Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Enhancement Program Manual

Canada

The Food Safety Enhancement Program (FSEP) Manual has been prepared in order to provide assistance to:

- the workforce of the Canadian Food Inspection Agency (CFIA)
- the management and employees of the food industry

Table of Contents

Page

Appendices

Glossary of Terms

Agency – The Canadian Food Inspection Agency (CFIA).

Agri-food product – Any meat, fruit, vegetable, egg, dairy, honey or maple product that is canned, cooked, dehydrated, refrigerated or otherwise preserved.

Auditor – A person, identified by the CFIA, who has the qualifications to perform regulatory system audits.

Audit checklist – A tool prepared by the auditor(s) and listing items that the audit will assess to determine whether the written program is being implemented as described and whether it is effective.

Audit finding – The result of the evaluation, against FSEP audit criteria, of objective evidence collected during an audit.

Audit frequency – The rate at which regulatory system audits are to be conducted.

Audit observation – A deviation that is identified during an audit but has no impact on the integrity of the HACCP system. An audit observation does not necessitate a written corrective action plan.

Audit team – A group of auditors including at least the lead auditor and the inspector responsible for conducting the audit.

Closed CAR – A Corrective Action Request (CAR) that has been closed by the Agency. The Agency closes a CAR after determining that an establishment's action plan to correct the non-conformity is completed and that the corrective actions are effective.

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

Company – See "Establishment."

Corrective Action Request (CAR) – A formal request, made by the Agency to the company's management, that sets out the actions required to correct a non-conformity identified during an audit.

Critical Control Point (CCP) – A point, step or procedure at or in which control 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 limits for a critical control point, or a failure to meet a standard identified in a prerequisite program.

Deviation procedure – A pre-determined and documented set of corrective actions (immediate and preventative) 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.

Establishment HACCP coordinator – An employee responsible for liaising between the company's senior management and its HACCP team. The coordinator leads in developing, implementing and maintaining the company's HACCP system.

Follow-up regulatory system audit – An audit performed subsequent to the completion of a regulatory system audit when a major non-conformity cannot be closed.

Food Safety Enhancement Program – A CFIA approach to encourage the development, implementation and maintenance of HACCP systems in all federally registered establishments, excluding federally registered fish establishments.

Generic model – See "HACCP generic model."

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 generic model – A generalized HACCP plan, designed for a specific product or product category, that can be used as an example or guideline for developing a plant-specific HACCP plan.

HACCP plan – A written document designed in accordance with the 12 steps of FSEP (including the 7 principles of HACCP as described by Codex *Alimentarius*) in order to control hazards associated with specific processes and/or products within an establishment.

HACCP system (Hazard Analysis and Critical Control Point system) – A system that includes prerequisite programs, one or more HACCP plan(s), and reassessment procedures as defined by the Food Safety Enhancement Program (FSEP).
HACCP team – A group of employees, representing such areas as production,

sanitation, quality control, food microbiology, etc., within a company, who are responsible for assisting the HACCP coordinator in developing, implementing and maintaining the HACCP system.

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

Immediate impact on food safety – A situation where a biological, chemical or physical contamination of a food product exists, resulting in the need for immediate corrective and/or compliance action. This action may include detention of the product and/or initiation of a recall procedure.

Kill step – Any step in a process that provides a sufficient level of intervention to control microbiological organisms and/or destroy the identified pathogens.

Lead auditor – The auditor responsible for leading the audit and making final decisions regarding the outcome of the audit.

Major non-conformity – An incident putting food safety at risk, where the establishment has not taken effective corrective action and the CFIA takes regulatory compliance action on the product **or** where the establishment has failed to implement effective corrective action from a previously identified non-conformity.

Manufacturer – See “Establishment.”

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

Non-conformity (N/C) – A non-conformity is a deviation identified during an audit that has an impact on the integrity of the HACCP system and necessitates a written corrective action plan.

Objective evidence – Factual and verifiable information describing an audit finding. This may include photocopies of documents, notes made as a result of observations and interviews, etc.

Organoleptic examination – An examination involving the use of the sensory organs in evaluating foods (taste, colour, odour and feel).

Prerequisite program – Universal 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 cause of a deviation. A preventative measure includes subsequent steps required to prevent reoccurrence of the deviation.

Quality Management Program (QMP) – A fish inspection and control system that includes procedures, inspections and records, for the purpose of verifying and documenting the processing of fish and the safety and quality of fish processed in Canada.

Reassessment of a HACCP system – A company's review of its HACCP system to ensure that any routine updates or other changes (e.g. to meet regulatory requirements, improve operations or processes, add new products, etc.) have been fully analyzed and are being implemented effectively.

Regulatory requirements – All pertinent acts, regulations, manuals of procedures and directives.

Regulatory system audit – A systematic assessment by the CFIA of an establishment's ongoing conformance to its HACCP system.

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.

Standard – Criteria or specifications that can be judged or evaluated and that define the limit of acceptability associated with prerequisite programs and/or a Regulatory Action Point (RAP).

Validation – The obtaining of evidence showing that control measures are capable of being consistently effective. Validation is performed when new control measures or a new food safety control system is designed, or when changes indicate the need for re-validation, in order to confirm that the control measures or food safety control systems, when implemented as intended, are capable of controlling the hazard to the appropriate level and that this level of control can be achieved consistently.

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.

List of Acronyms

AAFC - Agriculture and Agri-Food Canada

APR - Agricultural Policy Review

CAR - Corrective Action Request

CCP - Critical Control Point

CFIA - Canadian Food Inspection Agency

FSEP - Food Safety Enhancement Program

HACCP - Hazard Analysis Critical Control Point

HC - Health Canada

NASA - National Aeronautics Space Administration

N/C - Non-conformity

QA - Quality assurance

QC - Quality control

QMP - Quality Management Program

RTE - Ready-to-eat

SOP - Standard operating procedures

RAP - Regulatory Action Point

Chapter 1: Introduction and Background

Section 1 – Introduction to FSEP

The objective of the Food Safety Enhancement Program (FSEP) of the Canadian Food Inspection Agency (CFIA) is to ensure that the conditions under which food products are manufactured and the ingredients used in their manufacture lead to the production of safe food. FSEP applies to the following commodity groups: meat and poultry, dairy, processed fruit and vegetables, shell eggs, processed eggs, honey, maple, and hatcheries.

The safety of food products produced in Canada is ultimately the responsibility of the food industry. Food inspection programs administered by the CFIA confirm that establishments have taken the appropriate steps to produce safe food products.

In the past, food manufacturers relied almost entirely on end-product testing to determine the safety of their products. Now, industry representatives and government together have developed scientifically sound principles to control production. These principles allow operators to react quicky to hazards that arise during production. As scientific developments continue in the areas of food production and inspection, Canadian regulatory programs will evolve accordingly.

Hazard Analysis Critical Control Point (HACCP) was conceived in the 1960s when the US National Aeronautics and Space Administration (NASA) asked Pillsbury to design and manufacture the first foods for space flights. Since then, HACCP has been recognized internationally as a logical tool for adapting traditional inspection methods to a modern, science-based, food safety system. Based on risk-assessment, HACCP plans allow both industry and government to allocate their resources efficiently in establishing and auditing safe food production practices.

FSEP encourages establishments to adopt HACCP principles. An establishment's HACCP system includes its HACCP plans and prerequisite programs as well as procedures for the reassessment of the HACCP system.

The HACCP system prevents food safety problems by providing control throughout the manufacturing process at critical steps identified as Critical Control Points (CCPs). These points permit operators to detect and control hazards before products are distributed.

Under FSEP, establishments are required to monitor and verify manufacturing processes, maintain records of their HACCP system and update the HACCP system regularly. Although FSEP focusses on food safety issues, other non-food safety regulatory requirements and obligations will continue to be monitored by the CFIA.

Section 2 – Benefits of FSEP

2.1 International and national

2.1.1 International acceptance

Internationally, FSEP is consistent with the principles and application of the Hazard Analysis Critical Control Point (HACCP) system developed by Codex *Alimentarius*. As HACCP systems are accepted worldwide, FSEP will help the Canadian industry to maintain and expand its international markets.

2.1.2 National acceptance

FSEP meets national expectations that HACCP principles would be included in food safety programs. 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.

2.2 Industry and government

2.2.1 Responsibilities

FSEP clearly delineates the responsibilities of both government and industry for the production of safe food in Canada. While establishments are responsible for the food that they produce and market, the government oversees industry compliance with regulatory requirements.

2.2.2 Communication

In developing and implementing FSEP, the industry and the CFIA have had to communicate on an ongoing basis. This practice involves both informal and formal methods as the Agency evaluates HACCP systems.

2.2.3 Resources

FSEP allows government to use risk-management techniques in which the government allocates its resources proportionately to low-risk and high-risk establishments, on the basis of product type and establishment complexity. By focussing on food processing establishments or production lines that are considered higher risk, the CFIA and industry will use resources more effectively.

2.2.4 Product recall/destruction

FSEP improves employee awareness and responsibility by ensuring a rapid and efficient response to deviations at Critical Control Points. On-line monitoring throughout the production process results in fewer recalls and/or reduced product destruction.

2.2.5 Equivalency

With the implementation of FSEP, the Agency is able to negotiate the acceptance of equivalent food safety programs with other governments in Canadian export markets. It may be possible to come to agreements with specific trade partners to reduce requirements for direct inspection control over certain products.

Section 3 – Background

In 1986, after considering the Nielsen Report recommendations, the federal Cabinet concluded that Canada's food inspection system is effective and warrants a high degree of confidence among Canadians. Cabinet reconfirmed Agriculture Canada as the primary regulatory contact for food manufacturers that fall under the authority of the *Canada Agricultural Products Act*, and asked Agriculture Canada to focus on food safety in addition to food quality and to work more closely with other federal agencies responsible for food inspection (Health and Welfare Canada, Fisheries and Oceans Canada, and Consumer and Corporate Affairs Canada). To this end, the federal departments concerned with food safety agreed to establish minimum federal food safety inspection standards based on HACCP principles. These were to be applied in all registered and non-registered food processing establishments.

In its 1988 report on the Food Production and Inspection Branch of Agriculture Canada, the Office of the Auditor General made specific recommendations concerning inspection and food safety. The following are excerpts from its summary of the Main Points section:

- The Branch shares responsibility with industry and with provincial and other federal departments for the safety, health and wholesomeness of agricultural food products. It conducts a wide range of activities to protect the health and safety of Canadians and the viability of large sectors of Canada's food, plant and animal industries. Work remains to be done to fully determine which risks are most serious, so resources can be better concentrated where risk is greatest. (paragraph 8.2)

- The Branch needs to strengthen several key inspection practices to provide reasonable assurance that human health and safety threats posed by chemical and bacterial hazards associated with food and agricultural products are prevented or removed. Although it does extensive sensory inspections, it needs to use additional laboratory testing, generally the only way of detecting these hazards. (paragraphs 8.26 to 8.40 and 8.44 to 8.48)

The Department's Agricultural Policy Review (1989) confirmed that, in the minds of consumers, food safety ranks as very important. The review concluded that:

- responsibility for food safety must be shared by all participants in the food chain, including processors and consumers;

- Canada's food inspection system should adopt an open model, enabling consumers and industry to become directly involved; and

- to maintain consumer confidence, Canada should adopt internationally recognized food safety standards focussing on food safety risk assessment.

The Food Production and Inspection Branch of Agriculture Canada responded to the program review with the announcement of the Food Safety Enhancement Program (FSEP). This program translates the recommendations into practical terms, with the focus on food safety. It is consistent with international trends, emphasizing cooperation between government and industry, whose members are ultimately responsible for the safety of their own products.

The Agricultural Policy Review (APR) outlined the department's strategic priorities and the pillars of reform. These included the following:

- more market response
- greater self-reliance in the agri-food sector
- regional diversity
- an increase in environmental sustainability

The following initiatives resulted from the Review:

- Fisheries and Oceans Canada developed the Quality Management Program (QMP), based on HACCP principles. The QMP was subsequently implemented in all that department's registered establishments.

- Agriculture Canada developed the Food Safety Enhancement Program (FSEP), which incorporated HACCP principles. Pilot projects and expert committees were used to develop generic models to guide both industry and government.

- Federal departments developed a common approach for inspection activities in both registered and non-registered establishments. These principles were incorporated into FSEP.

In 1997, the food inspection components of Agriculture and Agri-food Canada, Health Canada and Fisheries and Oceans were amalgamated to create the Canadian Food Inspection Agency (CFIA). Responsibility for implementing FSEP and the QMP was transferred to the Agency.

Section 4 – Public perception of food safety

The food inspection programs provided by the Canadian Food Inspection Agency have evolved into a highly respected, multi-faceted service to industry and consumers that has earned international acclaim. These programs have come under scrutiny as a result of two factors: consumers' concern about the food they eat, and government's decision to use resources where risks are greatest.

The CFIA works jointly with international and domestic governments and industry to implement a food safety enhancement program that is based on HACCP principles as outlined by Codex *Alimentarius*.

Section 5 – FSEP and the marketplace

To maintain or expand its international trade markets, Canada must meet the standards and trade requirements of foreign countries (HACCP). The CFIA, in cooperation with industry, communicates proactively with these countries to ensure their acceptance of FSEP as equivalent to their own standards.

To maintain or expand their domestic markets, establishments will have to meet the expectations of consumers, who demand a safe food product. By implementing FSEP, federally registered establishments demonstrate to consumers their commitment to using the most effective food safety system available.

Section 6 – Program description

FSEP encourages all federally registered establishments, with the exception of fish and seafood establishments, to develop, implement and maintain a HACCP system.

FSEP takes a preventative approach to controlling food safety. It applies control throughout the food manufacturing process, while ensuring that all food safety regulations are being met.

Most companies will find that many of the controls required in a HACCP system are already in place and operating in their establishments.

HACCP plans must follow seven basic principles:

1) List the hazards associated with each step and incoming materials.
2) Apply the HACCP decision tree to determine CCPs.
3) Establish critical limits.
4) Establish monitoring procedures.
5) Establish deviation procedures.
6) Establish verification procedures.
7) Establish record keeping and documentation for Principles 1 through 6.

