(C) Equipment (see 3.1.1.3)

- C.1 Equipment General
  - C.1.1 Design & Installation
  - C.1.2 Equipment Maintenance and Calibration

(D) Personnel (see 3.1.1.4)

- D.1 Training
  - D.1.1 General Food Hygiene Training Program

    - D.1.2 Technical Training Program
- D.2 General Food Hygiene Program
    - D.2.1 General Food Hygiene Program

(E) Sanitation and Pest Control (see 3.1.1.5)

- E.1 Sanitation
    - E.1.1 Sanitation Program
- E.2 Pest Control
    - E.2.1 Pest Control Program

(F) Recall (see 3.1.1.6)

- F.1 Recall System
    - F.1.1 Recall Plan
    - F.1.2 Product coding and labelling

(G) Allergen Control (see 3.1.1.7)

- G.1 Allergen Control Program
    - G.1.1 Allergen Control Program

Each prerequisite program sub-element is organized under the following headings:

- The requirements
- Rationale – The rationale explains why the requirement exists

As the FSEP Manual applies to all food commodity groups, there will inevitably be situations where some of the specific requirements are not applicable. The requirements indicate where such questions are likely to arise by using the phrases “where necessary”, “where appropriate” or “where applicable”. In deciding whether a requirement is necessary or appropriate, an assessment of the risk and the regulatory requirements must be made and the result of the assessment must be recorded.

3.1.1.1 (A) Premises

A.1 Outside Property

A.1.1 Outside Property

Requirements

A.1.1.1
Building facility is located away from or protected against potential sources of external contaminants that may compromise the safety of food.

The surrounding/roadways are free of debris and refuse, adequately drained and maintained to minimize environmental hazards.

Rationale

- Outside sources of contamination (e.g., excessive dust, pest infestation, airborne microbial and chemical contaminants) can lead to source of exterior contamination that can enter an establishment.

A.2 Building

A.2.1 Building Design, Construction and Maintenance

Requirements

A.2.1.1
The building is designed and constructed:

- To meet regulatory and CFIA program requirements;
- So its access is secure;
- So the roof, air intakes, foundation, walls, doors and windows prevent leakage and entry of contaminants and pests;
- To effectively separate incompatible operations;*
- To provide hygienic operations by means of a regulated flow from point of entry to the premises to the final product;*
- To effectively prevent cross-contamination due to employee traffic pattern, food product flow and equipment;*
- So living quarters and areas where animals are kept are separated from and do not open directly into food processing or packaging areas;
- So incoming materials (food, non-food, packaging) are received in an area separate from food processing areas;
- So washrooms, lunchrooms and change rooms are separated from and do not open directly into food processing areas;
- So separate and adequate facilities are provided for:
    - The storage of waste and inedible products,*
    - The cleaning and sanitizing of waste/inedible equipment,*
    - The cleaning of equipment;*
- To prevent cross-connection between:
    - the effluent of human wastes and production drainage wastes in the establishments,
    - potable water lines and non-potable water supply systems;
        - Non-potable re-circulated/reused/recycled water has a separate distribution system which is readily identifiable in the facility
- So the sewage and the waste effluent system do not pass directly over or through production unless they are controlled to prevent contamination;
- So drainage and sewage systems are equipped with functional traps and vents;
- So floors permit liquids to drain to trapped outlets;
- So floors, walls, doors, windows, ceilings, overheads and other structures in rooms or areas where food is manufactured, stored, packaged, received or shipped are cleanable, prevent contamination, prohibit deterioration, are suitable for the activities in each area and are free of any noxious constituents.**

** If the building is not designed to effectively separate incompatible operations and/or to prevent cross-contamination, operational procedures to control cross-contamination must be defined in the General Food Hygiene Program D.2.1.1. and/or the Sanitation Program E.1.1.1.*
***Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products can be found at:*
http://www.inspection.gc.ca/english/fssa/reference/refere.shtml
***See B.2.1.1 for purchasing control of construction material*

A.2.1.2
The building is maintained so:

- The roof, air intakes, foundation, walls, doors and windows prevent leakage and entry of contaminants and pests;
- The drainage and sewage systems prevent backflow and pooling liquids on floors;
- Floors, walls, ceilings, overheads, doors, windows, stairs, elevators and other structures exhibit no evidence of degradation that would cause contamination and are cleanable.

Rationale

- Screens on windows, doors that are tight, a roof that does not leak and air intakes located away from potential contaminants are examples of good establishment conditions which will minimize the potential for hazards such as rodents, pests, insects, non-potable water and the like entering the establishment and compromising activities.
- Operational flows such as employee entry to the establishment and flow to work rooms, ingredient/product flows and/or adequate separation or control between incompatible operations will prevent microbiological, chemical or physical contamination of the product.
- The absence of cross-connections between the sewage system and other waste systems will facilitate sanitary operations, ensure segregation of waste and prevent potential for contamination.
- Adequate drainage and/or an adequate waste disposal system will prevent cross-contamination of food, ingredients, packaging material, food contact surfaces or the potable water supply (e.g., drain back-ups leading to flooding).
- The presence of mechanisms to prevent backflow (e.g., trapping, venting) will prevent sewer gases, pests, microorganisms or other contaminants from entering the establishment through the plumbing system.
- Floors that are designed to permit liquids to drain to trapped outlets will prevent water pooling or stagnant water on floors during operation.
- Some materials have the potential to cause biological, chemical or physical hazards. These materials should not be used in the construction of the establishment's internal fittings where food products are manufactured.
- Structures and materials that can be effectively cleaned will minimize the development of unsanitary conditions (e.g., presence of bacteria, mould).
- Materials that are durable or suitable for the environment or activities in the area will minimize unsuitable conditions (e.g., flaking or peeling rust or paint or loose materials).
- Ceilings and overhead structures that are well designed will minimize the build-up of dirt, condensation and the shedding of particles.
- Windows that are sealed or equipped with close-fitting screens and doors that are tight fitting will prevent entry of contaminants and pests.
- Windows constructed of, or protected with, unbreakable materials will prevent foreign material contamination of food, ingredients, packaging materials and food contact surfaces.

A.2.2 Lighting

Requirements

A.2.2.1
Lighting is appropriate such that food colour is not altered and the intended production or inspection activity can be effectively conducted.

A.2.2.2
Light bulbs and fixtures located in areas where there is exposed food or packaging materials are of a safety type or are protected to prevent contamination of food in case of breakage.

Rationale

- If lighting levels are inadequate for the inspection of food or if the light source alters or changes the natural colour of food, an incorrect assessment of the food may result.
- If lighting levels are inadequate to perform the required tasks (including but not limited to inspection to determine product disposition, inspections during processing, inspections post-sanitation to ensure cleanliness and/or inspections in storage areas, as well as lighting levels that are adequate for the maintenance of equipment), this may prevent an employee from identifying the potential for or presence of biological, chemical or physical contamination.
- If a light bulb or lighting fixture breaks over exposed food, ingredients, packaging materials or food contact surfaces, then a physical foreign material hazard can occur.

A.2.3 Ventilation

Requirements

A.2.3.1
Ventilation provides sufficient air exchanges to prevent unacceptable accumulations of steam, condensation or dust and to remove contaminated air.
Filters are cleaned or replaced as appropriate.

A.2.3.2
Ventilation systems ensure that air flows from the least contaminated areas to the most contaminated areas.

A.2.3.3
Where required, ambient air, compressed air or gases utilized in processing equipment that contact product or packaging are appropriately sourced and treated to minimize contamination of product and packaging.

Rationale

- Adequate ventilation minimizes airborne contamination of food (e.g., from aerosols or condensation droplets).

- The flow of contaminated air through an establishment can be a source of bacterial contaminants for microbiologically sensitive food processing areas (e.g., Ready-to-Eat processing rooms and aseptic rooms).
- The correct location of air intakes, the correct size of filters, filter cleanliness and the use of food grade gases all contribute to the prevention of airborne contamination.

A.2.4 Waste and Inedible/Food Waste Disposal

Waste is defined as unwanted materials left over from the manufacturing processes. This includes but is not limited to garbage, discarded packaging, broken pallets, discarded construction materials etc.

Inedible product or food waste is defined as any food product that is not considered suitable for human consumption as defined in applicable legislation.

Requirements

A.2.4.1
The establishment has and implements documented procedures to control the hazards associated with waste and inedible/food waste products. The procedures shall include but are not limited to:

- An identification system for utensils and containers used for collection and holding of waste and inedible/food waste materials;
- The frequency of removal of waste during operations;
- If applicable, the frequency of removal of inedible/food waste products during operations;
- If applicable, procedures for storage of waste and inedible/food waste products;
- If applicable (see regulatory requirement for the commodity), a denaturing protocol, including methods and chemical(s) used for denaturing;
- The frequency of removal of waste from the establishment;
- If applicable, the frequency of removal of inedible/food waste product from the establishment;
- Procedures for maintenance of waste/inedible/food waste equipment (Equipment must be leak proof and where appropriate, covered).

Rationale

- Clearly identified containers and utensils used for waste and inedible materials will prevent container or utensils misuse and cross-contamination of edible products

- Effective procedures will prevent the accumulation of waste, inedible or food waste products and the potential contamination of food handling areas, and will minimize the attraction of pests and prevent objectionable odours.

A.3 Sanitary Facilities

A.3.1 Employees Facilities

Requirements

A.3.1.1
Washrooms have hot and cold or warm potable running water, soap dispensers, soap, sanitary hand drying equipment or supplies and cleanable waste receptacles.
Hand washing notices are posted in appropriate areas.

A.3.1.2
As required, washrooms, lunchrooms and change rooms are provided with adequate floor drainage and ventilation. They are maintained in a manner to prevent contamination.

Rationale

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- Adequate washroom, change room and lunchroom facilities will ensure that an appropriate degree of personal hygiene is maintained to protect the safety of food.
- Providing an acceptable area for employees to change into work clothes will prevent exterior contaminants from entering the processing areas.
- Providing adequate lunch room facilities will discourage employees from eating and drinking in production areas which can lead to contamination of product.

A.3.2 Hand-washing Stations and Sanitizing Installations

Requirements

A.3.2.1
Where required or appropriate, areas of the establishment are provided with an adequate number of conveniently located hands free hand-washing stations with trapped waste pipes to drains.

Hand-washing stations are properly maintained and are provided with hot and cold or warm potable running water, soap dispensers, soap, sanitary hand drying equipment or supplies and cleanable waste receptacles.
Hand-washing notices are posted in appropriate areas.

A.3.2.2
Where required/appropriate, areas of the establishment are provided with sanitizing installations, such as:

- Sanitizing installations for hands
- Sanitizing installations for boots
- Sanitizer for operational equipment

Sanitizing installations are properly maintained and are provided with potable water at temperatures and, where applicable, chemical concentrations appropriate for their intended use.

Rationale

- Personnel are a major source of contaminant.
- If there are enough hand-washing stations and they are located in areas that are easy to access, personnel are more likely to wash their hands.
- Sanitizing stations are used to control the potential for cross-contamination from operational equipment and employees.
- Hand-washing stations and sanitizing installation can become a source of contaminants if they are not properly maintained.

A.4 Water/Ice/Steam Quality, Protection and Supply

A.4.1 Water/Ice/Steam Quality, Protection and Supply

Requirements

A.4.1.1
The establishment has and implements documented water safety procedures to ensure that water and ice meet the potability requirements of the appropriate regulatory authority.

The water safety procedures shall include but are not limited to:

- Name or title of personnel responsible for the implementation of the water safety procedures;
- Identification of the source of water supply (municipality, private well(s), storage tank(s), etc);
- Water sampling and testing schedule(s);
- Identification of the sampling site(s);
- Water and ice sampling procedures;
- Description of testing activities to be performed;
- Water potability criteria;
- Documentation requirements (records should include the water source(s), sampling site(s), analytical results, analyst and date of sample(s);
- Deviation procedures when water testing results indicate water potability criteria have not been met;
- Deviation procedures to be applied at the establishment in instances where the municipality identifies a failure with the water system;
- Record(s) to be kept.

A.4.1.2
Where applicable, the establishment has and implements documented water treatment procedures to ensure that:

- Boiler feed water treatment or any chemically treated water (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;
- Water mixed with chemical and applied on product to reduce the microbial load meets the acceptable chemical concentration for the intended purpose;
- Re-circulated water for reuse meets the appropriate regulatory requirement.

The water treatment procedures shall include but are not limited to:

- Name or title of personnel responsible for the implementation of the water treatment procedures;
- Identification of water treatment activities to be performed;
- Water treatment method/frequency;
- Chemicals used;
- Proper handling and application of water treatment chemicals;
- Acceptable chemical concentrations;
- If applicable, description of any automatic warning control;
- Testing procedure, including testing frequency, to ensure proper concentration is consistently met;
- Documentation requirements (records should include method of treatment, sample site, analytical result, analyst and date);
- Deviation procedure when the criteria have not been met;
- Record(s) to be kept.

A.4.1.3
Where required, hoses, taps or other similar sources of possible contamination are designed to prevent back-flow or back siphonage.

A.4.1.4
Where filters are used they are kept effective and maintained in a sanitary manner.

A.4.1.5
The volume, temperature and pressure of the potable water/steam are adequate for all operational and cleanup demands.

A.4.1.6
Where it is necessary to store water or ice, storage facilities are adequately designed, constructed, and maintained to prevent contamination.

Rationale

- Water, ice and steam can be a source of biological or chemical contaminants.
- Since water, ice and steam can be used for a variety of purposes (e.g., sanitation, hand washing, as an ingredient or processing aid), it is important to perform water sampling and testing to confirm potability.
- Collecting water samples from different outlet(s) for each test will ensure that the establishment's water distribution system functions properly and is not a potential source of water contamination.
- Treated water can be a source of contaminants if the chemical treatment or treatment process is incorrectly performed and/or monitored.
- An adequate supply of potable water with appropriate facilities for its storage and distribution will prevent contamination of water and ensure the safety of food.
- 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).

3.1.1.2 (B) Transportation, Purchasing/Receiving/Shipping and Storage

B.1 Transportation

B.1.1 Food Carriers

Requirements

B.1.1.1
Carriers used for transport of food:

- Are designed, constructed, maintained and cleaned to prevent contamination, damage and deterioration of the food product;
- Are equipped, where applicable, to maintain food products in a refrigerated or frozen state;
- Are not being used for the transport of any material or substance that might adulterate the food product.

B.1.1.2
Carriers are loaded, arranged and unloaded in a manner that:

- Prevents outside contaminants from entering the establishment;
- Prevents damage and contamination of the finished product, ingredients and incoming materials that come in contact with the product or are used in preparing the product.

Rationale

- Conveyance vehicles or containers that are not properly constructed, maintained or cleaned can lead to a number of hazards including:
    - Physical contaminants from dust and foreign material;
    - Chemical contaminants from unsuitable surfaces or trace chemicals from previous loads;
    - Microbiological contaminants from previous loads.
- Adequate temperature control during transportation will minimize microbial growth, toxin formation and spoilage of the food product.
- Transporting food products and loads of non-compatible materials in one vehicle or container can lead to contamination of the food product. A risk assessment should be performed to ensure food safety if this situation occurs.
- Carriers that are properly sealed to the building when loading or unloading will prevent outside contaminants/pests from entering the establishment.
- Proper handling of incoming and outgoing material will prevent damage and contamination of the food and materials.
- When loads are not properly handled, loaded and unloaded, contamination can occur from a variety of sources. For example:
    - Forklifts can puncture holes in product containers leading to the introduction of microorganisms or physical contaminants;
    - Incompatible products (e.g., non food chemical product versus food product) can cross-contaminate each other leading to the introduction of chemical contamination;
    - Temperature abuse from prolonged loading and unloading times can lead to the growth of micro organisms.

B.2 Purchasing/Receiving/Shipping and Storage

B.2.1 Purchasing/Receiving/Shipping

Requirements

B.2.1.1
The establishment has and implements documented purchasing procedures to ensure that:

- Ingredients are ordered from suppliers/sources approved by the establishment;
- The required information on ingredients is maintained on file (e.g., specifications, letters of guarantee, certificate of analysis);
- Construction materials, packaging materials and non-food chemical products are listed in CFIA's *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products**. Otherwise, the manufacturer has a letter of no objection from Health Canada.

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

Note: Some chemicals have received generic acceptance from Health Canada for specific applications within some commodities. Registered establishment management may contact the appropriate CFIA Program Specialists for further information on these chemicals.

B.2.1.2
Returned, defective or suspect product is clearly identified and isolated in a designated storage area, where it is assessed to determine the appropriate disposition.

B.2.1.3
Where applicable, receiving of live animals is controlled as per regulatory requirements.

Only approved ingredients and materials are received into the establishment.

Incoming ingredients are assessed at receiving, where possible, to ensure that the purchasing specifications have been met.*

**Where organoleptic inspections are not effective as a means of confirming material acceptability for these materials, certificate of analysis may be used as a means to verify the commitment made by the suppliers.*

B.2.1.4
All food safety specifications or requirements of the finished product have been met prior to shipping to retail/the customer. (e.g., temperature, certificate of analysis)

Finished product is adequately protected against intentional or unintentional contamination and deterioration prior to shipping.

Rationale

- Prevention of food, ingredient and packaging material contamination begins with control of incoming materials, including live animals.
- Inadequate incoming material controls can result in product contamination, inadequate processing or misrepresentation of the product.
- Packaging materials shall not impart any undesirable substance to the food product, either biologically, chemically or physically and shall protect the food product sufficiently to prevent contamination.
- Returned product left the control of the establishment and may have been subjected to improper handling causing contamination or deterioration of the product.
- Control of returned food products will prevent the contamination of other products.
- Controls prior to shipping will demonstrate that the finished product met all specifications prior to shipping.

B.2.2 Storage

Requirements

B.2.2.1
Temperatures of storage areas, processing areas, coolers and freezers meet regulated and/or acceptable temperatures.

B.2.2.2
Ingredients, finished products and packaging materials are handled and stored in a manner to prevent damage, deterioration and contamination.

Where applicable, ingredients and finished products are prepared in a manner to prevent time and temperature abuse associated with food safety or shelf life.

Where appropriate, rotation is controlled to prevent deterioration.

B.2.2.3
Non-food chemicals are received and stored in a dry, adequately ventilated area which is designed such that there is no possibility for cross-contamination of food, packaging materials or food contact surfaces.

When required for ongoing use in food handling areas, non-food chemicals are stored in a manner that prevents contamination of food, food contact surfaces or packaging material.

Non-food chemicals are mixed in clean, correctly labelled containers and dispensed and handled only by authorized and properly trained personnel.

Rationale

- Storing of foods in an appropriately controlled environment will prevent contamination and deterioration of foods.

- The protection of ingredients, food containers and packaging materials during storage will prevent contamination from micro organisms, chemicals and foreign material (e.g., dust, insects, wood chips).
- Ingredients and finished products that are not properly rotated can reach their expiry date increasing the risk for the consumer.
- If chemicals are stored securely and separately from food, ingredients, packaging materials and food contact surfaces, contamination like spillage, accidental use or leakage will be prevented.

3.1.1.3 (C) Equipment

C.1 Equipment General

C.1.1 Design & Installation

Requirements

C.1.1.1
Equipment is designed, constructed and installed to ensure that:

- It meets regulatory and CFIA program requirements;
- It is capable of delivering the requirements of the process and the sanitation program;
- It is accessible for cleaning, sanitizing, maintenance and inspection and is easily disassembled for those purposes;
- Contamination of the product and food contact surfaces is prevented during operations;
- It permits proper drainage and where appropriate, it is connected directly to drains;
- It is smooth, non corrosive, non absorbent, non toxic, free from pitting, cracks and crevices where there are food contact surfaces;
- It is, where necessary, exhausted to the outside to prevent condensation.

Utensils are constructed of non-toxic materials, do not present a foreign material hazard that could contaminate the food, and are easy to clean and sanitize.

Rationale

- Well constructed and maintained equipment will minimize the potential for biological, chemical and physical hazards.
- Pits, cracks and crevices can provide areas for residues to accumulate and micro organisms to grow.
- Food residues that accumulate can contain allergenic components or micro organisms that can cause cross-contamination.
- Poor installation can result in parts or areas that cannot be properly cleaned, sanitized and inspected.
- Equipment that cannot be adequately inspected can result in hazards not being detected.
- Equipment food contact surfaces that are not suitable for the activities being performed can impart hazards to the products.

- Equipment used for cleaning and sanitizing that is capable of delivering the requirements of the sanitation program will facilitate a sanitary environment. (e.g., temperature indicators, racks, reels, hoses, CIP system).

C.1.2 Equipment Maintenance and Calibration

Requirements

C.1.2.1
The establishment has and implements a documented Preventative Equipment Maintenance Program which includes but is not limited to:

- A list of equipment that may impact on food safety requiring regular maintenance;
- A preventative maintenance schedule or frequency of preventative maintenance activities;
- The maintenance procedures to perform for each preventative maintenance task;
- Records to be kept to demonstrate that the preventative maintenance tasks have been completed.

Note: The maintenance procedures are based on the equipment manufacturer's manual or equivalent, or are based on operating conditions that could affect the condition of the equipment.

C.1.2.2
The establishment has and implements a documented Equipment Calibration Program which includes but is not limited to:

- A list of equipment monitoring and controlling devices that may impact on food safety requiring regular calibration;
- A calibration schedule or frequency of calibration activities;
- The calibration procedures to perform for each calibration task;
- Records to be kept to demonstrate that the calibration tasks have been completed.

Rationale

- An effective maintenance program will ensure that equipment performs consistently as intended and prevents contamination of food, ingredients or packaging materials.
- Controlling devices must be accurate because they are used in critical processes which impact on food safety.

3.1.1.4 (D) Personnel

D.1 Training

D.1.1 General Food Hygiene Training

Requirements

D.1.1.1
The establishment has and implements a documented general food hygiene training

program which includes but is not limited to:

- The establishment's general food hygiene program (see D.2.1.1);
- A list of employee positions who must receive the training;
    - All food handling employees and other employees that may work in food handling areas (e.g., maintenance staff, quality assurance (QA) staff, supervisors, etc.)
- The frequency of training;
    - The training is delivered at the start of employment, whenever changes are made to the program and reinforced at appropriate intervals
- Records to be kept to prove completion of personnel training.