6.1 References

For more details, please refer to the following documents:

- *Recommended International Code of Practice General Principles of Food Hygiene*, developed by Codex *Alimentarius*
- *HACCP Principles and Application Guidelines*, developed in 1997 by the National Advisory Committee on Microbiological Criteria for Foods
- *Developing HACCP Plans*, published by the International Association for Food Protection

Section 7 – Program responsibilities

Under FSEP, members of the food industry are responsible for designing and implementing their HACCP systems. The role of the CFIA is to define the requirements in consultation with the food industry and to verify the effectiveness of the HACCP system in each federally registered establishment.

Industry is responsible for:

- providing a corporate commitment to HACCP;
- developing and implementing prerequisite programs, HACCP plans and HACCP system reassessment procedures;
- maintaining the necessary records;
- ensuring that appropriate staff are trained in their areas of responsibility;
- submitting any new HACCP plans to the CFIA for review; and
- providing necessary assistance to CFIA staff during the recognition process and during subsequent system audit activities.

The Canadian Food Inspection Agency is responsible for:

- recognizing establishments;
- auditing establishment records;
- assessing corrective actions taken by establishments;
- observing on-site monitoring and verification activities;
- ensuring that establishments continue to maintain their HACCP systems; and
- ensuring that establishments comply with all acts, regulations and program requirements.

Chapter 2: Developing a HACCP System

Section 1 – Purpose of Chapter 2

Chapter 2 provides personnel in both industry and government with guidelines for the development of HACCP systems.

> **Please note:** throughout Chapter 2, the personal pronoun "you" refers to designated personnel in a registered establishment.

Section 2 – Prerequisite programs

Prior to developing HACCP plans, each company must develop written prerequisite programs, monitor them and verify that they are effective in meeting all regulatory and program requirements.

Your company will need to designate someone to develop and evaluate its prerequisite programs. You may wish to assemble a HACCP team for this task. (Please see the guidelines for the assembly of a HACCP team, Section 4.1 of this chapter.)

Prerequisite programs comprise universal steps or procedures to control the operational conditions within a food establishment. They promote environmental conditions that are favourable to the production of safe food.

Begin by reviewing your company's existing programs to determine whether they meet all prerequisite program requirements and whether they include all the necessary controls and documentation (e.g. monitoring, deviation and corrective actions, verification procedures and record keeping). See Guidelines for a Complete Written Program, Appendix VI.

Once your prerequisite programs have been developed and implemented, your establishment may use the FSEP Prerequisite Program Checklist (Appendix II) to perform an internal audit (also called a self-evaluation) of the prerequisite programs.

During the self-evaluation, written and on-site, note any deficiencies you observe. Arrange to correct these immediately and to implement preventative measures. If a deficiency cannot be corrected immediately, you will need to develop written action plans, both short- and long-term. The short-term action plan must include the establishment of a CCP or monitoring and verification procedures to ensure that the short-term corrective actions are implemented effectively. Once your plant has implemented long-term action plans and verified that they are effective, you will be able to remove the short-term CCPs or monitoring and verification procedures.

The importance of the prerequisite programs cannot be overstated. If they are not implemented properly, you will have difficulty developing an effective HACCP system.

The prerequisite program requirements below (recommended by Codex *Alimentarius*) are generic. Your establishment will need to ensure that the criteria in these programs (including regulatory requirements) are being met within the plant environment.

Each prerequisite program is structured according to the following example:

A	Program (e.g. Premises)
A 1	Element (e.g. Building Exterior)
A 1.1	Sub-element (e.g. Outside Property and Building)
A 1.1.1	Bullet (e.g. Building facility not located close to any environmental contaminants and the surroundings/ roadways are free of debris and refuse, adequately drained and maintained to minimize environmental hazards)

You may use Appendix II to assess the completeness of each written program. Conduct your final assessment at the sub-element level for each prerequisite program. The CFIA will use Appendices II and VI to audit your prerequisite programs.

The six prerequisite programs include the following:

A Premises

A 1 Building Exterior

- A 1.1 Outside Property and Building

A 2 Building Interior

- A 2.1 Design, Construction and Maintenance
- A 2.2 Lighting
- A 2.3 Ventilation
- A 2.4 Waste Disposal
- A 2.5 Inedible Areas

A 3 Sanitary Facilities

A 3.1 Employee Facilities

A 3.2 Equipment Cleaning and Sanitizing Facilities

A 4 Water/Ice/Steam Quality and Supply

A 4.1 Water/Ice/Steam

B Transportation, Receiving and Storage

B 1 Transportation

B 1.1 Food Carriers

B 1.2 Temperature Control

B 2 Receiving and Storage

B 2.1 Incoming Material Receiving and Storage

B 2.2 Non-Food Chemical Receiving and Storage

B 2.3 Finished Product Storage

C Equipment

C 1 General Equipment

C 1.1 Equipment Design and Installation

C 1.2 Equipment Maintenance and Calibration

D Personnel

D 1 Training

D 1.1 General Food Hygiene Training

D 1.2 Technical Training

D 2 Hygiene and Health Requirements

D 2.1 Cleanliness and Conduct

D 2.2 Communicable Diseases and Injuries

E Sanitation and Pest Control

E 1 Sanitation

E 1.1 Sanitation Program

E 2 Pest Control

E 2.1 Pest Control Program

F Recalls

F 1 Recall System

F 1.1 Recall Program
F 1.2 Product Code Identification and Distribution Details

Use the criteria outlined in each of the sub-elements below, and any commodity-specific program requirements, to develop your company's written prerequisite programs. You must meet all the requirements outlined in Guidelines for a Complete Written Program, Appendix VI. You may also use Appendix V, Prerequisite Program Generic Model, as a template for developing your prerequisite programs.

A Premises

Building and surroundings are designed, constructed and maintained in a manner to prevent conditions that may result in the contamination of food. "Premises" includes all elements in the building and building surroundings: the outside property, roadways, drainage, building design and construction, product flow, sanitary facilities, and water/ice/steam quality and supply.

A 1 Building Exterior

A 1.1 Outside Property and Building

Land is free of debris and refuse and is not close to environmental contaminants (e.g. objectionable odours, smoke, dust or other contaminants).

Roadways are properly graded, compacted, dust proof and drained. Premises, shipping and receiving areas provide or permit

good drainage.

Buildings are of sound construction, are maintained in good repair, and do not present any chemical, biological or physical hazards to the food. Each building is designed to:

- provide suitable environmental conditions;
- allow adequate cleaning and sanitation;
- minimize contamination by extraneous materials;
- prevent access by pests; and
- provide adequate space for conducting all operations.

The construction and layout of buildings reflect the approved blueprints, where applicable.

A 2 Building Interior

A 2.1 Design, Construction and Maintenance

Floors, walls and ceiling materials (as well as various coatings and joint sealants) are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products, published by the Canadian Food Inspection Agency. If this is not the case, the manufacturer must obtain a “letter of no objection” from Health Canada.

Where required or appropriate, areas of the establishment are provided with conveniently located hands-free handwash stations. Waste pipes connected to handwash stations are adequately trapped. Sanitizer hand-dips are available, where appropriate.

Floors, walls and ceilings are constructed of material that is durable, smooth, cleanable and suitable for the production conducted in the area. Where appropriate, joints are sealed and angles are coved to prevent contamination and to facilitate cleaning. Floors are sufficiently sloped for liquids to drain to trapped outlets.

Windows are sealed or equipped with close-fitting screens. Where it is possible that glass windows might break and glass particles might contaminate the food, windows are constructed of alternate materials or are adequately protected.

Hygienic operations are promoted throughout the facilities by means of a regulated flow in the process, from the arrival of raw

material to the final product. Physical or operational separation occurs to prevent contamination of food via employee traffic patterns, product flow and equipment. The traffic pattern of personnel and visitors prevents cross-contamination of food products. Blueprints or drawings are available as required.

Living quarters, and areas where animals are kept, are separated and do not open directly into food handling, processing or packaging areas. Incompatible operations are physically and operationally separated to prevent cross-contamination of food.

A 2.2 Lighting

Lighting is appropriate, permits the intended production or inspection activity to be conducted effectively, and does not alter food colour. Lux requirements meet the respective program standards.

In areas containing exposed food or packaging materials, light bulbs and fixtures are of a safety-type or are protected in order to prevent contamination of food in case of breakage.

A 2.3 Ventilation

Ventilation prevents build-up of heat, steam, condensation or dust and removes contaminated air. In microbiologically sensitive areas, positive air pressure is maintained. Ventilation openings are equipped with tight-fitting screens or are otherwise protected with non-corrodible material. Air intakes are located to prevent the entry of contaminated air. Air used as a processing technique (e.g. pneumatic conveying, air agitation, air blows, air dryers, etc.) is appropriately sourced and treated (air intakes, filters, compressors) to reduce any source of contamination.

A 2.4 Waste Disposal

Drainage and sewage systems are equipped with appropriate traps and vents. Establishments are designed and constructed to prevent cross-connection between the effluent of human wastes and any other wastes in the establishment. No drainage pipes pass directly over or through production areas, unless they are controlled to prevent contamination.

Facilities are provided for the storage of waste and inedible

material prior to their removal from the establishment. These facilities are designed to prevent contamination.

Containers used for waste are clearly identified and are leak proof.

A 2.5 Inedible Areas

A separate facility is provided for cleaning and sanitizing all equipment used for inedible materials.

A sufficient number of inedible areas are provided and are located, ventilated and refrigerated (where necessary) in such a way as to prevent cross-contamination of edible products.

Inedible products are isolated and denatured as per program requirements.

A 3 Sanitary Facilities

A 3.1 Employee Facilities

Washrooms with self-closing doors are provided. Washrooms, lunchrooms and change rooms are adequately ventilated and maintained. They are separate from and do not lead directly into food processing areas.

Washrooms have handwash facilities with a sufficient number of maintained sinks that are properly trapped to drains. Handwash facilities are adequately maintained and have hot and cold running potable water, soap, sanitary hand-drying supplies or devices, and, where required, a cleanable waste receptacle.

Handwash stations, hand dips and footbaths are maintained in all applicable areas of the facility.

Notices to wash hands are posted at all handwash stations.

A 3.2 Equipment Cleaning and Sanitizing Facilities

Equipment cleaning and sanitizing facilities are constructed of corrosion-resistant materials that can be cleaned easily. Potable water is provided at temperatures appropriate for the cleaning chemicals used.

Equipment cleaning and sanitizing facilities are adequately separated from food storage, processing and packaging areas to prevent contamination of food.

A separate facility is provided for cleaning and sanitizing equipment used for inedible materials. Where required, cleaning and sanitizing equipment is designed for its intended use and is properly maintained.

A 4 Water/Ice/Steam Quality and Supply

A 4.1 Water/Ice/Steam

Water meets the requirements of Health Canada's Guidelines for Drinking Water Quality. Water from sources other than municipal supplies must be treated as necessary and tested to ensure potability.

Water, ice and steam are analyzed by the establishment at a frequency adequate to confirm their potability, or as per regulatory and program requirements. Records of water and ice potability include:

- the water source sampling site
- the analytical results
- the analyst's name
- the date of the analysis

Records of water potability, and of the water treatments applied, are maintained, filed, and made available upon request.

Boiler treatment chemicals used are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products, published by the Canadian Food Inspection Agency, or the establishment has a "letter of no objection" from Health Canada.

Steam coming into direct contact with food or food contact surfaces is generated from potable water with no harmful substances added. Steam supply is adequate to meet operational requirements.

Only potable water is used in all food processing, handling, packaging or storage areas. No cross-connections occur between potable and non-potable water supply systems. Hoses, taps,

cross-connections or similar sources of possible contamination are equipped with backflow prevention devices, if required.

In areas for food processing, handling, packaging and storage, water temperatures and pressures are adequate for all operational and clean-up needs.

Where water filters are used, they are changed or maintained effectively as required.

Where required, facilities for storage and distribution of water (e.g. water storage tanks) protect the water from contamination.

The treatment process for and the use of recirculated water has been accepted by the regulatory agency having jurisdiction. Recirculated water is treated and maintained in a condition such that no health hazard results from its use. Recirculated water has a separate distribution system, which is readily identified in the facility.

Water treatment chemicals are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products, published by Canadian Food Inspection Agency, or the establishment has a “letter of no objection” from Health Canada.

Ice used as an ingredient or coming into direct contact with food is made from potable water and is handled and stored to protect it from contamination.

B Transportation, Receiving and Storage

The establishment ensures that incoming material (raw material, ingredients, livestock, hatching eggs, chicks, packaging material, returned finished product, food and non-food chemicals) are transported, received, stored and handled in a manner to prevent chemical, physical or microbiological contamination of food.

Effective measures are taken by the establishment to prevent contamination of raw materials, ingredients and packaging materials.

The establishment does not accept incoming materials if they are known to be contaminated with the following:

- parasites
- undesirable microorganisms
- pesticides
- veterinary drugs
- toxic substances
- decomposed or extraneous matter

However, the establishment may accept contaminated materials if, through sorting and/or processing, it has the ability to reduce these contaminants to an acceptable level.

Where required, the establishment obtains certificates of analysis and/or letters of guarantee to ensure that its purchasing specifications are being met.

B 1 Transportation

B 1.1 Food Carriers

The establishment verifies that carriers are suitable for transporting food. Upon receiving goods or prior to loading goods for shipment, the establishment inspects carriers to ensure that they are free from contamination and suitable for transporting food.

Where appropriate, materials used in carrier construction are suitable for contact with food. The establishment has a program in place to verify the adequacy of cleaning and sanitizing of all carriers.

Carriers are loaded, arranged and unloaded in a manner that prevents damage to and contamination of food. Finished products are transported under conditions that prevent biological, physical and chemical contamination of food.

Incoming materials are received in an area separate from the processing area(s).