Rationale

- Establishment personnel play a major role in the production of safe food.
- Proper training reduces the risk of biological, chemical and physical contamination.
- Training increases awareness of potential hazards and the responsibilities that personnel have to minimize contamination risks.

D.1.2 Technical Training

Requirements

D.1.2.1
The establishment has and implements a documented Technical Training Program which includes but is not limited to:

- The prerequisite programs;
- The CCP(s), if applicable;
- The process control(s), if applicable;
- Any additional external technical training that is necessary to ensure current knowledge of equipment and process technology (e.g., licenses/certification required to operate equipment - HTST operator's certification / retort operator certification);
- A list of employee positions who must receive the training;
    - Designated employees involved in the delivery of procedures developed in response to the prerequisite programs requirements, CCPs, and process controls
- The frequency of training;
    - The training is delivered before the beginning of assignment and reinforced whenever changes are made and at appropriate intervals
- A method to confirm that the training has been effectively understood;
- Records to be kept to prove completion of personnel training.

Rationale

- Training is delivered to ensure that personnel understand and are competent in procedures which they are designated to perform.
- Proper training reduces the risk of biological, chemical and physical contamination of food.

D.2 General Food Hygiene Program

D.2.1 General Food Hygiene Program

Requirements

D.2.1.1
The establishment has and implements a documented General Food Hygiene Program which includes, but is not limited to:

- Good Manufacturing and Personnel Hygiene Practices:
    - Methods for hand washing/sanitizing;
    - Correct use of protective clothing, hair coverings, gloves, footwear;
    - Prohibited practices at the establishment;
    - Hygienic handling of food;
    - Correct use of utensils and equipment;
    - Storage of personal effects to prevent cross-contamination;
    - Where required, restricted access to areas of the facilities by specific employees to prevent cross-contamination;
    - When required, procedures to prevent contamination due to the process flow, employee flow, product flow, equipment or incompatible operations;
    - When required, procedures to prevent cross-contamination during production. For example:
        - Glass control and breakage procedures
        - Procedures to follow when:
            - Product falls on the floor,
            - Product is exposed to dripping condensation;
- Procedures for visitors and contractors during production including:
    - Restricted access,
    - Hygienic practices;
- Personnel Health Status:
    - The program must clearly state that personnel must advise management when known to be suffering from a disease likely to be transmitted through food;
    - No person is permitted to work in a food handling area when he or she is known to be suffering or a carrier of a disease likely to be transmitted through food;
    - Employees having open cuts or wounds should not handle food or food contact surfaces unless the injury is completely protected by a secure waterproof covering.

Rationale

- Establishment employees play a major role in the production of safe food
- Employees, visitors or contractors that do not follow the establishment's rules can cause contamination of food.
- Personnel suffering from disease through food (e.g., Salmonella, Hepatitis A) can contaminate the food being produced. The contaminated food products can transmit the disease to the consumer.
- Developing and enforcing a food hygiene program will reduce potential hazards and minimize contamination risks.

3.1.1.5 (E) Sanitation and Pest Control

E.1 Sanitation

E.1.1 Sanitation Program

Requirements

E.1.1.1
The establishment has and implements a documented Sanitation Program which includes but is not limited to:

- The sanitation schedule/frequency for all equipment, and for all rooms that, if not kept in a clean/sanitary condition, would have a negative effect on food safety within the establishment including livestock holding facilities, utensils, waste and inedible/food waste equipment and facilities, work gear etc that, if not kept in a clean/sanitary condition, would have a negative effect on food safety;
- Cleaning and sanitizing procedures including:
    - Details and specifics describing the method and procedures for equipment and room cleaning and sanitizing,
    - The chemicals required,
    - The chemical concentration level required,
    - Proper handling and application of chemicals (duration of application, etc)
    - The chemical solution temperatures, where applicable,
    - Equipment disassembly and assembly instructions,
    - Methods to prevent cross-contamination, where necessary;
- Housekeeping and sanitation procedures required during operations;
- Pre-operational inspection procedures;
- Environmental sampling procedures, if any;
- Corrective actions to be taken for non-compliant situations observed during pre-operational inspection activities and unsatisfactory environmental testing results;
- Records to be kept.

Rationale

- Improper or inadequate sanitation activities can lead to contamination of food, ingredients, packaging materials and food contact surfaces.
- The use of improper chemical concentrations and/or improper chemical application or rinsing procedures can lead to both chemical contamination (e.g., chemical residue due to poor rinsing, no-rinse chemicals in excess of approved concentration) and biological contamination (e.g., bacteria not effectively removed from food contact surfaces).
- Chemical contamination can also be caused by allergens that are not effectively removed from food contact surfaces.
- Chemical or biological contamination can be caused by cross-contamination from cleaning activities during operation.

E.2 Pest Control
E.2.1 Pest Control Program

Requirements

E.2.1.1
The establishment has and implements a documented Pest Control Program which includes but is not limited to:

- Where applicable, the name of the pest control company or the name of the person contracted for the pest control program;
- The name of the person at the establishment assigned responsibility for pest control;
- A schedule or frequency of pest control activities;
- Pest control procedures for the exterior and interior of the establishment including:
    - The pest control activities to be performed;
    - The chemicals required for the effective implementation of the pest control program;
    - The methods for proper handling and application of pest control chemicals;
    - The type and location of pest control devices;
    - Corrective actions to be taken for non-compliant situations observed during pest control activities,
    - Records to be kept.

Rationale

Pests (e.g., insects, rodents and birds) can contaminate food, ingredients, packaging materials and food contact surfaces. Pests in or around an establishment can lead to contamination from dropping, larvae and dead insects or animals.

3.1.1.6 (F) Recall

F.1 Recall System

F.1.1 Recall Plan

Note: For detailed information on developing a recall plan, please refer to the following CFIA Web site: www.inspection.gc.ca/english/fssa/recarapp/rap/mgguide.shtml

The CFIA representatives will use the information described on the CFIA Web site to assess completeness of the establishment written recall plan.

Requirements

F.1.1.1
The establishment has and implements a documented Recall Plan which includes but is not limited to:

- Names of employees on the Recall Management Team including position, contact phone numbers and responsibilities.

- Notification/Complaint File including:
    - Recording of the initial notification/complaint information;
    - Investigation of the notification/complaint and a record of the findings;
    - Action taken based on the investigation findings;
    - Record of action taken.
- Recall Contact List – CFIA Notification including:
    - Title of the CFIA contact;
    - Contact telephone number;
    - Contact fax number.
- Methods to trace product.
    - Maintain product identification throughout the process until final packaging, including:
        - Raw ingredient tracing;
        - Premixing of ingredients ahead of use;
        - Rework.
    - Coding system documentation.
- Method(s) to record the amount of each lot code of each product produced.
- Distribution records and distribution record system for each lot of product including:
    - Name of the account and address;
    - Type of account (e.g., manufacturer, distributor, retailer);
    - Product name and lot code;
    - 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);
    - Amount of product shipped to each account.
- Procedure(s) for developing, producing and maintaining recalled product records.
- Step by step recall procedures which will be followed during a recall, including:
    - Assemble the recall management team;
    - Notify the CFIA;
    - Identify all products to be recalled;
    - Detain and segregate all products to be recalled which are in the establishment's control;
    - Prepare the press release, if required;
    - Prepare the distribution list;
    - Prepare and distribute the notice of recall;
    - Verify the effectiveness of the recall;
    - Control the recalled product(s);
    - Disposition of the recalled product(s);
    - Identify and correct the cause of the recall if the problem occurred at the establishment.
- Methods to assess the effectiveness of the establishment's recall notification.
- Procedures for testing the recall plan (mock recall exercise).
- Records to be kept in case of recalls.

Rationale

- Food recalls can be triggered by a number of hazards within or external to a facility.

- Quickly re-gaining control of implicated lots of product is crucial in preventing the risk of hazard to consumers.

F.1.2 Product Coding and Labelling

Requirements

F.1.2.1
The establishment has and implements documented operational procedures to ensure that:

- Finished products are correctly and legibly coded;
- The finished product label information accurately represents the product name and the composition of the product on which the label is affixed.

The procedure to prevent incorrect labelling/coding shall include but is not limited to:

- The names or title of personnel responsible for particular task;
- Frequency of activity;
- Description of the task to be performed;
- Corrective actions to be taken when product is mislabelled or miscoded;
- Operational records to be kept.

Rationale

- Food product must be correctly labelled to enable the next person in the food chain to handle, display, store, and use the product safely.
- Incorrectly coded expiry dates can result in consumers storing the product past the intended shelf life, leading to potential food safety hazards.
- Incorrect labelling or coding can make product recall difficult or unfeasible if a hazard is associated with the mislabelled or miscoded product.

3.1.1.7 (G) Allergen Control

For hypersensitive individuals, certain foods and their derivatives can cause allergic reactions. Food allergy is an abnormal immune response to proteins found in food. Allergic reactions cannot occur in the absence of proteins. These proteins (antigens) are capable of stimulating the production of antibodies in the body, thereby, triggering allergic reactions. Immediate response to an allergic reaction can range in severity from a skin rash or itching of the mouth, to migraine headaches, a drop in blood pressure, anaphylaxis (a very severe allergic reactions to food involving failure of multiple organ systems), and death. There is no cure for food allergies and the only way for an allergic individual to protect themselves is strict avoidance of the allergen.

This section outlines the requirements that an Allergen Control Program must meet to control the use of ingredients identified as allergens in an establishment, as well as to prevent or identify the presence of undeclared allergen ingredients in finished food products.

Unlike microbial hazards, there is no lethality or post processing step that will reduce or eliminate the presence of undeclared allergens in food products. Allergen hazard control is dependent on prevention throughout the process as well as appropriate product

labelling to ensure full disclosure of a product's contents.

The list of the priority food allergens is available on the CFIA website at the following address: *http://www.inspection.gc.ca/english/fssa/labeti/allerg/allerge.shtml*

Although sulphites are not considered to be true allergens, for sensitive persons they produce an adverse reaction which can be life threatening. It is the serious outcome of the reaction that has resulted in the inclusion of sulphites on the priority allergen list.

Ingredients which can cause non-immune reactions such as lactose intolerance should be considered when developing this control program.

A company may have to identify additional allergens of specific concern to its product or its target market. Manufacturers exporting outside of Canada should be aware that the list of priority allergens in other countries may be different from those listed in Canada.

G.1 Allergen Control Program

G.1.1 Allergen Control Program

NOTE 1: Each of the requirements outlined below may not be applicable to an establishment. In deciding whether a requirement is necessary or appropriate, an establishment must conduct a risk assessment and the result of the assessment must be recorded.

NOTE 2: Reference to existing prerequisite programs or CCPs that cover the requirements mentioned in this section is acceptable. The purpose of the allergen control program is to gather all of the allergen controls in one location in the HACCP system.

Requirements

G.1.1.1
Where applicable, procedures and/or policies are developed and implemented to ensure proper control of new or modified product formulations. This must include a minimum of:

- A product development and approval process flow including steps to be followed when modifications to existing product formulations are made;
- Communication links among all the steps in the chain of production once a new formulation or changes in a formulation have been approved.

G.1.1.2
Where applicable, procedures and/or policies related to purchasing of ingredients are developed and implemented to ensure proper control and identification of allergens for incoming ingredients. This must include a minimum of:

- Identification of any allergens not allowed in an establishment if such a policy is in place;
- A list of approved suppliers and ingredients;
- Supplier specification for each ingredient or ingredient blend clearly listing each ingredient and, where applicable, components of ingredients;
- Documentation indicating that the supplier will:

- Meet the establishment's specifications;
- Notify the establishment when a change is made to their ingredient blend formula which adds or eliminates an allergen or in the case of sulphites, increases or decreases the level of sulphites.

G.1.1.3
Where applicable, procedures and/or policies are developed and implemented to ensure proper control of new or modified labels. This must include a minimum of:

- A label approval process including steps to be followed in case of re-approval of product labels resulting from modifications to existing product formulations;
- Communication links among all the steps in the chain of production once a new label, or changes to a label, have been approved.

G.1.1.4
Where applicable, procedures and/or policies related to receiving of ingredients and externally printed labels are developed and implemented to ensure that:

- Only approved ingredients from approved suppliers/sources are received;
- The labels of approved ingredients received match the establishment's finished product list of ingredients and components of ingredients;
- Externally printed labels meet the specifications.

G.1.1.5
Where applicable, procedures associated with Weighing/Blending/Mixing/Formulation are developed and implemented to ensure that the correct ingredient is added to the correct product as indicated in the formula. This must include a minimum of:

- The names or titles of personnel responsible for these particular tasks;
- Methods or instructions for the task(s) to be performed;
- Corrective actions to be taken when deviant situations occur during any of these steps;
- Operational records to be kept.

G.1.1.6
Where applicable, procedures and/or policies related to the use of rework are developed and implemented to ensure that the rework formulation ingredients and the product formulation ingredients match, specifically as it applies to allergen ingredients.

G.1.1.7
Where applicable, procedures related to labelling of finished product are developed and implemented to ensure that the finished product label information accurately represents the product name and the composition of the product on which the label is affixed.

This must include a minimum of:

- The names or title of personnel responsible for particular tasks;
- Frequency of activity;
- Methods or instructions for the task(s) to be performed;
- Corrective actions to be taken when product is mislabelled;
- Operational records to be kept.

G.1.1.8
Where applicable, procedures and/or policies for disposal of obsolete materials are developed and implemented to prevent their inadvertent use. Obsolete materials include:

- Labels (refers to any pre-printed packaging that bears a list of ingredients);
- Formula documents;
- Ingredients and work in process.

G.1.1.9
Where applicable, procedures and/or policies are developed and implemented to control cross-contamination of undeclared allergens in the food products. Procedures include as a minimum, the management and control of:

- Production scheduling if dedicated lines for allergens are not available;
- Traffic patterns of employees who handle allergens and non allergens;
- The traffic flow and handling of ingredients containing allergens during receiving, storage, processing and packaging;
- Dedicated or segregated storage of ingredients containing allergens;
- The identification and sanitation of bulk containers housing allergens or ingredients containing allergens;
- Dedicated utensils, equipment and areas used to handle allergens;
- The handling and storage of rework product(s) containing allergen ingredients;
- Cleaning of equipment/food contact surfaces/areas during operations if dedicated lines/equipment/areas for allergens are not available.

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Rationale

- Consumers who have food allergies and intolerances rely on accurate label information on food products to avoid eating foods that contain ingredients to which they may be sensitive.
- If these foods, or their derivatives, are undeclared or declared incorrectly on the label, or if inadvertent cross-contamination occurs during production, the results can be serious and sometimes fatal.

3.1.2 Monitoring procedures

Documented monitoring procedures shall be established for each prerequisite program bullet and shall specify any tests, measurements or observations to assess whether:

- The programs, policies, standard operating procedures and tasks defined or referenced in the prerequisite programs are effectively implemented;
- The standards are met.

The monitoring procedure shall at least include:

- Name or title of personnel responsible for the monitoring and evaluation of monitoring results;
- Monitoring frequency;
- The standard(s) to be met;
- Methods or instructions for testing, measurements or observations to be performed;
- Exact title of the record(s) used to document monitoring results;
- Record keeping instructions (see 3.1.4).

The monitoring frequency must:

- Be auditable/measurable (i.e., “as required” is not auditable);
- Provide effective control to ensure the prerequisite program requirements are consistently met;
- Be at a minimum of once per year.

Standards are criteria or specifications that can be judged or evaluated and that define the limit of acceptability associated with a prerequisite program requirement. Criteria must be measurable. These may either be quantitative (e.g., degrees) or qualitative (e.g., no holes in the carrier, product is stored off the floor). Criteria must be clearly described to be easily understood and uniformly applied by those responsible for monitoring.

There may be specific regulatory standards that apply to specific prerequisite program requirements. The regulatory standards must be addressed in the HACCP system. The establishment may require higher standards than the existing regulatory requirements. In this case, the CFIA staff would verify compliance to the regulatory standards.

To ensure validity of results, tests, methods and instructions must be described in enough detail to ensure consistency in delivery between different monitors.

3.1.3 Deviation procedures

Documented deviation procedures shall specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that:

- The programs, policies, standard operating procedures and tasks defined or referenced in the prerequisite programs are not effectively implemented;
- The standards are not met.

The deviation procedure shall at least include:

- Name or title of personnel that have the responsibility and authority to take actions;
- Instructions on corrective actions to be taken*;
- Exact title of the record(s) used to describe the deviation and to document all actions taken in response to a deviation;
- Record keeping instructions (see 3.1.4).

** The deviation procedure for prerequisite programs shall at least instruct the responsible employees to perform and document the following activities:*

- *Describe the deviation and its cause.*
- *Take immediate actions to control affected or potentially affected product**.*
- *Implement corrective actions to restore control of the prerequisite program requirement(s.*
- *Verify the effectiveness of corrective actions taken.*
- *Evaluate the need to implement additional measures to prevent reoccurrence of the deviation***.*
- *Verify effectiveness of preventative measures if taken.*

***When product is affected or potentially affected, the individual with authority shall:*

- *Prevent the on-going production of non-compliant product;*

- *Control the non-compliant product that has been produced;*
- *Assess if other products are implicated in relation to the cause of the deviation;*
- *Perform an assessment of the affected product to determine if the product may be released (see 3.2.7.3.1);*
- *Determine the disposition of noncompliant product (see 3.2.7.3.2).*

****Preventative measures shall be applied when:*

- *Product is affected or potentially affected;*
- *Repeated deviations are noted during monitoring activities which may indicate a trend toward a loss of control.*

3.1.4 Record keeping

Records shall be kept to demonstrate the effective application of the prerequisite programs and to facilitate official verifications by the CFIA or other competent authority. Records shall be established to document:

- The monitoring results, including the recording of actual quantifiable values (e.g., temperature), when applicable;
- All information and actions taken in response to a deviation identified as a result of monitoring.

Records must be up-to-date, legible, accurate and properly filed.

Each monitoring record and/or action taken in response to a deviation shall be signed or initialed by the employee making the entry using a permanent ink pen or, when computer records are used, the record may be signed electronically. Monitoring records and/or action taken in response to a deviation shall be dated.

Deviation records shall identify a target date for completion of preventative measures.

Any incorrect entry made to a record and subsequently changed shall be crossed out and initialed by the employee making the change.

3.2 HACCP plan(s)

Establishments shall conduct a complete hazard analysis for all of their processes and products in order to identify and control all hazards effectively.

A HACCP Plan is a written document designed in accordance with the following steps to ensure control of food safety hazards within an establishment.

There are 12 steps to developing each HACCP plan. These steps are as follows:

1. Assemble the HACCP team
2. Describe the product and identify its intended use
3. List product ingredients and incoming material
4. Construct a process flow diagram and confirm its accuracy
5. Construct a plant schematic and confirm its accuracy
6. Identify and analyze hazards (Principle 1)
7. Determine critical control point(s) (CCP) and other control measures i.e. process

control (PC) and prerequisite programs (PP) (Principle 2)
8. Establish critical limits for CCP (Principle 3)
9. Establish monitoring procedures for CCP (Principle 4)
10. Establish deviation procedures for CCP (Principle 5)
11. Establish verification procedures for CCP (Principle 6)
12. Establish record keeping for CCP (Principle 7)

Steps 1 to 5 are preliminary steps to enable hazard analysis. Steps 6 to 12 incorporate the 7 principles of HACCP developed by the Codex Alimentarius Commission.

All relevant information needed to conduct the preliminary steps, the hazard analysis, and the establishment of the critical control points and process controls shall be documented, updated whenever there are changes, and reassessed at least annually.

FSEP has created 10 specific forms that can be used for the documentation of a HACCP plan. If an establishment uses forms other than those found in this manual, the content must be equivalent and provide sufficient detail as outlined on the FSEP forms.

The 10 FSEP-HACCP Plan forms are:

Form 1: Product Description
Form 2: List of Product Ingredients and Incoming Material
Form 3: Process Flow Diagram
Form 4: Plant Schematic
Form 5: Biological Hazard Identification
Form 6: Chemical Hazard Identification
Form 7: Physical Hazard Identification
Form 8: Decision Tree - CCP determination and other Control Measures (PP, PC)
Form 9: Hazards Not Controlled by the establishment
Form 10: Critical Control Point(s)

The 11 blank template forms, including an example of an alternative form that will allow for the combination of forms 5, 6, 7, 8 and 9 can be found in section 3.5.

In performing the step-by-step analysis above, the HACCP team may determine that several products share similar hazards, processing steps or equipment. In that case, the HACCP team may group these products or processes into one HACCP plan.

If an establishment chooses to group dissimilar processes or products into one HACCP plan, they will be required to demonstrate to the CFIA that the HACCP plan identifies and controls all potential hazards.

3.2.1 Describe product and identify its intended use (Form 1)

The description of finished products shall be documented in form 1 or equivalent to the extent needed to conduct the hazard analysis, including information on the following, as appropriate:

- Process/product type name;
- Product name;
- Important product characteristics;

- Intended use;
- Packaging;
- Intended shelf life and storage conditions;
- Where the product will be sold;
- Labelling instructions relating to food safety;
- Special distribution control.

The HACCP team shall identify regulatory food safety requirements related to the above.

3.2.1.1 Process/product type name

The generic or common name of the product family or process covered by the HACCP plan shall be documented in form 1 or equivalent.

3.2.1.2 Product name

The brand name and/or common name of the individual products covered by the HACCP plan shall be documented in form 1 or equivalent. Reference to a list of product names is acceptable.

3.2.1.3 Important product characteristics

The physio-chemical characteristics of the product (such as pH, Aw, salt content, concentration of preservatives, etc.) that could affect food safety if not properly controlled shall be documented in form 1 or equivalent.

3.2.1.4 Intended use

The intended use is based on the expected uses of the product by the end user (e.g., ready-to-eat food product, ready-to-cook, for further processing).

The intended use shall be described in form 1 or equivalent.

3.2.1.5 Packaging

All types of packaging to be used by the establishment for the final product (e.g., drums, pails, cryovac bags, modified atmosphere, hermetically sealed) and their applicable size (e.g., consumer-size, bulk packs destined for further processing) shall be documented in form 1 or equivalent to enable hazard analysis.

A reference to a list of types of packaging and applicable sizes is acceptable.