B 1.2 Temperature Control

Materials requiring refrigeration (both incoming materials and finished products) are transported at a regulated and/or acceptable temperature and are appropriately monitored.

Frozen ingredients and frozen finished products are transported at temperatures that do not permit thawing.

B 2 Receiving and Storage

B 2.1 Incoming Material Receiving and Storage

This section covers incoming materials, finished products (including returned goods) and non-food chemical products.

The establishment keeps on file all letters of guarantee required to certify that incoming materials meet its purchasing specifications.

Materials are inspected at receiving, where possible, to confirm that they meet purchasing specifications. Where organoleptic inspections or temperature readings are not possible for these materials, certificates of analysis or supplier audits can be used to verify the letters of guarantee.

Incoming materials that require refrigeration are stored at regulated and/or acceptable temperatures and are appropriately monitored.

Frozen ingredients are stored at temperatures that do not permit thawing.

Incoming materials are handled and stored in a manner to prevent damage and/or contamination.

Ingredients and, where appropriate, packaging material are rotated according to age to prevent deterioration and spoilage.

Incoming materials that are sensitive to humidity are stored under appropriate conditions to prevent deterioration.

B 2.2 Non-Food Chemical Receiving and Storage

Chemicals are received and stored in a dry, well-ventilated area that is separate from all food handling areas. Non-food chemicals are stored in designated areas such that no possibility exists for cross-contamination of food or food contact surfaces. Where required for ongoing use in food handling areas, chemicals are stored in a manner that prevents contamination of food, food contact surfaces or packaging materials.

Chemicals are stored and mixed in clean, correctly-labelled containers and are dispensed by trained, authorized personnel.

All non-food chemicals used are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products, published by the Canadian Food Inspection Agency, or the establishment has a “letter of no objection” from Health Canada.

B 2.3 Finished Product Storage

Finished products are stored and handled under conditions that prevent deterioration.

Stock rotation is controlled to prevent deterioration and spoilage.

Returned, defective or suspect products are controlled, clearly identified, and isolated in a designated area until they can be disposed of appropriately.

Finished products are stored and handled in a manner that prevents damage (e.g. stacking heights are controlled and forklift damage is prevented).

C Equipment

Equipment and containers used in the establishment are designed and constructed so as to ensure that they can be adequately cleaned, disinfected and maintained to avoid the contamination of food.

C 1 General Equipment

C 1.1 Equipment Design and Installation

Equipment and/or utensils are designed, constructed and installed so as to ensure that they are:

- capable of delivering the requirements of the process (e.g. pasteurization, thermal processing, etc.); and
- accessible for cleaning, sanitizing, maintenance and inspection.

Adequate space is provided within and around equipment to prevent contamination of food products during operations. Where appropriate, equipment is properly drained and connected directly to drains.

Equipment is designed so that all food contact surfaces are smooth, non-corrosive, non-absorbent, non-toxic and free from pitting, cracks and crevices.

All chemicals, lubricants, coatings and paints used on equipment that comes into contact with food are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products, published by the Canadian Food Inspection Agency, or the establishment has a “letter of no objection” from Health Canada.

Where required, equipment is properly vented. Equipment is maintained in a clean and sanitary manner in accordance with the company’s sanitation program.

Equipment and utensils used to handle inedible material are not used to handle edible material.

C 1.2 Equipment Maintenance and Calibration

Any equipment that has an impact on food safety functions as intended and does not introduce hazards into the operation. The establishment’s preventative maintenance program ensures that equipment functions properly.

The establishment maintains a list of all equipment that requires regular maintenance. It also sets out procedures and frequencies for each maintenance task (such as equipment inspection, adjustment and part replacement, etc.). These are based on the equipment manufacturers’ instructions. In cases where the manufacturers’ instructions are less rigorous or more demanding than warranted by the establishment’s operating conditions, the establishment sets out maintenance procedures and frequencies adequate for the production of safe food.

The establishment has a calibration program for all equipment that affects food safety. For equipment requiring calibration (e.g. thermometers, pH meters, a_w (water activity) meters, refrigeration unit controls, pasteurizers, scales, recording charts,

hygrometers, etc.), the establishment details calibration procedures and provides a schedule of frequencies associated with each calibration task.

D Personnel

The personnel program ensures that employees follow safe food handling practices. The program:

- sets out how the establishment trains personnel; and
- verifies the effectiveness of that training.

D 1 Training

D 1.1 General Food Hygiene Training

The establishment trains employees in appropriate personal hygiene and hygienic handling of food. Training in food hygiene is provided at the beginning of employment and is reinforced and updated at appropriate intervals.

D 1.2 Technical Training

The establishment provides technical training appropriate for the complexity of the manufacturing process and the tasks assigned. For example, personnel learn:

- the importance of the CCPs for which they are responsible;
- applicable critical limits;
- procedures for monitoring the program;
- action to be taken if critical limits are not met; and
- procedures for completing records.

Personnel responsible for maintaining and calibrating equipment that affects food safety have been appropriately trained to perform these functions. These employees are able to identify deficiencies that affect food safety and to take the necessary corrective actions.

Personnel and supervisors responsible for the sanitation program are trained to understand the principles governing and the methods required for effective cleaning and sanitizing.

The establishment keeps its employees' knowledge up to date

through additional training in process technology and new equipment operation as appropriate (e.g. specific technical training, apprenticeship programs, etc.).

D 2 Hygiene and Health Requirements

D 2.1 Cleanliness and Conduct

The establishment has and enforces a policy to ensure good personal hygiene and hygienic behaviour and habits that prevent the contamination of food products. The policy includes procedures for hand washing and/or sanitizing, protective clothing and personal hygiene.

All employees who work in food handling areas must maintain personal cleanliness.

Whenever employees enter a food production area, they must wash their hands thoroughly with soap under warm, running potable water. Hands are always washed after handling contaminated materials and after using toilet facilities. Where required, employees use disinfectant hand dips and/or footbaths.

Protective clothing, hair coverings, gloves and footwear applicable to the operation are worn and maintained in a sanitary manner.

Before any employees enter a food handling area, they remove from their person any objects that may fall into or otherwise contaminate food. Jewellery is not worn or carried into food handling areas. Jewellery that cannot be removed (medic alert bracelets, etc.) is adequately covered.

Tobacco, gum and food are not permitted in food handling areas.

Access of personnel and visitors is controlled to prevent food contamination.

D 2.2 Communicable Diseases and Injuries

The establishment requires employees to advise management when they are suffering from a communicable 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 from or be a carrier of a disease likely to be transmitted through food.

Employees who exhibit infected wounds, skin infections or sores or who suffer from diarrhea are not permitted to work in food handling areas where contamination of food may occur. Employees who have open cuts or wounds do not handle food or food contact surfaces unless the injury is completely protected by a secure waterproof covering.

E Sanitation and Pest Control

The objective of the sanitation and pest control program is to ensure that the facilities and equipment are clean and that pests are excluded from the establishment.

E 1 Sanitation

E 1.1 Sanitation Program

For each area, each piece of equipment and each utensil, the written cleaning and sanitizing program specifies the following:

- chemicals and concentrations to be used
- water temperature requirements
- procedures and frequencies for cleaning and sanitizing
- instructions for disassembling and assembling equipment

Chemicals are used in accordance with the manufacturer's instructions and are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products, published by the Canadian Food Inspection Agency, or the manufacturer has a "letter of no objection" from Health Canada.

The sanitation program is carried out in a timely manner. Food or packaging materials are not contaminated during or subsequent to cleaning and sanitizing of equipment.

The sanitation program outlines general housekeeping and special sanitation procedures to be carried out during operations (e.g. mid-shift cleanup).

The written sanitation program specifies the following:

1) The area(s) and equipment to be cleaned, the frequency and the person responsible for each

2) Instructions for cleaning the specified equipment and areas

3) The cleaning equipment to be used and the instructions for its proper operation (e.g. pressure, volume, etc.)

4) The detergents and sanitizers to be used (including commercial and/or generic names) and their concentration levels, water temperature, etc.

5) The method of applying cleaning and sanitizing solutions (e.g. contact time, foam consistency, etc.)

6) Rinsing instructions, including, if necessary, water temperature

The establishment monitors and verifies the effectiveness of its sanitation program by conducting:

- microbiological testing;
- routine sensory inspections of areas and equipment; and
- direct, on-site observation of cleaning procedures.

The sanitation program is adjusted as necessary to incorporate new cleaning procedures (e.g. new equipment, new chemicals, etc.).

The sanitation program may be used to provide control over cross-contamination issues associated with the production of non-allergenic and allergenic products.

Operations begin only after all sanitation requirements have been met (e.g. pre-operation inspection).

E 2 Pest Control

E 2.1 Pest Control Program

The establishment has a written and effective pest control program. Birds and animals other than those intended for slaughter are prevented from entering the establishment.

The written pest control program includes the following:

1) The name of a contact person for pest control at the establishment

2) The name of the pest control company, where applicable, or the name of the person responsible for the program

3) A list of chemicals and methods of application used

4) A map of pest control devices and/or bait stations

5) The frequency of inspection

6) A survey of pests and control information

Chemicals are used in accordance with the manufacturer's instructions and are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products, published by the Canadian Food Inspection Agency. Pest control chemicals are used in a manner that prevents the contamination of food.

F Recall

The recall program outlines the procedures that the establishment must implement in the event of a recall. The objective of the establishment's written recall program is to ensure that, once a food has been identified as unsafe for human consumption, it is rapidly and efficiently removed from the marketplace. The recall program must be tested periodically to validate its effectiveness (e.g. through a mock recall).

F 1 Recall System

F 1.1 Recall Program

The written recall program includes the following:

1) Documentation associated with the product coding system. Food products are identified with a production date or code that identifies each lot. The product coding system allows the establishment to trace raw ingredients, packaging materials and finished products. For each lot, the establishment records the amount of product produced.

2) Procedures for storing records of finished product distribution. Records are maintained for a period of time that exceeds the shelf life of the product and adheres to regulatory requirements. In the event of a recall, the records are effective in allowing the establishment to locate all products.

3) Procedures for maintaining the food safety complaint file. Records that document all complaints related to food safety and the actions taken are filed.

4) Identification of individuals in the recall team, including their respective telephone numbers at work and home. Each member of the recall team has a designated alternate person, whose name and contact information is included in the list. The roles and responsibilities of each team member are clearly defined

5) Step-by-step procedures to follow in the event of a recall. These procedures specify the extent and depth of the recall (e.g. consumer to retailer or wholesaler), according to the recall classification.

6) Procedures and means for notifying affected customers, according to the types of hazard involved. The instructions identify method(s) of communication (fax, telephone, radio, letter or other means) to be used to trace back and recover all affected product.

7) Control measures, including disposal, for returned product and product found in the establishment. These are described according to the type of hazard involved.

8) Procedures for assessing the progress and efficacy of the recall. The procedures specify a method (such as a mock recall) of checking recall effectiveness.

For additional information on developing a recall plan, please refer to the following CFIA Web site:

www.inspection.gc.ca/english/fssa/recarapp/rap/mg1e.shtml

Any establishment initiating a recall must notify the CFIA, as well as the regulatory agency that has jurisdiction, and provide the following information:

1) Reason for the recall, including a detailed description of the nature of the problem

2) Details of any complaints received or any illnesses reported

3) Label(s) of the product(s) recalled

4) Name, brand, size, code marks or lot numbers, establishment number (Canadian or foreign), date of production and date of importation or exportation (if applicable)

5) Amount of recalled product involved, including:

   - Total quantity of the recalled food originally in the company's possession
   - Total quantity distributed at the time of the recall
   - Total quantity remaining in the company's possession

6) Distribution of the recalled food by area, city, province and, if exported, by country. Identify all retailers and wholesalers, and provide their most up-to-date addresses and telephone numbers

7) Specific dates upon which the product was distributed

8) Details on any other product which may be affected by the same hazard

9) Name and telephone number(s) of the establishment's employee who will serve as primary contact for the CFIA

10) The name and telephone number(s) of the establishment's after-hours contact

F 1.2 Product Code Identification and Distribution Details

Each prepackaged food has permanent, legible code marks or lot numbers on the packages.

For each lot of product, the manufacturer must have:

- records of customer names, addresses and telephone numbers; and
- records of production, inventory and distribution by lot that are available for the lot tested.

Section 3 – Generic models

To help establishments develop their specific HACCP plans, the Canadian Food Inspection Agency and industry representatives have developed generic models. These models were designed by type of product or process. Individual establishments will customize the pertinent models for their own operations. Generic models are available as follows:

A. Meat and Poultry Products

1) Beef Slaughter
2) Boneless Beef
3) Cooked Sausage
4) Meat Spread (Cretons)
5) Fermented Smoked Sausage
6) Assembled Meat Product (Pizza)
7) Dried Meat (Beef Jerky)
8) Cooked/Sliced Ham
9) Ready-to-eat Poultry Products (Fully Cooked Chicken Wings)
10) Ready-to-cook Poultry Products (Chicken Breast Fillets)
11) Chinese-style Dried Sausage
12) Mechanically Separated Meat (Chicken)
13) Poultry Slaughter (Chilled Ready-to-cook Whole Chicken)
14) Hog Slaughter
15) Ready-to-cook Poultry Products (Seasoned Formed, Breaded Chicken Burger)
16) Prosciutto (Salted Ham)
17) Fresh/Frozen Stored Products (Meat, Non-meat, Food, Non-food)

B. Egg and Processed Egg

Generic models for Egg and Processed Egg are not available at this time.

C. Processed Products (fruits, vegetables, honey, maple)

18) Low-Acid Canned Food
19) Acidified Low-Acid (Pickles)
20) Frozen Vegetables
21) Aseptic Fruit Juice
22) Pasteurized Honey
23) Maple Syrup (Packer)

D. Dairy Products

24) Unsalted Butter
25) Ice Cream
26) Soft-serve Ice Cream
27) UHT Milk

E. Hatcheries

Generic models for Hatcheries are not available at this time.

3.1 How to select a generic model

The generic models can be found on the following CFIA Web site:

www.inspection.gc.ca/english/fssa/polstrat/haccp/haccpe.shtml

Your HACCP coordinator or team may select, from the list above, a model that best represents the process under review. You may need to add components from more than one model to accurately reflect your operation. (For example, your operation may include aspects similar to those in the generic models for both boneless beef and mechanically separated meat.)

3.2 Limitations of generic models

Generic models serve as guidelines for various types of processes and products. You may find one or more of them useful as a starting point or template, but your establishment must adapt them to reflect specific plant conditions. By no means do the generic models list all hazards and/or control measures associated with each type of process and/or product.

The HACCP team at each establishment is responsible for identifying and controlling all hazards specific to the establishment's food processing operation. As a result of customizing HACCP generic models, HACCP

teams may need to identify additional hazards that pertain to their establishments.

Similar considerations apply to sample flow diagrams that accompany the generic models. Your team must develop specific process flow diagrams and flow schematics to reflect the particular processes and layout of your establishment.

3.3 Products or processes not covered

Although the generic models do not cover all products and processes, the models may contain processing steps that you would find useful for the development of a HACCP plan for similar products or processes.

For products or processes that differ significantly from any available generic model, the HACCP team must ensure that they continue to follow the seven principles of HACCP.

Section 4 – Developing HACCP plan(s)

Each establishment must conduct a complete hazard analysis for all of its processes and products in order to identify and control all hazards effectively. In performing the step-by-step analysis below, you may determine that several of your 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 your establishment chooses to group dissimilar processes or products into one HACCP plan, you will be required to demonstrate to the CFIA recognition team (see Chapter 3) that the HACCP plan identifies and controls all potential hazards.

There are 12 steps to developing each of your HACCP plans; these steps incorporate the 7 principles of HACCP. These steps are as follows:

1) Assemble your HACCP team.
2) Describe your product and identify its intended use.
3) List product ingredients and incoming material.
4) Construct a process flow diagram and a plant schematic.
5) Verify, on site, your process flow diagram and plant schematic.
6) List the hazards associated with each step and incoming material in your plant's process (Principle 1).
7) Apply the HACCP decision tree to determine CCPs (Principle 2).
8) Establish critical limits (Principle 3).
9) Establish monitoring procedures (Principle 4).

10) Establish deviation procedures (Principle 5).
11) Establish verification procedures (Principle 6).
12) Establish record keeping and documentation procedures for Principles 1 through 6 (Principle 7).

FSEP has taken these 12 steps and created 10 specific forms (found at the end of this chapter) that can be used for the development of your HACCP plan.

Your company must perform a self-evaluation (internal audit) of its HACCP plan(s). You may use the FSEP/HACCP Plan Review and HACCP System Reassessment Checklist (Appendix IV). During the self-evaluation, written and on-site, note any deficiencies you observe. If a deficiency becomes known during the company's self-evaluation, either it must be corrected immediately or the company must develop a written action plan with specified time frames in which to address the deficiency.

4.1 Assemble your HACCP team

Prior to selecting the members of your HACCP team, you will need to obtain, from all levels of management, full support for the HACCP initiative. Management will demonstrate such commitment by allocating resources to develop and implement HACCP. For example, resources will be needed for training employees who are responsible for HACCP and for maintaining the HACCP system on an ongoing basis.

Assemble a team of people with the expertise necessary to develop a HACCP plan. The team should be multidisciplinary and may include representatives from production, sanitation, quality assurance, food microbiology, maintenance and engineering.

The HACCP team should include personnel who are directly involved in the daily processing activities, since they will be familiar with the variability and limitations of the operations. By including these employees in the plan's development, you will foster a sense of ownership within your establishment. Your team may also solicit assistance from independent consultants for the development of its HACCP plans. However, a plan developed totally by outside sources may lack the support required from plant personnel.

When selecting the team, choose individuals who can help identify hazards, determine CCPs, and monitor and verify CCPs.

HACCP team members should understand:

- the technology or equipment used on processing lines;
- the practical aspects of food operations;
- the flow and technology of processes;
- the applied aspects of food microbiology; and
- HACCP principles and techniques.

The remainder of this chapter describes how to complete the 10 forms that you may use for the development of your HACCP plan(s). If an establishment uses forms other than those found in this chapter, the content must be equivalent and provide sufficient detail as outlined on the FSEP forms.

4.2 Description of product and identification of intended use (Form 1)

Provide a complete description of each food product. This will help the team identify hazards inherent in either the ingredients or the packaging materials.

To adequately identify and address hazards (including those affecting sensitive segments of the population), the HACCP team must be familiar with the product's properties, destination and use.

On Form 1, describe each product listed in the HACCP plan. Provide the following information:

4.2.1 Process/product type name

Indicate the generic or common name of the product family or process covered by this HACCP plan. For example, in a dairy processing establishment, the HACCP plan for "Ice Cream" may apply to a process line for several varieties and flavours of products (ice cream, ice milk, frozen yogurt).

4.2.2 Product name(s)

List, by brand name and/or common name, the individual products covered by this HACCP plan. Attach an additional page to Form 1 if you require more space.

In the dairy example mentioned above:

- the process/product type name is “Ice Cream;”
- the product names are “Cowland’s Heavenly Hash Ice Cream,” “No Name Chocolate Ice Milk” and “Cowland's Premium Vanilla Frozen Yogurt.”

4.2.3 Important product characteristics

Indicate those properties or characteristics of the product group that affect food safety.

Formulation or process schedules for specific characteristics are referenced. In this case, any reference documents shall be made available at the time of review or subsequent audits.

4.2.4 How the product will be used

Describe the uses of your product (e.g. ready-to-eat food product, ready-to-cook food product, or ingredient for a product destined for further processing).

4.2.5 Packaging

List all types of packaging for this product (e.g. drums, pails, cryovac bags) and their applicable sizes. Include consumer-size packaging as well as bulk packs destined for further processing.

4.2.6 Shelf life

List the anticipated shelf life of the product under normal marketing conditions at a given storage temperature and humidity. The generic model may indicate an industry-accepted shelf life. Confirm its applicability to your own food products. If your product’s shelf life differs from that of the generic model, conduct validation studies to confirm the shelf life that your team has specified.

4.2.7 Where the product will be sold

List the points of sale or target groups for your product (e.g. retail – general population, retail – infant food, hospital).

4.2.8 Labelling instructions

On the form, record any safe handling and usage information concerning the product. If applicable, include cooking and storage instructions and a “best before” date.

4.2.9 Special distribution control

Describe special controls required during shipping and storage (e.g. temperature, humidity).

Product Description	**Form 1**
Process/product type name: Pork Stew	
1. Product name(s)	Pork Stew
2. Important product characteristics (a_w, pH, preservatives, etc.)	N/A
3. How the product will be used	For further processing. Will be used in a prepared meal.
4. Packaging	Bulk product packaged in plastic pails with plastic liner and sealed with tamper-evident tape.
5. Shelf life	Frozen product: 12 months if kept at -18°C or colder Refrigerated product: “X” days at 4°C or less
6. Where it will be sold	Food processing establishment
7. Labelling instructions	(Frozen product) Keep frozen Production code (Refrigerated product) Keep refrigerated “Best before” date “Ready to eat” identified on label
8. Special distribution control	(Frozen product) Refrigerated truck -18°C or colder (Refrigerated product) Refrigerated truck +4°C or less

4.3 List of product ingredients and incoming material (Form 2)

List all ingredients, incoming materials and processing aids that come in contact with the product or are used in preparing the product.

The HACCP team needs to ensure that all incoming materials and ingredients have been approved by the applicable regulatory agencies. Take particular care to check approvals for additives, processing aids and ingredients (including second generation ingredients), which are often approved for specific products only.

List of Product Ingredients and Incoming Material — **Form 2**

Product name: Pork Stew

Meat	**Non-meat ingredients**	**Packaging materials**
Pork meat Product rework	Frozen vegetables Dried oregano Salt Pepper Dried gravy preparation (dehydrated vegetables [onions, garlic], salt, wheat flour, potato starch, corn syrup solids, MSG, sugar, natural flavour, canola oil, colour, spice, modified milk ingredient, sulphites) Water	Plastic liner Plastic pails

4.4 Process flow diagram and plant schematic

4.4.1 Process flow diagram (Form 3)

Construct the process flow diagram on Form 3 using information your team has gathered through interviews, observations of operations, and other sources (e.g. blueprints). In your process flow diagram, identify each step in the process, from receiving to final shipping. Include details useful in identifying hazards. The diagram should be simple; avoid cluttering it with unnecessary details.

4.4.2 Plant schematic diagram (Form 4)

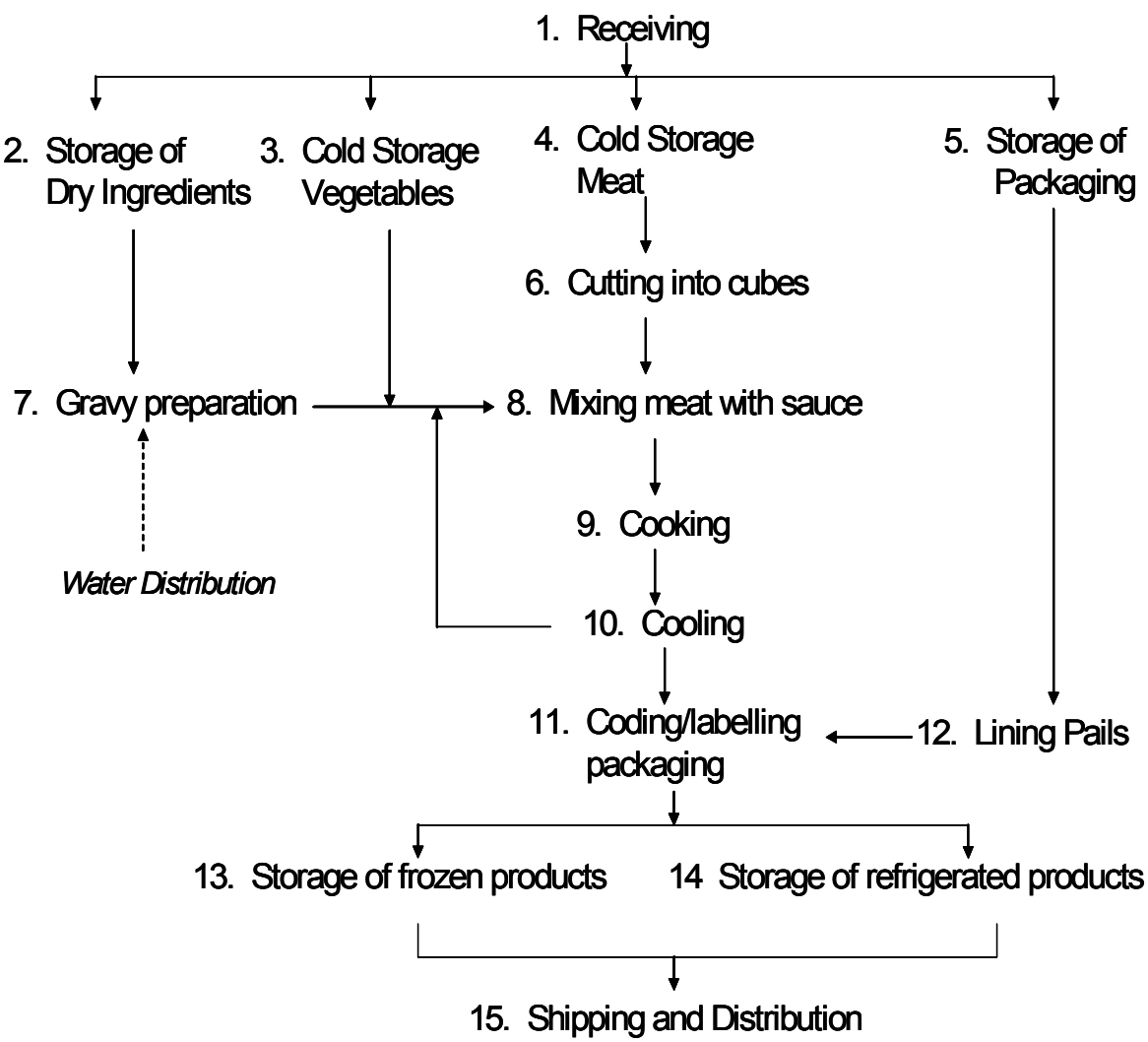
Construct the plant schematic diagram on Form 4. Indicate the flows of finished and raw products as well as employee traffic. Include the flows of all ingredients and packaging materials from the moment they are received through storage, preparation, processing, packaging, finished product holding and shipping. Indicate employee movement throughout the establishment, including change rooms, washrooms and lunchrooms. This diagram should be your primary tool for identifying potential areas of cross-contamination (e.g. locations where allergen ingredients, food additives or raw ingredients could come into unplanned contact).

4.5 On-site verification of process flow diagram and plant schematic

Once the process flow diagram and plant schematic have been drafted, conduct an on-site verification of their accuracy and completeness. Ensure that all the major process steps have been identified. Validate product and employee flows throughout the facility.