3.2.1.6 Intended shelf life and storage conditions

The intended shelf life of the product under normal marketing conditions at a given storage temperature and, where applicable, humidity shall be documented in form 1 or equivalent to enable hazard analysis.

When establishing product shelf life, it is the responsibility of the manufacturer to ensure and to demonstrate that the safety of the food product can be retained throughout the

maximum period specified.

3.2.1.7 Where the product will be sold

The points of sale, target groups of users and, where appropriate, more specific groups of consumers shall be identified on form 1 or equivalent for each product (e.g., retail, general population, infants, hospital). More specifically consumer groups known to be especially vulnerable to specific food safety hazards shall be considered.

3.2.1.8 Labelling instructions related to food safety

Any labelling instructions for handling, preparation and usage which have an impact of food safety shall be identified in form 1 or equivalent (e.g., cooking and storage instructions, best before date).

3.2.1.9 Special distribution control

Special controls required during transportation and storage (e.g., temperature, humidity) shall be documented in form 1 or equivalent.

3.2.2 List product ingredients and incoming materials (Form 2)

All ingredients, including composition of formulated ingredients (with reference to other documents if needed), additives, processing aids and incoming materials that come in contact with the product or are used in preparing the product shall be described in form 2 or equivalent, to the extent needed to conduct the hazard analysis.

Particular care must be taken for additives, processing aids and ingredients (including second generation ingredients), that have received regulatory approval for specific products only.

3.2.3 Construct a process flow diagram and confirm its accuracy (Form 3)

Flow diagram(s) shall be prepared for the product(s) or process categories covered by the HACCP plan. Flow diagrams shall provide a basis for evaluating the possible occurrence or introduction of and/or increase in food safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include:

- The sequence and interaction of all steps in the operation from receiving to final shipping;
- The introduction of ingredients and intermediate products into the process flow;
- The introduction of product for reworking.

The HACCP team shall verify the accuracy and completeness of the flow diagrams by on-site checking.

3.2.4 Construct a plant schematic and confirm its accuracy (Form 4)

A plant schematic shall be prepared for the products or process categories covered by the HACCP plan. Plant schematic provides a basis for evaluating potential areas of

cross-contamination.

Plant schematic shall be clear, accurate and sufficiently detailed. Plant schematic shall at least include:

- The flows of raw products, ingredients and finished products;
- The flows of packaging materials;
- The employee traffic pattern throughout the establishment including change rooms, washrooms and lunchrooms;
- The flows of the waste, inedible products and other non-food products that could cause cross-contamination;
- The hand/boot washing and sanitizing installations.

The HACCP team shall verify the accuracy and completeness of the plant schematic by on-site checking.

The overall evaluation of potential areas of cross-contamination at the establishment should include any other plant schematic from other HACCP plan(s).

3.2.5 Identify and analyze hazards (HACCP Principle 1) (Forms 5, 6, 7)

The hazard identification shall be based on:

- The information collected according to 3.2.1 to 3.2.4;
- Employees' knowledge and experience on practical aspects of the establishment operations;
- Documented production issues such as files on production rework, returned products, product complaints and recalls;
- External information including reference texts, scientific publications, and government guides such as the CFIA's *Reference Database for Hazard Identification.*

If biological (B), chemical (C) or physical (P) hazards associated with the ingredients and incoming materials are identified, the letters B, C or P shall be indicated in form 2 or equivalent beside each corresponding ingredient or incoming material. The hazards shall be fully described in forms 5, 6, 7 or equivalent.

If biological, chemical or physical hazards associated with the processing steps are identified, the letters B, C or P shall be indicated in form 3 or equivalent beside each corresponding step. The hazards shall be fully described in forms 5, 6, 7 or equivalent.

If biological, chemical or physical hazards associated with cross-contamination points are identified, the letters B, C or P shall be indicated in form 4 or equivalent at the corresponding cross-contamination point. The hazards shall be fully described in forms 5, 6, 7 or equivalent.

3.2.6 Determination of CCP and other control measures (HACCP Principle 2) (Form 8)

For each hazard identified, an analysis shall be conducted to determine:

- The likely occurrence of the hazard;
- The severity of possible adverse health effect associated with the hazard;
- If the identified hazard is controlled by prerequisite programs;
- If the identified hazard is partially controlled by a process control;
- If the identified hazard is controlled at a CCP;
- If the identified hazard is out of the establishment's control.

The establishment shall use Form 8 or equivalent to document the hazard analysis as well as the prerequisite programs, the process controls (PC) and the CCP selected to control the food safety hazards identified.

All PC(s) and CCP(s) associated with the processing steps shall be indicated beside the corresponding step in form 3 or equivalent.

NOTE: To facilitate verification by CFIA representatives, FSEP recommends establishments number the CCP sequentially and identify the hazard(s) each controls i.e., B for biological, C for chemical, P for physical hazards. (e.g., CCP1-BCP, CCP2-B).

3.2.6.1 Using form 8 - decision tree – CCP determination and other control measures (PP, PC)

Form 8 – Column 1

List each ingredient and incoming material, process step and cross-contamination point where a hazard has been identified. Use one line per hazard.

Form 8 – Column 2

Categorize (biological, chemical, physical) and fully describe each of the identified hazards. Where multiple hazards exist at one point, each hazard should be analyzed separately.

For each hazard, determine whether it is fully controlled by one or more prerequisite programs. If the answer is "yes", identify the prerequisite program bullet(s) that provides full control over this hazard.

To assess whether the hazard is fully controlled by a prerequisite program, the HACCP team must first review the documented written program(s) for the specific bullet(s). They must then conduct a record review and on-site observations to ensure that the policies and procedures in place provide effective control over the hazard identified in the HACCP plan.

If the HACCP team determines that the hazard is not fully controlled by a prerequisite program, proceed to Question 1.

Form 8 – Question 1

Q1. Could a control measure(s) be used by the establishment at any process step?

Could a control measure occur at this step – or at any other process step – to control the hazard? Does the establishment have or could they add a process step to control the hazard?

If the answer is "yes", describe the control measure and proceed to Q2.
If the answer is "no" (a control measure cannot be implemented at a process step), identify how the hazard will be controlled before or after the manufacturing process on Form 9 or equivalent and proceed to the next identified hazard.

Form 8 – Question 2

Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?

Question 2 refers to the probability and seriousness of the hazard. If there were no controls in place, how likely is this hazard to occur in excess of acceptable levels*?

**Acceptable level – The level at which the finished product will not cause harm to the consumer when it is prepared and/or consumed according to its intended use.*

Conduct a hazard analysis based on all the information that the HACCP team has gathered.

If information gathered suggests that contamination with the identified hazard could increase to an unacceptable level and result in a health hazard, answer "yes" and proceed to Question 3. Identify the acceptable level of the food safety hazard in the finished product, wherever possible.

If contamination is not likely to occur, or is not known to affect the safety of the product, answer "no" and proceed to the next identified hazard. For further reference, the HACCP team must document the reasons for answering "no".

Form 8 – Question 3

Q3. Is this process step specifically designed to prevent, eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?

If the process step has been specifically designed to prevent, eliminate or reduce the likely occurrence of the hazard to an acceptable level, answer "yes". Designate this process step as a CCP and identify it in the last column.
If the answer is no, proceed to Question 4.

Note: Question 3 applies only to processing steps. For incoming materials, write "not applicable" (N/A) and proceed to Question 4.

Form 8 – Question 4

Q4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?

Answer “no” if no subsequent processing steps listed on the process flow diagram will eliminate or reduce the hazard to an acceptable level. Designate this process step a CCP and identify it in the last column and proceed to the next identified hazard.

If the answer is “yes”, identify the subsequent step or steps that control the hazard. Then proceed to Question 5.

Form 8 – Question 5

Q5. Does this step provide partial control of the identified hazard?

If the answer is “yes”, this process step is a process control. Enter the process control number in the last column then proceed to the next identified hazard.
If the answer is “no”, proceed to the next identified hazard.

3.2.6.2 Hazards not controlled by the establishment (Form 9)

All hazards that affect the establishment products shall be analyzed. Hazards that are out of the control of the establishment, as well as a description of how the hazard is controlled before or after the production process shall be documented on form 9 or equivalent.

3.2.7 Critical control points (Form 10)

A CCP is a point or a step at which a control measure is applied and where it is essential to prevent or eliminate one or more food safety hazards or reduce them to an acceptable level.

Each CCP shall be documented in form 10 or equivalent and shall include the following information:

- Hazard(s) to be controlled at the CCP and description of control measure(s);
- Critical limit(s) (see 3.2.7.1);
- Monitoring procedure(s) (see 3.2.7.2);
- Deviation procedures (see 3.2.7.3);
- Verification procedure(s) (see 3.2.7.4).

The record keeping shall meet the requirements defined in 3.2.7.5

The CCP shall be validated, updated whenever there are changes associated with the CCP and reassessed at least annually.

Note: The individual(s) responsible for monitoring, deviation and verification procedures may be identified by a position title or the term “designate”. In this case, the establishment must be able to demonstrate that individuals have received adequate training.

3.2.7.1 Critical limits (HACCP Principle 3)

Critical limits are criteria that separate acceptability from unacceptability. These parameters, if properly maintained, will confirm the safety of the product.

Critical limits shall be determined for the monitoring established for each CCP. One or more critical limits may be used to control the identified hazards.

Critical limits shall be established to ensure that the identified acceptable level of the food safety hazard in the finished product is not exceeded. Where government regulations exist, the critical limit, at a minimum, must meet those regulations. In this case, the CFIA staff would verify compliance to the regulations.

Critical limits shall be measurable. Critical limits based on subjective data (such as visual inspection of product) shall be clearly described to be easily understood and uniformly applied by those responsible for monitoring.

3.2.7.2 Monitoring procedures (HACCP Principle 4)

Documented monitoring procedures shall be established for each CCP and shall specify any tests, measurements or observations to assess whether:

- The control measure is functioning as intended;
- The critical limits are met.

The monitoring procedures shall at least include:

- Name or title of personnel responsible for the monitoring and evaluation of monitoring results;
- Monitoring frequency;
- Methods or instructions for tests, measurements or observations to be performed;
- Exact title of the record(s) used to document monitoring results;
- Record keeping instructions (see 3.2.7.5).

The monitoring methods and frequency shall be able to detect loss of control at the CCP in time for the product to be isolated before it leaves the control of the producing establishment.

All monitoring devices/equipment requiring maintenance and calibration for accuracy must be controlled through the preventative maintenance and calibration programs.

3.2.7.3 Deviation procedures (HACCP Principle 5)

Documented deviation procedures shall specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that:

- The control measure is not functioning as intended;
- The critical limits are not met.

The deviation procedure shall at least include:

- Name or title of personnel that have the responsibility and authority to take actions;

- Instructions on corrective actions to be taken*;
- Exact title of the record(s) used to describe the deviation and to document all actions taken in response to a deviation;
- Record keeping instructions (see 3.2.7.5).