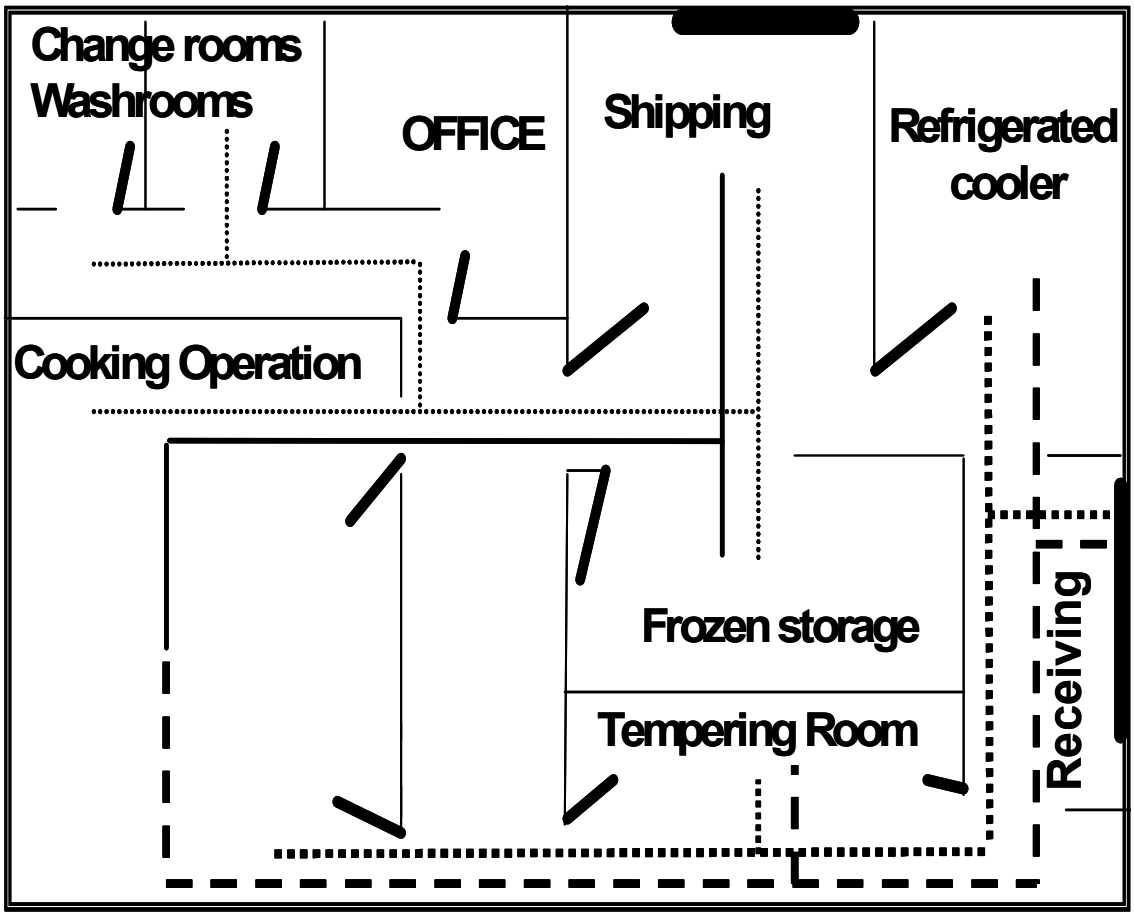
Process Flow Diagram **Form 3**

Product name(s): Pork Stew



Plant Schematic **Form 4**

Product name(s): Pork Stew



4.6 Hazard identification and analysis

Hazard identification and analysis is one of the most important steps in developing your HACCP plan. Incorrect hazard identification and analysis inevitably results in an inadequate plan. To properly identify all hazards, your team will require technical and scientific expertise in various fields.

4.6.1 Preparing for hazard identification and analysis

The first step is to conduct a brief, preparatory literature search to gain an up-to-date, scientific basis for identifying and controlling food safety hazards.

Such information is available from the following sources:

a. CFIA reference database for hazard identification
The hazard database identifies and describes hazards associated with incoming materials and process steps. Use it as a guide only, not as a substitute for expertise in your HACCP team.

b. Reference texts and scientific publications
Many reference texts and scientific publications discuss HACCP. Community colleges, universities and Internet sources (e.g. the Codex *Alimentarius* Web site) provide access to such material.

c. Industry associations
Many industry associations have developed model HACCP systems. Contact your industry association to find out what resources it offers.

Next, your HACCP team needs to review establishment-specific information pertinent to hazards in your operation. Review the complaint file and determine the causes of complaints. Review other documented production issues, such as files on production rework, returned products and recalls, etc. Interview employees who have knowledge and experience in the operation.

4.6.2 Identifying and analyzing hazards

Your team will now identify all the food safety hazards related to your establishment's operation. If the team has any doubt about whether a hazard exists at a specific point, it must conduct scientifically based validation studies for that point. Your team must always conduct hazard identification and analysis wherever a change takes place in the following:

- Building layout
- Equipment
- Raw material
- Product formulation
- Product preparation
- Processing
- Packaging
- Distribution
- Intended use of the product
- Product flow
- Employee flow

Hazards may vary from one establishment to another even when the processes are similar. Differences in sources of ingredients, formulations, equipment, plant layout, preparation and processing methods, duration of process or storage, and experience, knowledge and attitude of establishment personnel will all affect the incidence of hazards.

Identify and analyze the hazards by following the steps below:

4.6.2.1 Review incoming material

Review the product description form (Form 1) and note all product characteristics. For example, a ready-to-eat product must be pathogen-free. If the end product is not intended to be ready to eat and a further step, such as cooking, will destroy pathogens, it may be acceptable to find some bacteria in the end product.

For each incoming ingredient or packaging material, identify the biological, chemical or physical hazards directly on Form 2. Then describe each hazard fully on the following forms:

- Form 5 for biological hazards
- Form 6 for chemical hazards
- Form 7 for physical hazards

Provide detailed and complete information. Identify specific organisms and other contaminants (e.g. *Listeria monocytogenes* in incoming milk).

Answer the following questions for each incoming material:

a. Could pathogenic microorganisms, toxins, chemicals or physical objects possibly be present on or in this material? If so, note the hazard on the appropriate forms.

b. Are any returned or reworked products used as ingredients? If yes, is there a hazard linked to this practice?

c. Could any ingredients, if used in amounts lower than recommended or if left out, result in a hazard due to outgrowth of microbial vegetative or sporulated cells? If yes, note this on the biological hazard form. The opposite is also true for some ingredients (such as nitrite) where too much is a chemical hazard.

d. Does the amount and type of acid ingredients, and the resulting pH of the final product, affect the growth or survival of microorganisms?

e. Do the type of humectants and the a_w (water activity) of the ingredients have an effect on microbial growth in the final product? Do they affect the survival of microorganisms?

f. Should adequate refrigeration be maintained for products during transit or in holding?

4.6.2.2 Evaluate operations for hazards

Your team will now identify hazards related to each processing step, the product flow and the employee traffic patterns.

Directly beside each processing step on your process flow diagram (Form 3), indicate whether biological, chemical or physical hazards exist. Then describe each hazard fully on the following forms:

- Form 5 for biological hazards
- Form 6 for chemical hazards
- Form 7 for physical hazards

Provide detailed and complete information. Identify specific contaminants (e.g. metallic contaminants in food products).

Using your schematic diagram (Form 4), review product flow and employee traffic patterns. Directly on the diagram, note all hazards associated with cross-contamination. Indicate whether they are biological, chemical or physical. Then describe each hazard fully on the following forms:

- Form 5 for biological hazards
- Form 6 for chemical hazards
- Form 7 for physical hazards

Provide detailed and complete information. Identify specific contaminants (e.g. same production line being used for peanut product and non-peanut product).

Evaluate whether contaminants (e.g. allergens) could reach the product during processing. Consider factors such as employees' hands, contaminated equipment or material, and cross-contamination from such sources as raw material, leaking valves or plates, dead ends (niches), splashes, etc. Always evaluate whether microorganisms of concern may multiply to the point where they become a hazard.

4.6.2.3 Observe operating practices

To identify hazards accurately, your HACCP team must be familiar with every detail of the operation.

- Observe the operation long enough (on-site observations) to be confident that you are observing the usual process and practices.
- Determine whether the team has accurately identified all hazards associated with the process steps. (For example, observe employee hygienic

behaviour and determine whether cross-contamination may occur with hands, gloves or equipment used for finished products.)

4.6.2.4 Take measurements

To confirm actual operating conditions and hazards, you may need to measure important processing parameters. Before measuring, make sure all devices are accurate and correctly calibrated.

For example, you may need to do the following:

a. Measure product temperatures. Consider heat processing and cooling or chilling. When evaluating heat processing, take measurements at the coldest point of the product. When evaluating cooling or chilling, measure at the warmest point of the product. You may need to scientifically validate the finding of cold spots and hot spots.

b. Measure processing times and temperatures for operations such as cooking, pasteurization, canning (appertization), cooling (rates), storing, thawing, reconstitution, etc.

c. Measure the dimensions of containers used to hold foods that are being cooled. Measure the depth of the food mass.

d. Measure the pressure, headspace, venting procedure, adequacy of the container closure and initial temperatures as well as any other factors critical to the successful delivery of a scheduled process.

e. Measure the pH of the product during processing and the pH of the finished product. If possible, measure pH at room temperature.

f. Measure the water activity (a_w) of the product. Whenever possible, obtain duplicate samples to compare variations.

g. Conduct sampling, inoculated pack studies and microbial challenge studies, when information on hazards is not otherwise available (e.g. for new products or for assessing the expected shelf life).

4.6.2.5 Analyze measurements

To ensure that your team interprets the results correctly, a qualified individual (with a proper scientific background) must analyze the measurements. To interpret the data, the analyst may need to do the following:

a. Plot time and temperature measurements on a graph.

b. Interpret controlled data versus optimal growth temperatures of microorganisms, and the temperature ranges at which they can multiply.

c. Estimate and evaluate the probable cooling rate by comparing measured temperatures with optimal temperature ranges for the bacteria of concern. Packaging material or product storage methods may influence cooling times and effectiveness (e.g. delayed cooling rates may occur due to covers or stacking practices).

d. Compare a_w and pH values to ranges at which microorganisms multiply or are eliminated

e. Evaluate the shelf-stability of products.

After identifying all hazards, your HACCP team will determine critical control points.

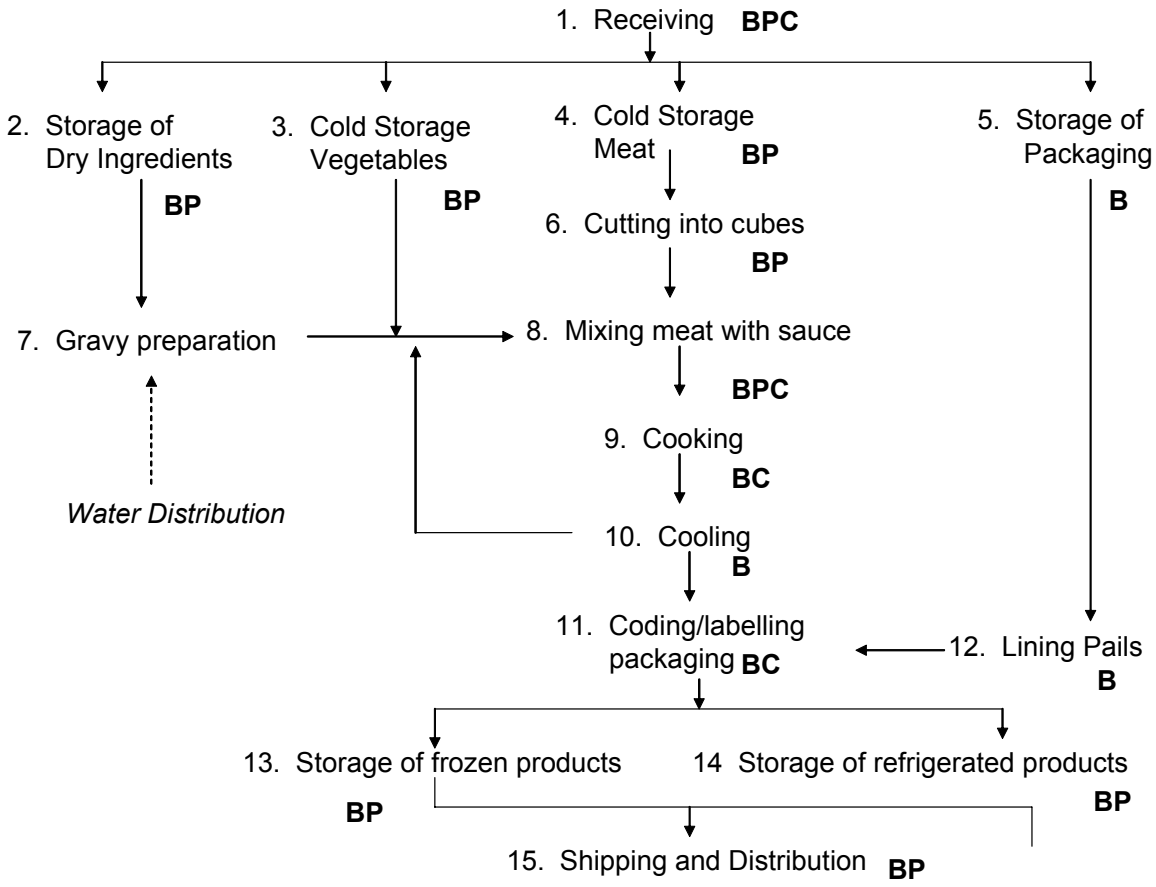
List of Product Ingredients and Incoming Material **Form 2**

Product name: Pork Stew

Meat	**Non-meat ingredients**	**Packaging materials**
Pork meat **BCP** Product rework **BP**	Frozen vegetables **BCP** Dried oregano **BCP** Salt **CP** Pepper **BCP** Dried gravy preparation (contains a dairy ingredient) **BCP** Water **BC**	Plastic liner **BC** Plastic pails **B**