** The deviation procedure for a CCP shall at least instruct the responsible employees to perform and document the following activities:*

- *Describe the deviation and its cause.*
- *Take immediate action(s) to control affected or potentially affected product(s)**.*
- *Implement corrective action(s) to restore control of the CCP.*
- *Verify the effectiveness of corrective action(s) to ensure that the parameter(s) controlled at the CCP is (are) brought back under control.*
- *Implement measures to prevent reoccurrence of the deviation.*
- *Verify the effectiveness of preventative measures taken.*

***When product is affected or potentially affected, individual with authority shall:*

- *Prevent the on-going production of non-compliant product;*
- *Control the non-compliant product that has been produced;*
- *Assess if other products are implicated in relation to the cause of the deviation;*
- *Perform an assessment of the affected product to determine if the product may be released (see 3.2.7.3.1);*
- *Determine the disposition of noncompliant product (see 3.2.7.3.2).*

Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated.

When an unforeseen hazard is identified, the company should perform a reassessment to determine whether the newly identified hazard should be incorporated into the HACCP plan.

Any deviation at a CCP will require an evaluation of the supporting PC(s), where appropriate, as part of the deviation procedures associated with that CCP.

3.2.7.3.1 Assessment for release

No product that is injurious to health or otherwise adulterated as a result of the deviation may be allowed to enter commerce. When found to be in deviation, each lot of product shall only be released as acceptable when any of the following conditions apply:

- Evidence other than the monitoring data demonstrates that the CCP has been effective.
- Evidence shows that the combined effect of multiple control measures for that particular product complies with the identified acceptable levels for the hazard(s) concerned.
- The results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the hazard(s) concerned.

The controls and results of the assessment shall be documented.

3.2.7.3.2 Disposition of noncompliant product

Following assessment, if the lot of product is not acceptable for release it shall be handled by one of the following activities:

- Reprocessing or further processing within or outside the establishment, as per applicable regulatory requirements, to ensure that the hazard is eliminated or reduced to acceptable levels, or
- Destruction and/or disposal as waste.

The disposition of the noncompliant product shall be documented.

3.2.7.4 Verification procedures (HACCP Principle 6)

Verification is the application of methods, procedures, tests, sampling and other evaluations, in addition to monitoring, to determine whether:

- A control measure within a CCP is or has been operating as intended;
- Monitoring and deviation procedures are conducted according to the written program;
- The record keeping meets the requirements defined in 3.2.7.5;
- The CCPs are under control;
- There are trends in monitoring results that may indicate development towards loss of control.

Documented verification procedures shall be established and shall at least include:

- Name or title of personnel responsible for the verification;
- Verification frequency;
- A description of the activities to be conducted, including but not limited to:
    - Direct observation of monitoring activities;
    - Interview of persons responsible for monitoring and deviation procedures;
    - Direct observation of corrective actions taken, if possible;
    - Review of records documenting the monitoring activities;
    - Review of records documenting the actions taken in response to a deviation;
    - When applicable, product testing to confirm that the CCP is properly implemented and achieves the intended outcome;
- Deviation procedures when the results of the verification demonstrate that:
    - The monitoring or deviation activities are not conducted according to the written program;
    - The CCP is not effective to maintain control of the hazard;
    - There is a trend towards a loss of control;
- Exact title of the record used to document verification results;
- Record keeping instructions (see 3.2.7.5).

Note: A distinction should be made on the verification record to differentiate between a record review and an on-site observation.

Verification shall be carried out by someone other than the person who is responsible for performing the monitoring activities (i.e. Verifiers cannot verify their own work).

The frequency of verification should be sufficient to confirm that the CCP(s) remains in

control of any hazards. For example, at a dairy plant, staff responsible for the daily monitoring of the pasteurization step fails to take the necessary corrective action. Verification conducted once per month will not be frequent enough to prevent a broad-based recall.

3.2.7.5 Record keeping (HACCP Principle 7)

Records shall be kept to demonstrate the effective application of the critical control points and to facilitate official verifications by the CFIA or other competent authority.

Records shall be established to document:

- The monitoring results, including, when necessary, the recording of quantifiable values (e.g., temperature, time, Aw, pH) as prescribed in the CCP(s);
- All information and actions taken in response to a deviation identified as a result of monitoring and verification;
- The verification results.

Records must be up-to-date, legible, accurate and properly filed.

Each entry on a monitoring, deviation or verification record shall include the date and the exact time of the event, and shall be signed or initialed by the employee making the entry using a permanent ink pen or, where computer records are used, electronically.

Deviation records shall identify a target date for completion of preventative measures.

Any incorrect entry made to a record and subsequently changed shall be crossed out and initialed by the employee making the change.

3.2.8 Process controls

Where more than one step in an overall process may contribute to the reduction of a particular hazard, process controls may be developed for the early points of the process where the hazard cannot be fully controlled, but a subsequent step will result in the elimination or reduction of this particular hazard to an acceptable level. This final control would be determined to be a CCP.

In the Meat and Poultry commodity, CFIA has designed some process controls as an integral part of an overall inspection program, such as the Modernized Poultry Inspection Program. In this case, the PCs are mandated. The mandated PC standards are published in the applicable CFIA specific program Manual of Procedures (MOP), and must be implemented as outlined in the MOP. If additional mandated PCs are developed by the CFIA, they will be published in the appropriate manuals.

In any commodities (including Meat & Poultry) subject to FSEP, operators may also develop their own process controls, where multiple process steps provide control over one specific hazard. These operators would be expected to validate the entire procedure to demonstrate that their process control meets all of the necessary parameters and is effective. The resulting material must be submitted to the CFIA Area FSEP Coordinator for review and acceptance, prior to implementation.

Each PC shall be documented and shall include the following information:

- Food safety hazard(s) to be controlled at the PC;
- The CCP number to which the PC is linked;
- Monitoring procedures (see 3.2.8.1);
- Deviation procedures (see 3.2.8.2);
- Verification procedures (see 3.2.8.3).

The record keeping shall meet the requirements defined in 3.2.8.4.

The PCs shall be updated whenever there are changes associated with the process control requirements and reassessed at least annually.

3.2.8.1 Monitoring procedures

Documented monitoring procedures shall specify any tests, measurements or observations to assess whether the process control standards are met.

The monitoring procedures shall at least include:

- Name or title of personnel responsible for the monitoring and evaluation of monitoring results;
- Monitoring frequency;
- The standard(s) to be met;
- Methods or instructions to take measurements, perform tests or conduct observations;
- Exact title of the record(s) used to document monitoring results;
- The record keeping instructions (see 3.2.8.4).

3.2.8.2 Deviation procedures

Documented deviation procedures shall specify any planned or appropriate corrective actions to be taken when monitoring results demonstrate that the PC standards are not met.

The deviation procedure shall at least include:

- Name or title of personnel that have the responsibility and authority to take actions;
- Instructions on corrective actions to be taken*;
- Exact title of the record(s) used to describe the deviation and to document all actions taken in response to a deviation;
- The record keeping instructions (see 3.2.8.4).

** The deviation procedure for process controls shall at least instruct the responsible employees to perform and document the following activities:*

- *Describe the deviation and its cause.*
- *Implement corrective actions to restore control of the PC.*
- *Verify the effectiveness of corrective actions taken.*

If the immediate actions are not found to be effective, the following additional activities must be performed and documented:

- *Perform an immediate monitoring activity at the related downstream CCP to assess potential product impact.*

- *Implement measures to prevent reoccurrence of the PC deviation.*
- *Verify the effectiveness of preventative measures for the PC deviation.*

3.2.8.3 Verification procedures

Documented verification procedures shall specify any planned sequence of observations, tests and other evaluations, in addition to monitoring, to determine whether:

- Monitoring and deviation procedures are conducted according to the written program;
- The record keeping meets the requirements defined in 3.2.8.4;
- The controls in place are effective to meet the PC standards.

The verification procedures shall at least include:

- Name or title of personnel responsible for the verification;
- Verification frequency;
- A description of the activities to be conducted, including but not limited to:
    - Direct observation of monitoring activities;
    - Interview of persons responsible for monitoring and deviation procedures;
    - Direct observation of corrective actions taken, if possible;
    - Review of records documenting the monitoring activities;
    - Review of records documenting the actions taken in response to a deviation;
- Deviation procedures when the results of the verification demonstrate that:
    - The monitoring or deviation activities are not conducted according to the written program;
    - The PC is not effective to maintain control of the standards;
- Exact title of the record used to document verification results;
- The record keeping instructions (see 3.2.8.4).

Verification shall be carried out by someone other than the person who is responsible for performing the monitoring activities (i.e., verifiers cannot verify their own work).

3.2.8.4 Record keeping

Records shall be kept to demonstrate the effective application of the process controls and to facilitate official verifications by the CFIA or other competent authority.
Records shall be established to document:

- The monitoring results, including, when necessary, the recording of quantifiable values as prescribed in the process control
- All information and actions taken in response to a deviation identified as a result of monitoring and verification
- The verification results

Records must be up-to-date, legible, accurate and properly filed.

Each entry on a monitoring, deviation or verification record shall include the date and the exact time of the event, and shall be signed or initialed by the employee making the entry using a permanent ink pen or, where computer records are used, electronically.

Deviation records shall identify a target date for completion of preventative measures.

Any incorrect entry made to a record and subsequently changed shall be crossed out and initialed by the employee making the change.

3.3 Validation

Every establishment shall demonstrate that the critical control points are capable, on a consistent basis, of achieving the intended level of hazard control.

Validation is performed at the time the CCP is designed, or when changes indicate the need for re-validation. Validation of a CCP is, whenever possible, performed before it is fully implemented.

Depending on the CCP that is being validated, the validation documentation may include:

- Scientific, technical or regulatory support to demonstrate that the selected critical limit is effective for control of the hazard;
- Commissioned testing data specific for a piece of equipment (e.g. pasteurizer) to demonstrate that the equipment is capable of meeting the selected critical limit;
- Supporting data to demonstrate that the monitoring procedures are effective enough to detect loss of control at a CCP before the finished product leaves the control of the producing establishment.

CFIA may request validation documentation for control measures covered by prerequisite programs that have an immediate impact on food safety (e.g., new technology for water treatment).

For more information on the validation process, the CFIA recommends the Guidelines for the Validation of Food Safety Control Measures developed by the Codex Alimentarius Committee. *http://www.codexalimentarius.net/download/standards/11022/cxg_069e.pdf*

3.4 Maintenance and reassessment of the HACCP system

3.4.1 HACCP system maintenance procedures

Whenever any changes or situations occur that could affect the hazard analysis or alter the HACCP system, the establishment shall:

- Update the parts of the HACCP system affected by the changes or situations;
- Reassess completeness and effectiveness of the updated part of the HACCP system;
- Revalidate all CCPs affected by the changes.

Here are examples of potential triggers which could lead to the need to update and/or to perform a reassessment of parts of the HACCP system:

- New regulatory requirements related to food safety
- New product
- Noncompliant situations identified during monitoring and verification activities
- Consumer/client complaints
- Food safety recalls

- Unsatisfactory laboratory results
- Non compliance identified during CFIA verifications
- New product line that can potentially cause cross-contamination
- New ingredients or incoming materials that come in contact with the product or are used for preparing the product
- New process step
- New technology or piece of equipment that impacts on the level of a hazard
- New/on-going construction or change in the product flow and or employee traffic patterns resulting in a potential for cross contamination
- New control measure for an identified hazard
- Change made in product formulation or preparation
- Change made in production volume which impacts on the product flow, sanitation schedule, employee training, etc.
- Change made in the application of a CCP (e.g. change in critical limit)

The establishment has and implements documented procedures to ensure that the HACCP system is effectively maintained.