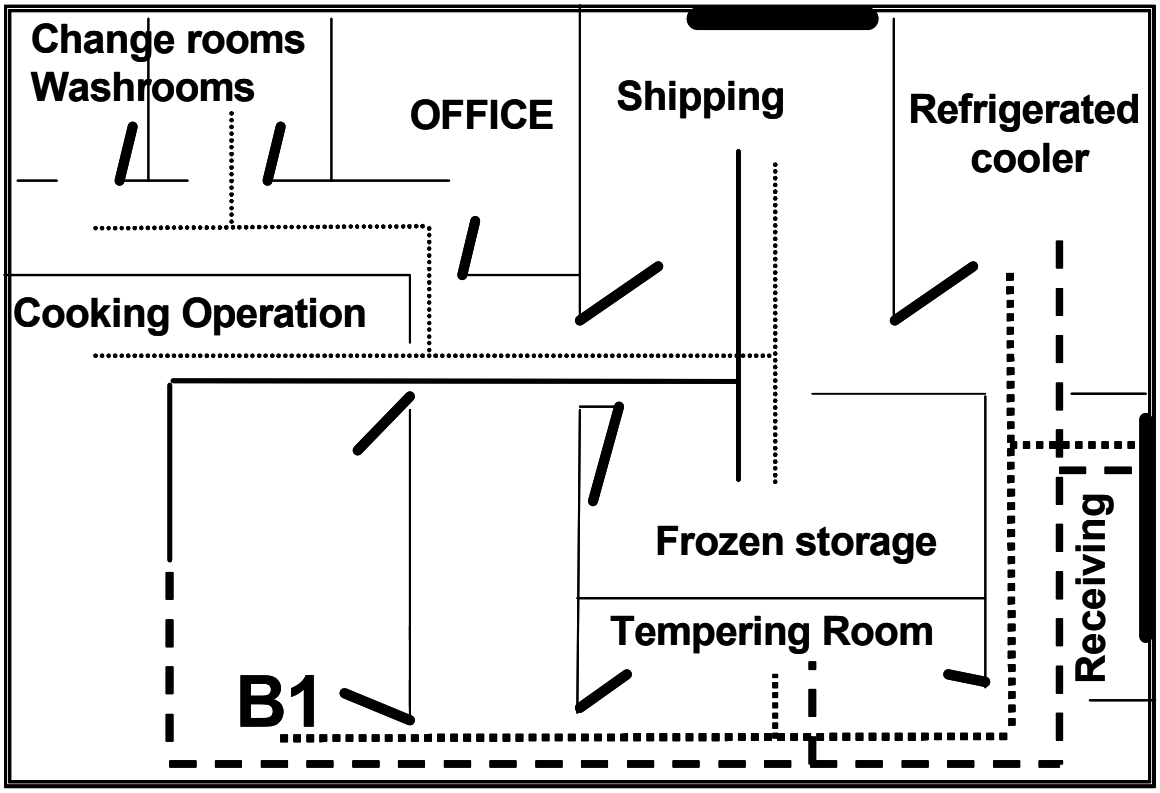
Process Flow Diagram **Form 3**

Product name(s): Pork Stew



Plant Schematic **Form 4**

Product name(s): Pork Stew



Please note: the following forms (5, 6 and 7) provide limited examples of the hazards listed on the process flow diagram and plant schematic diagram. The examples are not comprehensive.

Hazards Identification **Form 5**

Product name(s): Pork Stew

List all biological hazards related to ingredients, incoming material, processing, product flow, etc.

Identified biological hazards (Bacteria, parasites, viruses, etc.)	**Controlled at**
Ingredients/materials	
- Pork meat: presence of sporulating and non-sporulating pathogens (*Salmonella* sp.*, E. coli, Listeria, Clostridium perfringens* and *Staphylococcus aureus*) - presence of *Trichinella spiralis*	
Process steps	
Step 9 – Cooking: survival of pathogenic bacteria (*Salmonella* sp.*, E. coli, Listeria, Clostridium perfringens* and *Staphylococcus aureus*) and *Trichinella* due to inadequate cooking time/temperature	
Step 14 – Storage of Refrigerated Product: bacterial growth of *Listeria, Clostridium perfringens, Staphylococcus aureus* due to inappropriate product temperature at storage	
Schematic diagram	
B1. Potential pathogenic bacteria cross-contamination of cooked product due to employee movements into and out of the RTE room (*Salmonella* sp.*, E. coli, Listeria, Staphylococcus aureus,* etc.)	

Hazards Identification	**Form 6**
Product name(s): Pork Stew **List all chemical hazards related to ingredients, incoming material, processing, product flow, etc.**	
Identified chemical hazards	**Controlled at**
Ingredients/materials	
Pork product: antibiotics, drug residues introduced at farm level	
Process steps	
Step 11 – Coding, Packaging and Labelling: improper labelling of food products containing allergens	

Hazards Identification	**Form 7**
Product name(s): Pork Stew **List all physical hazards related to ingredients, incoming material, processing, product flow, etc.**	
Identified physical hazards	**Controlled at**
Ingredients/materials	
Pork meat: contamination from metallic and non-metallic contaminants	
Process steps	
Step 6 – Cutting into Cubes: contamination from hazardous metallic fragments (e.g. pieces from cutting blade)	

4.7 Determination of CCPs (decision tree)

The second HACCP principle involves determining critical control points (CCPs). A CCP is any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level.

4.7.1 Introduction to determining CCPs

To determine Critical Control Points (CCPs), you will assess, for each process step, the severity and likely occurrence of hazards as well as the measures that can be taken to eliminate, prevent or reduce the hazards.

Select CCPs on the basis of:

- the identified hazards and their likely occurrence in relation to what constitutes unacceptable contamination;
- operations to which the product is subjected during processing and preparation; and
- the intended use of the product.

You need not designate a separate critical control point for each hazard. Your team must, however, eliminate, prevent or reduce to an acceptable level all identified hazards.

Certain operations may have many CCPs. Three of the most common CCPs are:

- cooking
- chilling
- formulation control

We discuss each of these below, by way of illustration.

4.7.1.1 Cooking

Incoming raw foods often contain pathogens and spoilage organisms. Adequate cooking will inactivate these biological hazards; therefore, a CCP exists at the cooking process.

4.7.1.2 Chilling

The cooling process is a CCP for some products. Rapid lowering of the temperature of pasteurized foods is important. Pasteurization is not considered to be sterilization, as it only reduces the bacterial load to a certain level, depending on the process time and the temperature. If a non-shelf-stable product is improperly cooled or inadequately refrigerated during storage, spores that have survived pasteurization will grow. Bacterial growth and the germination of sporulating bacteria may represent a food safety hazard.

4.7.1.3 Formulation

Product formulation may be a CCP. Some ingredients affect the pH or water activity (a_w) levels of the food mixture and may prevent bacterial growth. Acidifiers will prevent growth or kill microorganisms if used in sufficient amounts to lower the pH.

Some ingredients are considered allergenic. Check the formulation process to ensure that proper labels are used and control measures are in place to prevent cross-contamination.

Curing salts (nitrites) create a selective environment for microbial growth. In sufficient concentration, they will prevent the outgrowth of heat-injured spores. A CCP at formulation would ensure that a specified concentration of salts and nitrites is used in food products.

Salt concentrations, temperatures and pH are crucial to creating conditions that select for and promote the multiplication of fermenting microorganisms. To ensure the safe production of fermented food products, you will need to control those conditions or add the following:

- starter cultures; or
- cultures from a previous batch (back slopping).

4.7.1.4 Microbiologically sensitive areas

In areas that are highly sensitive to microbiology (e.g. packaging of ready-to-eat products), specific handling and hygienic practices may need to be controlled through a CCP.

4.7.1.5 Reassessing CCPs

If processing procedures change and, as a result, are different from those originally assessed as safe, your team must repeat its hazard analysis and redefine the CCPs if necessary.

4.7.2 Decision tree: using Form 8

Your team will use the HACCP decision tree (Form 8) to determine the plant's Critical Control Points (CCPs). The decision tree was first developed by a Codex *Alimentarius* working group on HACCP in June 1991. It has since been modified during pilot projects and industry-government communication forums.

Please note: The examples provided on the sample Form 8 demonstrate how to complete this form. They do not address all hazards identified earlier on the sample Forms 5, 6 and 7.

Form 8 helps your HACCP team document and analyze all hazards related to incoming materials, process steps and establishment layout.

4.7.2.1 Form 8, Column 1

In the first column, list each incoming material, process step and cross-contamination point listed on Forms 5, 6 and 7 where a hazard has been identified. (In the case of multiple hazards at one point, you should analyze each hazard separately.)

4.7.2.2 Form 8, Column 2

In the second column, categorize and describe the hazards (biological, chemical or physical). For each hazard, determine whether it is fully controlled by one or more prerequisite programs. If you answer "yes," identify the prerequisite program bullet or bullets that provide full control over this hazard.

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

If you determine that the hazard is not fully controlled by a prerequisite program, continue on to the following four questions of the HACCP decision tree, listed on Form 8.

4.7.2.3 Form 8, Question 1: "Could a control measure(s) be used by the operator at any process step?"

Could a control measure occur at this step – or anywhere else in the food establishment – to control the hazard? Your HACCP team may answer "yes" to this question if a control measure could be implemented, even when one is not currently in place. Examples of control measures include temperature checks, visual examinations, use of metal detector, etc.

If you answer "yes" to Question 1, describe the control measure(s) and proceed to Question 2.

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 (e.g. antibiotic residues in meat) on Form 9 and proceed to the next identified hazard.

4.7.2.4 Form 8, Question 2: "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 (likelihood) and

seriousness of the hazard. Conduct a risk analysis based on all the information that your team has gathered. For future reference, you must document your team's reasons for answering "no."

Your research (company complaint files, Health Canada data, scientific literature, etc.) may suggest that contamination with the identified hazard could increase to an unacceptable level and result in a health hazard. In such a case, answer "yes" and proceed to Question 3.

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 hazard.

4.7.2.5 Form 8, Question 3: "Is this process step specifically designed to eliminate or reduce the likely occurrence of this identified hazard to an acceptable level?"

Process steps specifically designed to control hazards include retorts, pasteurization, chlorination of cooling water, metal detection, etc.

If the process step has been specifically designed to 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 process step has not been specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level, answer "no" and proceed to Question 4.

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

4.7.2.6 Form 8, Question 4: "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.

If you answer “yes,” this process step will not be a CCP. You must identify the subsequent step or steps that control the hazard. Then proceed to the next hazard.

4.7.2.7 CCP nomenclature

To facilitate regulatory system audits, FSEP recommends that your establishment number its CCPs sequentially and identify each with the hazard it controls. For example:

- **CCP-1B** refers to Critical Control Point 1, which controls a biological hazard
- **CCP-2BC** refers to Critical Control Point 2, which controls a biological hazard and a chemical hazard.

Product name	**CCP Determination**					**Form 8**
Incoming material/process step/ hazards on schematic diagram	**Category and identified hazard** **Determine if fully controlled by prerequisite program(s).** *** If yes = indicate "Prerequisite Program" and proceed to next identified hazard.** *** If no = proceed to Q1.**	**Q1. Could a control measure(s) be used by the operator at any process step?** *** If no = not CCP. Identify how this hazard will be controlled before and after the process. Then proceed to the next identified hazard.** *** If yes = describe the measure and proceed to Q2.**	**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?** *** If no = not CCP. Proceed to the next identified hazard.** *** If yes = proceed to Q3.**	**Q3. Is this process step specifically designed to eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?** *** If no = proceed to Q4.** *** If yes = CCP. Enter its number in the last column.**	**Q4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?** *** If no = CCP. Enter its number in the last column.** *** If yes = not a CCP. Identify subsequent (controlling) step and proceed to the next identified hazard.**	**CCP number** *** Proceed to next identified hazard.**
Incoming pork product	**Biological:** Presence of sporulating and non-sporulating pathogens Presence of *Trichinella spiralis* No	Yes, cooking	Yes	N/A	Yes, Step 9 – Cooking	
Incoming pork product	**Chemical:** Antibiotics, drug residues No	No See Form 9				
Process step #9 – Cooking	**Biological:** Survival of pathogens and *Trichinella* due to inadequate cooking time or temperature	Yes, time/temperature control to achieve desired lethality	Yes	Yes		**CCP-1B**
Process step #14 – Refrigerated Product Storage	**Biological:** Improper temperature of meat coolers Yes: Transportation, Receiving and Storage – Temperature Control, B 2.3.1					
Schematic – B1	**Biological:** Potential pathogenic bacteria cross-contamination of cooked product due to employee movements into the RTE room (*Salmonella* sp., *E. coli, Listeria, Staphylococcus aureus*) Yes: Premises, A 2.1.8.					

4.7.3 Hazards not controlled by the establishment

Each establishment must analyze all hazards that affect its products before and after the production process. Some hazards could be out of your control, but your HACCP team must analyze all hazards.

Whenever you answer "no" to Question 1, use Form 9 to describe the hazard not controlled by your establishment. In the "controlled at" column, describe how your company ensures that the hazard is controlled before or after the production process (e.g. producer education, cooking instructions on the label, etc.).

Form 9

Hazards Not Controlled by Operator

Product name(s): Pork Stew

List here any biological, chemical and physical hazards that are not controlled by the operator

Hazards	**Indicate how the hazard could be addressed (cooking instructions, public education, "use before" date, etc.)**
Chemical: Pork meat products: antibiotics, drug residues	

4.7.4 Controlling identified hazards

Once you have used the decision tree (Form 8) to analyze all hazards related to incoming materials, process steps and plant schematics, your team will review its work. Ensure that your analysis is correct and no hazards have been overlooked. During this review, complete the right-hand columns of Forms 5, 6 and/or 7, indicating how each hazard is controlled.

For hazards that are fully controlled by prerequisite programs, identify the specific bullet that provides the control measure for that hazard. Note this in the right-hand column of Forms 5, 6, and/or 7.

For hazards not controlled by prerequisite programs, refer to the applicable CCP or to Form 9. Note this in the right-hand column of Forms 5, 6, and/or 7.

Re-examine each hazard not controlled by an operator (hazards for which you answered "no" to Question 1 on Form 8) to ensure that no control measure could be used in the process.

Hazards Identification **Form 5**

Product name(s): Pork Stew

List all biological hazards related to ingredients, incoming material, processing, product flow, etc.