The procedures shall include as a minimum:

- Name or title of personnel responsible to make changes to the HACCP system;
- Name or title of personnel responsible to ensure that the changes are implemented effectively;
- A method to identify the revised versions;
- The use of a log book or equivalent which must at least contain the following information:
    - A description of the changes;
    - The signature or initials of responsible person who made the change;
    - Where the changes occurred in the HACCP system;
    - The dates when changes are implemented, reassessed and, if necessary, validated;
    - The signature or initials of responsible person who ensure that the changes are implemented effectively;
    - The revision date or number that correlates with document changed.

Benefits of implementing effective maintenance procedures:

- *HACCP system documents are approved for adequacy by competent personnel prior to issue.*
- *Changes are identified when a situation affecting the hazard analysis occurs which demonstrates effective maintenance of the HACCP system to CFIA or other competent authority.*
- *Revised versions are identified.*
- *Relevant versions of applicable documents are available at points of use.*
- *Unintended use of obsolete documents is prevented.*

3.4.2 HACCP system reassessment procedures

Whenever any changes or situations occur that could affect the hazard analysis or alter the HACCP system, the establishment shall reassess completeness and effectiveness of the updated part of the HACCP system and document the reassessment activities conducted in the HACCP system modification log book as described in 3.4.1.

At least annually, the establishment shall reassess its entire HACCP system to determine whether the system:

- Is up to date;
- Identifies all food safety hazards;
- Has control measures in place for all food safety hazards which may be controlled by the establishment;
- Results in the desired outcomes;
- Conforms to current regulatory and CFIA program requirements;
- Conforms to the requirements defined in the FSEP manual.

Documented reassessment procedures shall be established and shall include but are not limited to:

- The individual(s) responsible for the reassessment activities.
- The frequency of reassessment activities or "details and specifics" of reassessment activities (i.e., the establishment may specify that the required reassessment activities are conducted at various times over the course of the year).
- A review of the changes made to the HACCP system (see 3.4.1).
- A review of the actions taken in response to situations indicating a trend toward or a loss of control to ensure that the applicable sections of the HACCP system have been updated and reassessed accordingly. The following situations shall be included in the review:
    - Client or consumer food safety related complaints;
    - Unsatisfactory laboratory results;
    - Noncompliant situations identified during monitoring and verification activities;
    - Noncompliant situations resulting in a recall;
    - Non compliance identified during CFIA verifications.
- A review of the product descriptions, list of ingredients and incoming materials, process flow diagrams and schematic diagrams to ensure that they:
    - Are up to date;
    - Identify all food safety hazards.
- A review of all hazards identified in the HACCP plan in order to ensure that:
    - They are accurate;
    - Control measures are identified.
- A review of the Process Control(s) and CCP(s) to ensure that they:
    - Are up to date;
    - Result in the desired outcomes;
    - Conform to regulatory requirements;
    - Conform to the requirements defined in the FSEP manual.
- A written review, a record review and an on-site assessment of all prerequisite programs to ensure that they:
    - Are up to date;
    - Conform to regulatory requirements;
    - Conform to the requirements defined in the FSEP manual;
    - Are conducted according to the written programs;
    - Result in the desired outcomes.
- A review of the records used to document monitoring, deviation and verification results to ensure they are designed to provide all information required in the FSEP manual.

- Exact title of record(s) used to document:
    - Reassessment results;
    - Changes made to the HACCP system;
    - Any other corrective actions taken.

3.5 FSEP forms

Product Description	**Form 1**
Process/product type name:	
1. Product name(s)	
2. Important product characteristics	
3. Intended use	
4. Packaging	
5. Shelf life	
6. Where it will be sold	
7. Labeling instructions	
8. Special distribution control	

Date: _____ Approved by: _____

List of Product Ingredients and Incoming Materials		**Form 2**
Process/Product name:		

Date: _____ **Approved by:** _____

Process Flow Diagram	**Form 3**
Process/Product name(s):	

Date: _____ **Approved by:**_____

Plant Schematic	**Form 4**
Process/Product name(s):	

Date: _____ **Approved by:** _____

Hazard Identification **Form 5** **Process/Product name(s):** **List all biological hazards related to ingredients, incoming material, processing steps, cross-contamination points.**	
Identified biological hazards	**Controlled at**

Date: _____ **Approved by:** _____

Hazard Identification **Form 6** **Process/Product name(s):** **List all chemical hazards related to ingredients, incoming material, processing steps, cross-contamination points.**	
Identified chemical hazards	**Controlled at**

Date: _____ **Approved by:** _____

Hazard Identification **Form 7** **Process/Product name(s):** **List all physical hazards related to ingredients, incoming material, processing steps, cross-contamination points.**	
Identified physical hazards	**Controlled at**

Date: _____ **Approved by:** _____

Decision tree – CCP Determination and other Control Measures (PP, PC) **Form 8**

Process/Product name

List each ingredient, incoming material, process step where a hazard has been identified as well as any cross-contamination point	Identify category of hazard (B, C, P) Fully describe the identified hazard Determine if fully controlled by prerequisite programs	Q1. Could a control measure(s) be used by the establishment at any process step?	Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?	Q3. Is this process step specifically designed to prevent, eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?	Q4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?	Q.5 Does this step provide partial control of the identified hazard?	CCP and/or PC number
	If yes = indicate actual prerequisite program bullet(s) and proceed to the next identified hazard If no = proceed to Q1	If no = Indicate how the hazard will be controlled before and after the process on form 9. Then proceed to the next identified hazard. If yes = describe the control measure and proceed to Q2.	If no = Identify reason(s) why it is not likely to occur and proceed to the next identified hazard. If yes = Identify acceptable level of the hazard in the finished product, wherever possible, then proceed to Q3.	If yes = CCP. Enter CCP number in the last column. If no = proceed to Q4.	If no = CCP. Enter CCP number in the last column then proceed to the next identified hazard. If yes = not a CCP. Identify the subsequent controlling step and proceed to Q5	If yes = PC. Enter PC number in the last column and proceed to the next identified hazard If no = Proceed to the next identified hazard.	

Date: _____ **Approved by:** _____

Hazards Not Controlled by the Establishment **Form 9** **Process/Product name(s):** **List here any biological, chemical and physical hazards that are not controlled by the establishment**	
Hazards	**Indicate how the hazard could be addressed (cooking instructions, public education, "use before" date, etc.)**

Date: _____ **Approved by:** _____

Critical Control Points						Form 10
Product name						
CCP number	**Hazard Description and Control measure**	**Critical Limits**	**Monitoring Procedures**	**Deviation Procedures**	**Verification Procedures**	**HACCP Record**

Date: _____ **Approved by:** _____

EXAMPLE OF AN EQUIVALENT FORM – FSEP FORMS 5, 6, 7, 8 AND 9 COMBINED INTO ONE FORM

Hazard Identification and Decision tree – CCP Determination and other Control Measures (PP, PC) **Process/Product name**							
List each ingredient, incoming material, process step where a hazard has been identified as well as any cross-contamination point	Identify category of hazard (B, C, P) Fully describe the identified hazard Determine if fully controlled by prerequisite programs	Q1. Could a control measure(s) be used by the establishment at any process step?	Q2. Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?	Q3. Is this process step specifically designed to prevent, eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?	Q4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?	Q.5 Does this step provide partial control of the identified hazard?	Controlled at: #CCP #PC Prerequisite program bullets Before and after the process
	If yes = indicate actual prerequisite program bullet(s) in the last column and proceed to the next identified hazard If no = proceed to Q1	If no = Indicate how the hazard will be controlled before and after the process in the last column, then proceed to the next identified hazard. If yes = describe the control measure and proceed to Q2.	If no = Identify reason(s) why it is not likely to occur and proceed to the next identified hazard. If yes = Identify acceptable level of the hazard in the finished product, wherever possible, then proceed to Q3.	If yes = CCP. Enter CCP number in the last column. If no = proceed to Q4.	If no = CCP. Enter CCP number in the last column then proceed to the next identified hazard. If yes = not a CCP. Identify the subsequent controlling step and proceed to Q5	If yes = PC. Enter PC number in the last column and proceed to the next identified hazard If no = Proceed to the next identified hazard.	

Date: _____ **Approved by:** _____

Section 4 – Recognition Process

This section details the process for HACCP recognition by the CFIA. The recognition process applies to the following federally registered commodity groups:

- Dairy,
- Processed fruits and vegetables,
- Shell eggs,
- Processed eggs,
- Honey,
- Maple, and
- Hatcheries.

For establishments registered under the Meat Inspection Regulations in which a HACCP system in accordance with the FSEP Manual requirements is mandatory, please refer to the Meat Hygiene Manual of Procedures – Chapter 2 (Guidelines for the Applicant/Operator to the Registration of an Establishment and Licensing of an Operator).

Note: Subparagraph 29(2)(b)(iii) of the Meat Inspection Regulations, 1990, requires that an application for a licence to operate a meat registered establishment includes a description of the prerequisite programs and HACCP plans for the registered establishment. This includes HACCP plans for all human-food product lines in the registered establishment.

For the other commodities, when requesting recognition, a registered establishment must already be conducting its operations under a HACCP system for all product lines in the registered establishment.

The purpose of the recognition is to determine whether the establishment's HACCP system is complete (i.e., meets FSEP and regulatory/program requirements), and is implemented effectively as described.

The CFIA recognizes that companies invest time and resources in developing their customized HACCP systems we treat each system as proprietary to the company that developed it.

4.1 CFIA Area FSEP Coordinator responsibilities

The CFIA Area FSEP Coordinator is responsible for:

- Providing the applicant with all pertinent information concerning the HACCP recognition of an establishment;
- Providing interpretation of requirements for HACCP recognition of an establishment to the applicant as well as to the CFIA staff;
- Providing guidance to the applicant with respect to issues related to HACCP recognition of an establishment;
- Communicating all information related to the HACCP recognition from the Area to the National FSEP Coordinator for national tracking.

4.2 Recognition process steps

The process covers 6 steps, as follows:

- The establishment submits a letter requesting recognition by the CFIA (see 4.2.1)
- The CFIA holds a pre-meeting with the establishment's management (see 4.2.2)
- The establishment submits a documentation package (see 4.2.3)
- The CFIA reviews the establishment's HACCP system documentation (see 4.2.4)
- The CFIA conducts an on-site review of the establishment's HACCP system (see 4.2.5)
- The CFIA issues official notification recognizing the establishment's FSEP/HACCP status (see 4.2.6)

4.2.1 Letter requesting recognition by the CFIA

To begin the recognition process, an establishment must submit a letter to the CFIA's Area FSEP Coordinator. The letter must:

- Request recognition by the CFIA;
- Confirm that a HACCP system has been developed as per the FSEP requirements and is currently implemented;
- Be signed and dated by the establishment's senior management.

4.2.2 CFIA pre-meeting with the establishment's management

After receiving the establishment's letter, the CFIA Area FSEP Coordinator or their delegate will schedule a pre-meeting with the establishment to:

- Provide information about the recognition process, and
- Review a random selection of components from the establishment written HACCP system.

4.2.3 Submission of the HACCP system documentation package

The establishment must provide the CFIA Area FSEP Coordinator or their delegate with a documentation package that includes the following:

- Senior management letter of commitment (see 2.2.1);
- HACCP system performance reporting procedure (see 2.2.5);
- Name of HACCP team leader (see 2.2.2);
- Prerequisite programs (see 3.1);
- List of all products to be produced in the establishment and grouped under their respective HACCP plan;
- HACCP plan(s) (see 3.2);
- Process control(s), when applicable (see 3.2.8);
- Validation data of critical control points (see 3.3);
- HACCP system maintenance and reassessment procedures (see 3.4);
- Internal audit results*.

**The establishment must conduct an internal audit in order to ensure that its HACCP system is being implemented and is effective. Documentation must be available to support the internal audit. The establishment must have corrected any deficiencies identified during the internal audit or provided a plan of action to address such deficiencies.*

If the documentation package is incomplete, the applicant will be notified by the CFIA Area FSEP Coordinator or their delegate and asked to submit the incomplete items.

4.2.4 CFIA review of the HACCP system documentation package

The CFIA Area FSEP Coordinator or their delegate will review the entire HACCP system documentation package and communicate any unacceptable items from the HACCP documentation review to the applicant for correction prior to final on-site review.

The CFIA must follow-up on unacceptable items prior to the on-site review.

4.2.5 CFIA on-site review of the establishment's HACCP system

The on-site review determines whether the HACCP system has been implemented as described in the written programs and is effective in meeting food safety objectives. The on-site review is initiated only after the CFIA Area FSEP Coordinator or their delegate has deemed the establishment's written HACCP system complete.

The HACCP team leader or an on-site liaison person must be available during the on-site review.

The CFIA representatives must at least include the responsible inspector, a lead CFIA representative and if appropriate, a program specialist.

At the conclusion of the on-site review, the CFIA provides a verification report including any non-compliance identified during the on-site review.

Prior to recognizing an establishment, the CFIA must confirm that all non-compliance has been corrected by the establishment.

4.2.6 CFIA notification recognizing establishment's FSEP/HACCP status.

The Area FSEP Coordinator issues an official notice to the establishment's management confirming that the CFIA has reviewed the establishment's HACCP system and found that it currently meets all of the HACCP requirements of the Food Safety Enhancement Program.

Section 5 - Changes to a recognized HACCP System

5.1 New HACCP plan

When an establishment adds a new HACCP plan to its system, this must be communicated to the responsible inspector prior to the commencement of the new process.

The responsible inspector/supervisor must communicate this information with the Area FSEP Coordinator who must conduct a review of the new HACCP plan or assign a delegate to do so. CFIA may request a review of the new HACCP plan prior to the commencement of the new process.

5.2 Changes to a HACCP system

When an establishment changes its recognized HACCP system, it must enter the changes in the HACCP log book as described in section 3.4.1 of the FSEP manual. The data must be available for future review by the CFIA.

5.3 Changes in ownership

If there is a change in ownership in a FSEP recognized establishment and the originally recognized HACCP System is intact, the new owner will be required to submit a new letter of commitment to the CFIA Area FSEP Coordinator. The letter will confirm that the originally recognized HACCP System is intact and will not be changing as a result of the change in ownership. The letter will also confirm the commitment of the new owner as per the FSEP Manual.

If changes to the HACCP system are made, the new owner will be required to submit a new letter of commitment and a list of the changes made to the HACCP system to the CFIA Area FSEP Coordinator. The CFIA will evaluate the impact of the changes on the HACCP system and determine if the establishment has to undertake a new recognition process.

Section 6 – CFIA Verification of FSEP Voluntarily Recognized Establishments

This section describes the necessary information for industry about the CFIA verification of FSEP voluntarily recognized establishments. For establishments registered under the Meat Inspection Regulations, in which a HACCP system in accordance with the FSEP Manual requirements is mandatory, please refer to the Meat Hygiene Manual of Procedure – Chapter 18 (Compliance Verification System).

Note: FSEP voluntarily recognized establishments will continue to be inspected for compliance with requirements defined in applicable Acts and Regulations as per specific commodity inspection programs. The verification of compliance to FSEP requirements described in this section is in addition to the commodity inspection programs.

6.1 Objective

The objective of the verification by the CFIA is to confirm that the establishment's recognized HACCP system:

- Is up-to-date;
- Has been effectively reassessed;
- Meets the FSEP requirements;
- Is implemented as described;
- Is supported by Senior Management.

6.2 Frequency of verification

The verification frequency is once every two years and whenever the following situations occur.

- Submission of new HACCP plans.
- Follow-up after a food safety recall.
- When inspection results demonstrate that the establishment does not control the food safety related regulatory requirements.

6.3 Verification scope

The verification scope may include a review of:

- The HACCP system performance reporting process;
- The HACCP plan(s);
- The prerequisite programs ;
- The maintenance and reassessment procedures.

The scope selection will be based on CFIA inspection results and situations that have occurred at the establishment that should have resulted in an update and/or a reassessment of parts of the HACCP system by the establishment.

6.4 Opening meeting

The following information will be given and confirmed during the opening meeting with the establishment representatives:

- CFIA staff titles and roles;
- The objective and scope of the verification;
- The verification schedule and procedures;
- The date and time for the closing meeting.

6.5 Gathering objective evidence to determine compliance

The CFIA will gather objective evidence to confirm whether or not the HACCP system:

- Is up-to-date;
- Has been effectively reassessed;
- Meets the FSEP requirements;
- Is implemented as described;
- Is supported by Senior Management.

The CFIA will gather objective evidence by:

- Reviewing documentation and records;
- Observing procedures being implemented;
- Interviewing/questioning designated employees.

6.6 Communication of results and actions required

Results of the verification are communicated to the establishment through a verification report during the closing meeting.

The verification report includes the following information:

- Scope of the verification
- Corrective Action Request(s) (CAR)
- Conclusions (overall comments on the result of the verification)

A CAR is issued to an establishment whenever non-compliance is determined by the CFIA. The CAR identifies the non-compliance and requires the establishment to implement corrective measures by:

- Providing an acceptable action plan by a specified date;
- Effectively implementing the corrective and preventative measures as described in the action plan by a specified date.

6.7 Request for review of a CAR

An establishment may request a review of a CAR before the date specified for the submission of an action plan. The establishment must submit its reason for the request in writing, to the Area FSEP Coordinator. A written decision is forwarded back to the establishment.

If the CAR is upheld, the establishment must submit an acceptable action plan and correct the non-compliance noted by the dates specified by the CFIA.
If the CAR is overturned, the CAR will be cancelled.

6.8 Acceptable action plan

An acceptable action plan is to be submitted by the establishment to the CFIA on the

date specified when the CAR was issued. The entire action plan must be implemented by the establishment by the specified date for completion of corrective measures stated on the CAR.

The following table describes each component of an acceptable action plan as well as the objectives of each component.

Component 1 Description of the problem	The objective is to accurately describe the problem, which will assist to identify the: o Action to be taken on affected or potentially affected product. o Immediate measures necessary to restore control of the deviation. o Root cause(s). Establishments must collect information to find out the exact problem. One situation of non-compliance is typically the result of multiple problems or causes. o What is the non-compliance? o Did the problem affect product? o Where is the problem located? o How widespread is this problem? o When did the problem occur? o Who is involved in this problem? o Is this the first time the problem occurred? **Written Action Plan** o Describe the problem as it relates to the non-compliance noted on the CAR.
Component 2 Person(s) responsible for measures	The objective is to determine the people who have the knowledge, time, authority and competence to correct the non-compliance. **Written Action Plan** Identify the name or title of person(s) responsible for the immediate/short term and preventative measures.
Component 3 Description of Immediate /short term measures	The objectives are to: o Control affected product or other thing(s). o Take immediate measures to restore control over the deviation so that food products are produced within the legislative requirements. **Written Action Plan** o Describe the measures taken on affected or potentially affected product. o Describe the results of the assessment completed to determine if other products were implicated. o Describe the food safety assessment performed or to be performed on the affected or potentially affected product including any disposition of product. o Describe the immediate / short term measures taken to restore control over the deviation until permanent/preventative measures are planned and implemented. o Describe the procedure to verify the effectiveness of immediate/short term measures taken. Note: Depending on the non-compliance, immediate measures may not be required.
Component 4 Identification of root cause(s)	The objective is to identify the root cause(s) so establishments can form appropriate and comprehensive corrective measures that will prevent the recurrence of the deviation. Start with the problem description o Why has the CFIA found the deviation and not the establishment?

	o Identify all potential causes (Environment, Equipment, Personnel, Training, Written Programs, etc). o Some causes have already been corrected by immediate measures. o Identify the root cause(s). **Written Action Plan** Describe root cause(s).
Component 5 Description of Preventative measures	The objective is to identify and implement measures to eliminate the root cause(s) and prevent recurrence of the deviation. **Written Action Plan** o Describe the preventative measures. o Establish a date for completion of each planned preventative measures.
Component 6 Description of activities planned to verify the effectiveness of preventative measures	The objective is to provide feedback as to whether or not further adjustment is necessary. The assessment is the application of temporary procedures, tests or other evaluations to determine the effectiveness of the measures taken to correct the problem. Examples o On-site assessment of measures taken. o Ensuring that staff is adhering to new procedures/instructions by observing and interviewing them. o Temporarily increasing sampling. o Temporarily increasing monitoring procedures. If the problem is not resolved: o Additional corrective measures are required. **Written Action Plan** o Describe the activities planned to verify the effectiveness of preventative measures. o Establish a date for completion.

6.9 Action plan extension

The CFIA may grant an extension to the specified date for completion of the action plan under the following circumstances:

- Food safety is not compromised;
- The establishment will not meet the specified date for completion of corrective actions due to reasons beyond its control;
- The establishment submits a written request for an extension before the specified date for completion of the action plan;
- The written request includes the reason for the extension request and the proposed new completion date.

The establishment must submit its reasons, in writing, to the CFIA responsible inspector.

6.10 CFIA follow-up

After the date for completion of corrective measures has passed, the CFIA follows up at the establishment to ensure that the corrective measures have been completed as described and are effective. If the corrective measures have been implemented effectively, the CAR is closed. If the corrective measures have not been effectively

implemented, the CAR remains open and the CFIA takes the following actions:

- A warning letter is sent to the establishment's management.
    - The warning letter informs the establishment that a failure to implement effective corrective measures by the date specified in the warning letter will result in the loss of HACCP recognition.
- A follow-up evaluation of corrective measures is conducted after the date specified in the warning letter.
- If the corrective measures have been implemented effectively, the CAR is closed.
- If the corrective measures have not been implemented effectively, the establishment will lose HACCP recognition.

6.11 Loss of recognition

Loss of recognition will render the establishment ineligible for FSEP verifications. In this case, the establishment will no longer be eligible to use any labels or advertising associated with HACCP or make claims regarding HACCP recognition.

When an establishment loses recognition, the CFIA Area FSEP Coordinator sends a letter to the establishment's management informing them that the establishment is no longer recognized under FSEP. This letter voids the original recognition letter.

Following loss of recognition, if an establishment wishes to re-apply for recognition, they shall investigate to determine the root cause(s) of the failure of their HACCP system and implement corrective measures. The results of the investigation and the corrective measures taken shall be documented in the new letter requesting recognition by the CFIA.