Identified biological hazards (Bacteria, parasites, viruses, etc.)	**Controlled at**
Ingredients/materials	
- Pork meat: presence of sporulating and non-sporulating pathogens (*Salmonella* sp.*, E. coli, Listeria, Clostridium perfringens* and *Staphylococcus aureus*) - Presence of *Trichinella spiralis*	**CCP-1B**
Process steps	
Step 9 – Cooking: survival of pathogenic bacteria (*Salmonella* sp.*, E. coli, Listeria, Clostridium perfringens* and *Staphylococcus aureus*) and *Trichinella* due to inadequate cooking time/temperature	**CCP-1B**
Step 14 – Storage of Refrigerated Product: bacterial growth of *Listeria, Clostridium perfringens, Staphylococcus aureus* due to inappropriate product temperature at storage	Prerequisite Program – Transportation, Receiving and Storage, B 2.3.1
Schematic diagram	
B1. Potential pathogenic bacteria cross-contamination of cooked product due to employee movements into and out of the RTE room (*Salmonella* sp.*, E. coli, Listeria, Staphylococcus aureus*, etc.)	Prerequisite Program – Premises, A 2.1.8

Hazards Identification	**Form 6**
Product name(s): Pork Stew **List all chemical hazards related to ingredients, incoming material, processing, product flow, etc.**	
Identified chemical hazards	**Controlled at**
Ingredients/materials	
Pork meat: antibiotics, drug residues introduced at farm level	Form 9
Process steps	
Step 11 – Coding, Packaging and Labelling: improper labelling of food products containing allergens	**CCP-3BC**

Hazards Identification	**Form 7**
Product name(s): Pork Stew **List all physical hazards related to ingredients, incoming material, processing, product flow, etc.**	
Identified physical hazards	**Controlled at**
Ingredients/materials	
Pork meat: contamination from metallic and non-metallic contaminants	Prerequisite Program – Transportation, Receiving and Storage, B 2.1.3
Process steps	
Step 6 – Cutting into Cubes: contamination from hazardous metallic fragments (e.g. pieces from cutting blade).	Prerequisite Program – Equipment, C 1.2.1

Form 9

Hazards Not Controlled by Operator

Product name(s): Pork Stew

List here any biological, chemical and physical hazards that are not controlled by the operator

Hazards	**Indicate how the hazard could be addressed (cooking instructions, public education, "use before" date, etc.)**
Chemical: Pork meat products: antibiotics, drug residues	Producer education and practices; proper withdrawal periods

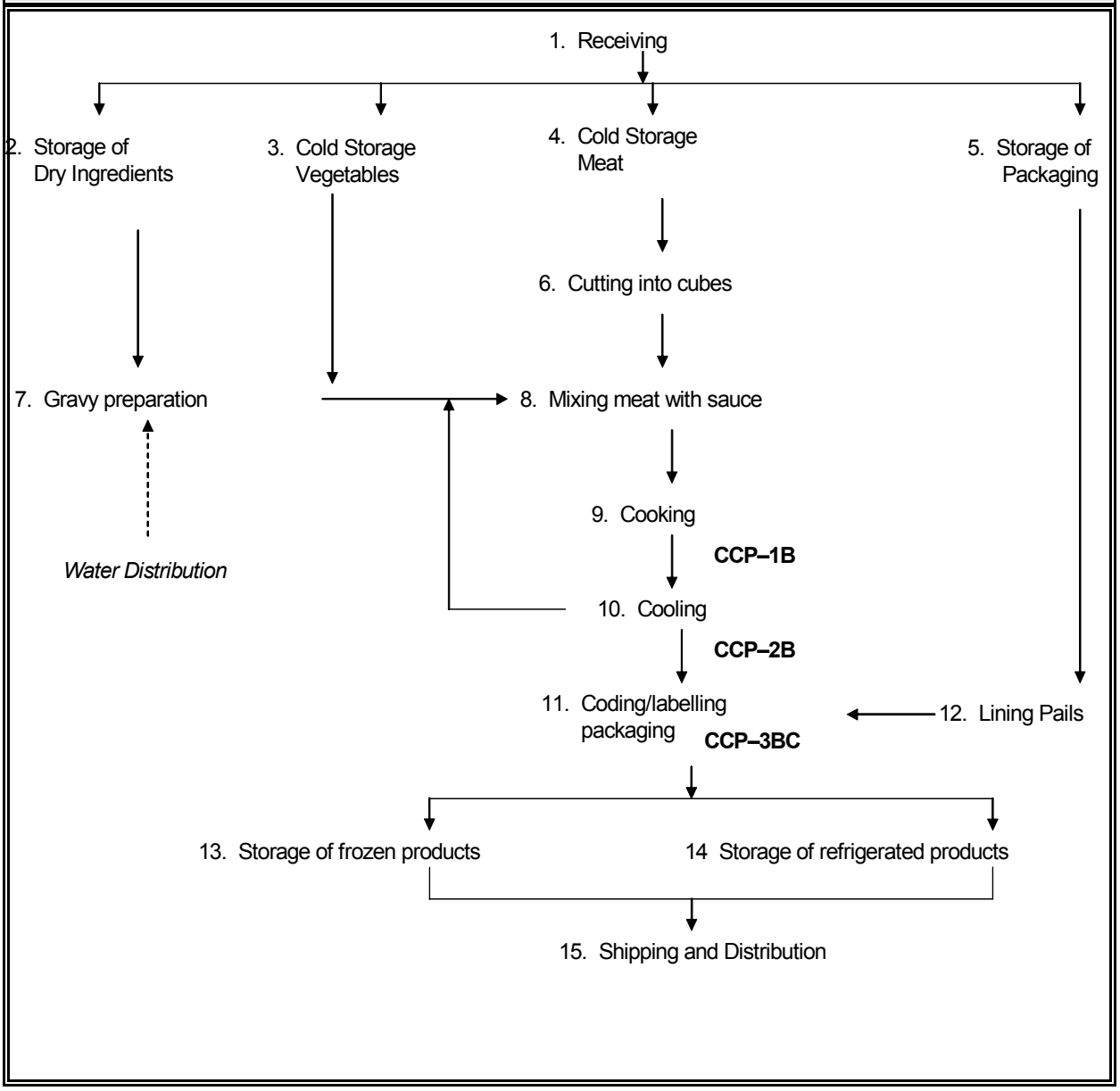
4.8 Critical control points

All CCPs should be identified on the process flow diagram (Form 3). Use Form 10 to document the control measures associated with each CCP as indicated by HACCP Principles 3 through 7, listed below.

In the appropriate columns on Form 10, state the critical limits, monitoring procedures, deviation procedures and verification procedures and identify records procedures for each CCP in your establishment's HACCP plan.

Process Flow Diagram **Form 3**

Product name(s): Pork Stew



4.8.1 Establish critical limits – HACCP Principle 3

Your team must determine critical limits for every CCP.

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

Base each critical limit on your establishment's specifications or on other scientific data. As a minimum, each critical limit must meet government regulations. Critical limits may exceed regulatory requirements, should your establishment require a higher standard.

One or more critical limits may be used to control an identified hazard. You may set critical limits for factors such as temperature, time (minimum time exposure), physical product dimensions, water activity, moisture level, etc. All critical limits must be measurable (e.g. quantitative and/or qualitative).

Critical limits – examples

1) An acidified beverage requires a hot fill and hold in the process. The HACCP team may identify "acid addition" and "temperature" in the CCP. If insufficient acid is added or if the temperature of the hot fill is insufficient, the product would be under-processed, allowing potential growth of pathogenic, spore-forming bacteria. The critical limits in this case would be pH and fill temperature.

2) Beef patties are cooked in a continuous oven. More than one critical limit may be set to control the survival of heat-resistant pathogens. The critical limits could be minimum internal temperature of the patty, oven temperature, time in the oven (determined by the belt speed), and patty thickness.

3) In a ready-to-eat operation, the final packaging step has been identified as a CCP. The hazard is biological in nature and can be described as pathogenic contamination of product due to employee mishandling. The critical limits are associated with the establishment's documented work procedures (e.g. utensils and gloves sanitized at prescribed frequencies).

4.8.2 Establish monitoring procedures – HACCP Principle 4

Monitoring is the act of conducting a planned sequence of observations, or measurements of control parameters, to assess whether a CCP is under control. Each establishment is responsible for monitoring its own CCPs.

For each CCP, your team must specify the monitoring requirements and the means to ensure that the CCP remains within the critical limits. Monitoring procedures generally relate to on-line processes. These may consist of rapid tests, visual observations, measurements, etc.

Your HACCP team must establish regular procedures for monitoring each CCP in order to ensure that it is implemented effectively as outlined in your written HACCP plan. In each case, specify the procedures (what/how), the frequency (when) and the individual responsible (who). See Appendix VI, Guidelines for a Complete Written Program.

Monitoring procedures must allow staff to obtain data on a timely basis and make quick decisions regarding the acceptability or unacceptability of the product at a particular stage in the operation.

Your company must keep a record of **all** of its monitoring activities, regardless of whether an exceptional occurrence takes place. It is not permissible for companies to maintain records of exception (documents that record deviations only and not regular monitoring activities).

Most monitoring procedures for CCPs must be carried out rapidly, because they relate to on-line processes and there is not sufficient time for lengthy, analytical testing. Rapid measurements or visual observations can serve as monitoring activities to indicate control of the hazard.

All monitoring equipment must be properly calibrated for accuracy and be controlled through the preventative maintenance program. Examples of monitoring activities include the measurement of temperature, time, pH, moisture level and water activity.

There are many ways to monitor critical control points. Your establishment may choose to monitor on a continuous basis or on a batch basis. Continuous monitoring provides 100 percent reliability and is preferred, where feasible. Your team must set a

monitoring frequency that is sufficient to substantiate that the hazard is under control at all times and that allows for any corrective actions to occur in a timely manner.

Your procedures must clearly identify the person(s) responsible for monitoring. You must also ensure that these individuals receive proper training in testing procedures and fully understand the purpose and importance of monitoring. Individuals responsible for monitoring must have ready access to the monitoring activity and must be unbiased in conducting monitoring and reporting activities.

Monitoring procedures – examples

1) The scheduled thermal process for a canned meat product in a steam-still retort is continuously monitored by the recorder-controller. The recorder-controller provides a permanent record of the process time and temperature. This record is checked by the retort operator as per SOP ### to ensure proper delivery of the thermal process, and is signed and dated by the retort operator.

2) In a slaughter establishment, the foreman monitors work techniques of employees to ensure they are following the standard developed by the establishment. The foreman observes all employees twice per hour, records his or her observations, and signs and dates the record.

   If a monitoring activity reveals that any one of the critical limits identified in the CCP is not being met, the CCP must be treated as “out of control” and the monitor must identify a deviation. Deviations may result in the production of hazardous or unsafe food products.

4.8.3 Establish deviation procedures – HACCP Principle 5

A) The written HACCP plan shall identify the corrective action to be taken in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken and assign responsibility for taking the corrective action, to ensure that:

   1) the cause of the deviation is identified and eliminated;
   2) the CCP will be under control after the corrective action is taken;

3) measures to prevent reoccurrence are established; and
4) no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

You must document your deviation procedures in sufficient detail so that, in the event of a deviation, any employee responsible for monitoring critical control points is able to understand and perform the appropriate corrective action(s). See Appendix VI, Guidelines for a Complete Written Program.

B) If a deviation not covered by a specified corrective action occurs, or if another unforseen hazard arises, the establishment shall:

1) segregate and hold the affected product, at least until the requirements of paragraphs (B)(2) and (B)(3) of this section are met;

2) perform a review to determine the acceptability of the affected product for distribution;

3) take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce; and

4) perform or obtain reassessment to determine whether the newly identified deviation or another, unforeseen hazard should be incorporated into the HACCP plan.

All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with Section 4.8.5.

Deviation procedures – examples

1) The scheduled thermal process for canned spaghetti is not complied with because of a loss in steam pressure during retorting. The operator notices the deviation before the end of the process time. The deviation procedure states that the operator should add on the required processing time and arrange for the affected lots to be held until a process authority authorizes and signs off on the release of the product. The process authority must determine what preventative measures need be taken (e.g. maintenance checks and repairs of equipment). All corrective actions are recorded on the thermal process record.

2) A rapid screening test detects antibiotics in incoming raw milk. The detected level exceeds the established critical limits. The milk receiver refers to the deviation procedure. It states that the milk is to remain in the truck and not be unloaded. The procedure also describes the follow-up action: the milk receiver must contact the provincial government, which will follow up with the milk shippers and the farmers to prevent reoccurrence. All corrective actions are recorded on the receiving form and in the report to the provincial government.

3) The foreman observes cooked sausages being sliced with equipment that has an inappropriate build-up of food residue, which may indicate bacterial contamination. The foreman is responsible for monitoring through pre-operational inspection. The operator has started production prior to the pre-operational inspection. The foreman records a deviation and follows the procedures. These require the holding of all product produced since the last recorded clean-up, pending microbiological laboratory results. The foreman notifies the sanitation supervisor to have the equipment re-cleaned. After the cleaning and prior to beginning production, the foreman conducts a pre-operational inspection. As a preventative measure, the foreman and sanitation supervisor reinforce training with the operator and the sanitation personnel.

4.8.4 Establish verification procedures – HACCP Principle 6

Verification is the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine the conformance and effectiveness of the HACCP system. Each establishment is responsible for verifying its own operations.

Your HACCP team must establish regular procedures for verifying each CCP to ensure that it is implemented effectively as outlined in your written HACCP plan. In each case, specify the procedures (what/how), the frequency (when) and the individual responsible (who). See Appendix VI, Guidelines for a Complete Written Program.

If CCPs for your operation appear in a related, generic model, you may find the generic verification procedures useful as a guide. You will need to adapt them to your plant's specific environment.

Your verification procedures must do the following:

- provide for on-site assessment of the monitoring procedures;
- require staff to review records for completeness;
- ensure that appropriate corrective actions are taken and recorded in the event of a deficiency;
- ensure that staff are adhering to sampling programs (e.g. of product and environment); and
- set a verification frequency that is adequate to ensure that your establishment remains in control of any hazards (for example: at a dairy, staff responsible for daily monitoring of the pasteurization step fail to take the necessary corrective action; verification conducted once per month will not be frequent enough to prevent a broad-based recall).

Verification procedures – examples

1) The raw material receiver monitors incoming peanuts for aflatoxin by testing each incoming lot. The receiver also examines the certificate of guarantee from the manufacturer to ensure that the peanuts meet the critical limits (aflatoxin-free). As well, every load is visually examined for mould.

In addition to monitoring records for completeness and conducting an on-site assessment of the monitoring activities, the plant audits the supplier's aflatoxin-free claim by having the peanuts analyzed at a private laboratory. A sample of peanuts from every tenth load is sent to a private laboratory to be tested for aflatoxin levels.

2) The pasteurizer operator monitors each lot of whole egg pasteurization for time and temperature. The pasteurization verification activities are numerous. One involves microbiological testing of the finished product to ensure that the pasteurization process is adequate. Another involves unannounced monthly observation of the pasteurizer operator's work practices and a check of the monitoring records for completeness.

3) On an hourly basis, the foreman monitors the state of equipment and utensil cleanliness in the post-cooking area. In one example of the verification activities, the Quality Assurance officer swabs product contact surfaces at designated intervals.

4.8.5 Establish record keeping and documentation – HACCP Principle 7

Records play an essential role in determining whether your establishment conforms to its written HACCP plan. Form 10 lists the required HACCP records for each CCP.

Personnel at your plant must document all their monitoring, deviation and verification activities. Each entry must include a date, the exact time and signature or initial of the individual(s) responsible for documenting them using a permanent ink pen. Each record must indicate:

- the results of monitoring, deviation and verification;
- corrective actions taken, including preventative measures;
- the name of the person (signature or initial) who recorded the information; and
- the date and exact time of the event.

The time requirement applies only to CCP monitoring, deviation and verification activities.

Records may take a variety of forms, including processing charts, written documentation and computerized files. They must provide details on the history of operations, including monitoring,

deviations and corrective actions (including disposition of product). Accurate records are critical for tracing back actual manufacturing conditions, and they aid in an investigation, should a problem arise.

Unless otherwise specified in program requirements, HACCP records must be retained for a minimum of one year or for the shelf life of the product, whichever is greater.

One cannot overemphasize the importance of records to your plant's HACCP system. Records will prove whether the CCPs are implemented effectively. They constitute an important element of an auditable system. Records must be up to date, legible, accurate and properly filed.

Record keeping – examples

1) Pasteurization charts record time and temperature data in processing. The records will show if a drop in temperature occurred, and the recording pen will indicate if a proper flow diversion occurred. The records register additional information such as temperature reading, lot size, operator, date and product.

2) The retort processing records show that a loss in steam occurred during the cook cycle and that the temperature dropped below that specified in the scheduled process. The records must acknowledge that this constituted a process deviation. The file must show any process calculations made by the process authority to determine the safety of the product. A record must also indicate actions taken with the product, including all corrective actions to prevent reoccurrence.

3) Cooked sausages are observed being sliced with equipment that has an inappropriate build-up of food residue, which may indicate bacterial contamination. The records must describe the deviation and must specify the corrective actions taken. Records must include information such as lot number, lot size, hold tag number, laboratory testing results and disposition of the sliced sausage. The records must also describe what follow-up action took place (such as notification of the sanitation supervisor) as well as preventative measures subsequently put in place (such as employee training).

HACCP Plan **Form 10**

Product name: Pork Stew

Process steps	CCP/ Hazard number	Hazard description	Critical limits	Monitoring procedures	Deviation procedures	Verification procedures	HACCP records
9 – Cooking	**CCP-1B**	**Biological:** Survival of pathogen bacteria and *Trichinella* due to inadequate cooking time or temperature	Cooking temperature minimum of "**Y**"°C for a minimum time of "**X**" minutes	The operator completes the cooking log sheet, including date, cooking, temperature and time (start/finish time), and signs the thermograph. Once the cook cycle time requirement has been met as indicated on the thermograph, for every batch the operator takes internal product temperature readings using a calibrated hand thermometer as per "SOP Z." The operator compares the internal temperatures taken to the thermograph chart to ensure that the product has reached the proper "**Y**"°C and records and initials the cooking log.	If minimum internal temperature "**Y**"°C has not been reached, the product will be further cooked. If cooking temperature cannot be achieved, the operator advises the supervisor. The product must be held and a food safety assessment completed as per "SOP H." The supervisor will determine the necessary corrective actions to be taken. These actions may include re-cooking the product, destroying the product and repairing faulty equipment. They will include corrective measures to prevent reoccurrence of the deviation. All actions are recorded in the deviation log book. The supervisor initials and dates the deviation log book.	Weekly, QC observes the operator completing one cook cycle and verifies the thermograph and cooking log for completeness. QC signs and dates the cooking log. Monthly, QC samples one batch of finished product for generic *E. coli* and *Salmonella* as per Microbiological Sampling SOP. Records, signs and dates the micro-analysis report.	Thermograph charts Cooking log sheet Deviation log book Micro-analysis report

Section 5 – Validation and reassessment of the HACCP system

1) Validation

Every establishment shall validate the adequacy of the HACCP system in controlling the food safety hazards identified during the hazard analysis and shall verify that the system is being implemented effectively.

Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine whether the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's critical limits, the monitoring and record keeping procedures, and the corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

Validation of the prerequisites is accomplished through initial self-evaluation and ongoing reassessment of the HACCP system.

Validation of food hygiene control measures is different from both verification and monitoring. Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether the control measures are capable, if implemented, of controlling the hazard to the appropriate level and whether this level of control can be achieved consistently. This is in contrast to monitoring and verification, which both take place only after the validated control measures have been implemented.

Need for re-validation

There are many changes that could lead to a need to re-validate a control measure, a combination of control measures or the entire food safety control system.

For example, the introduction into the food control system of a new product line, process step, control measure, technology or piece of equipment that impacts the control of the hazard means that part or all of the system may need to be re-validated. Similarly, changes made in product formulation or the application of current control measures (e.g. temperature changes) may result in the need for re-validation of

control measures. While minor changes are less likely to require re-validation of the control measures, multiple minor changes will almost certainly mean that re-validation is needed.

> The hazard(s) associated with a food or ingredient change as a result of (i) higher concentrations of a pathogen or pathogens than originally encountered and accounted for in the design, (ii) a change in the response of a hazard to control (e.g. adaptation), (iii) the emergence of a previously unidentified hazard, or (iv) new information indicating that the hazard is not being controlled to the level specified (e.g. new epidemiological findings or new analytical technologies). Any of these changes may result in the need for re-validation.

If monitoring or verification identifies failures that are above a pre-established rate and for which a process deviation cause cannot be identified, re-validation may be needed. Non-compliance with monitoring or verification criteria may indicate a change in the parameters (i.e. the selection and specification of the control measures) on which the design of the food safety control system is based.

2) Reassessment of the HACCP system

Every establishment shall reassess the adequacy of the HACCP system at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP system.

Your establishment must have in place written procedures that indicate how the company annually reviews and updates its entire HACCP system. These written reassessment procedures may specify that the company will conduct its required activities at various times over the course of a year.

Your reassessment plan must specify regular procedures for maintaining your HACCP system. In each case, specify the procedures (what) and how they will be applied (how), the frequency (when), the documents to be maintained (records) and the individual responsible (who) for these review procedures. As well, outline the procedures that the company will follow when a deviation is found during the review. Include actions to prevent reoccurrence of these deviations.

Reassessment procedures must include the following:

1) Procedures to ensure that all changes to the HACCP system are documented in a log book. The log book must describe the changes, state the location where they occurred in the HACCP system, and specify the date on which the changes were implemented. The log book must also identify the individual responsible for ensuring that the changes have been implemented and, if necessary, validated.

2) Procedures to review all sub-elements in the prerequisite program to ensure that the procedures reflect current processes and equipment at your establishment, as well as regulatory requirements, and that they continue to be effective.

3) Procedures to review the accuracy of the product descriptions, lists of incoming ingredients, process flow diagrams and schematic diagrams in your HACCP system.

4) Procedures to review all hazards identified in the HACCP system, in order to ensure that they are accurate and reflect your establishment's current processes, equipment and operating procedures. When new hazards are identified, your HACCP team must analyze them appropriately in accordance with to your HACCP system. Hazards that are not controlled by CCPs should continue to be controlled by other measures identified in the HACCP system (e.g. prerequisite programs, letters of guarantee, etc.).

5) Procedures to review each CCP (including validation studies such as microbiological sampling, challenge studies and process validation) to ensure that it continues to control the identified hazard(s).

6) Procedures to evaluate critical limits to ensure that they meet current program and regulatory requirements.

7) Procedures to review the monitoring, deviation and verification procedures for each CCP, in order to ensure that they continue to be implemented effectively.

Section 6 – FSEP forms

Product Description	**Form 1**
Process/product type name:	
1. Product name(s)	
2. Important product characteristics (a_w, pH, preservatives, etc.)	
3. How the product will be used	
4. Packaging	
5. Shelf life	
6. Where it will be sold	
7. Labelling instructions	
8. Special distribution control	

Date: _____ **Approved by: _____**

List of Product Ingredients and Incoming Material		Form 2
Product name:		

Date: _____ **Approved by: _____**

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

Date: _____ **Approved by: _____**

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

Date: _____ **Approved by: _____**

Hazard Identification **Form 5**

Product name(s):

List all biological hazards related to ingredients, incoming material, processing, product flow, etc.

Identified biological hazards (Bacteria, parasites, viruses, etc.)	**Controlled at**

Date: _____ **Approved by: _____**

Hazard Identification **Form 6**

Product name(s):

List all chemical hazards related to ingredients, incoming material, processing, product flow, etc.

Identified chemical hazards	Controlled at

Date: _____ **Approved by: _____**

Hazard Identification **Form 7**

Product name(s):

List all physical hazards related to ingredients, incoming material, processing, product flow, etc.

Identified physical hazards	Controlled at

Date: _____ **Approved by: _____**

Product name		**CCP Determination**				**Form 8**
Incoming material/ process step/ hazards on schematic diagram	**Category and identified hazard** **Determine if fully controlled by prerequisite program.** *** If yes = indicate "Prerequisite Program" and proceed to next identified hazard.** *** If no = proceed to question 1 (Q1).**	**Q1. Could a control measure(s) be used by the operator at any process step?** *** If no = not CCP. Identify how this hazard will be controlled before and after the process. Then proceed to the next identified hazard.** *** If yes = describe the measure and proceed to Q2.**	**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?** *** If no = not CCP. Proceed to the next identified hazard.** *** If yes = proceed to Q3.**	**Q3. Is this process step specifically designed to eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?** *** If no = proceed to Q4.** *** If yes = CCP. Enter its number in the last column.**	**Q4. Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?** *** If no = CCP. Enter its number in the last column.** *** If yes = not a CCP. Identify subsequent (controlling) step and proceed to the next identified hazard.**	**CCP number** *** Proceed to next identified hazard.**

Date: _____ **Approved by: _____**

Form 9

Hazards Not Controlled by Operator

Product name(s):

List here any biological, chemical and physical hazards that are not controlled by the operator

Hazards	**Indicate how the hazard could be addressed (cooking instructions, public education, "use before" date, etc.)**

Date: _____ **Approved by: _____**

HACCP Plan **Form 10**

Product name:

Process Steps	CCP/Hazard Number	Hazard Description	Critical Limits	Monitoring Procedures	Deviation Procedures	Verification Procedures	HACCP Records

Date: _____ **Approved by: _____**

Chapter 3: Recognition of an Establishment's HACCP System

Section 1 – Introduction

This chapter details the process CFIA staff follows to recognize an establishment's HACCP system under voluntary FSEP. For commodities for which **FSEP is mandatory**, please refer to Appendix VIII.

When it requests recognition, a registered establishment must already be conducting its operations under a HACCP system for all products in Risk Categories I and II. Within one year from the date of recognition, the company must incorporate non-registered lines and products in Risk Category III into its HACCP system.

The establishment's HACCP system must be reviewed by a CFIA team that includes a responsible inspector and a lead auditor, both of whom are trained in FSEP/HACCP. The team may include other members, and they must also have the appropriate scientific knowledge and commodity expertise.

The purpose of this review is to determine whether the establishment's prerequisite programs, HACCP plans and HACCP system reassessment procedures are complete (i.e. meet FSEP and regulatory requirements, etc.), and are implemented effectively as described.

The Agency 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.

For multi-commodity registered establishments that process agri-food, fish and seafood products, the Agency will evaluate their HACCP systems using the FSEP/QMP Audit Policy for Multi-Commodity Establishments, outlined in Appendix VII.

Section 2 – Steps in recognizing an establishment's HACCP system

The process covers nine steps, as follows (for a flow diagram of the recognition process, please see Figure 1):

1) The establishment's management submits a letter of commitment.
2) The CFIA (the Agency) holds a pre-meeting with the establishment's management.
3) The establishment submits a written notice to the Area FSEP/HACCP Coordinator indicating that the self-evaluation has been completed.
4) The establishment submits a documentation package.
5) The Agency reviews the establishment's written prerequisite program.
6) The Agency reviews the establishment's written HACCP plan(s).
7) The Agency reviews the establishment's written reassessment procedures for its HACCP system.
8) The Agency conducts at least two regulatory system audits of the company's HACCP system. A third audit may take place as necessary.
9) The Agency issues official notification recognizing the company's FSEP/HACCP status.

Agency staff will refer to the following criteria as they track the recognition process on Appendix I, FSEP Recognition Tracking Form.

2.1 The establishment's management submits a letter of commitment

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

- confirm corporate commitment and full support for developing, implementing and maintaining the establishment's HACCP system;
- indicate that adequate training and resources have been provided;
- request recognition by the CFIA; and
- be signed and dated by the establishment's senior management.

2.2 The Agency holds a pre-meeting with the establishment's management

After receiving the establishment's letter of commitment, the CFIA 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's written HACCP system.

2.3 The establishment submits written notice to the Area FSEP/HACCP Coordinator indicating that self-evaluation has been completed

The establishment must conduct an internal audit (and may use Appendices II and IV to do so) in order to ensure that its prerequisite programs and HACCP plans are being implemented and are effective. The company must have documentation available to support the internal audit. The company must submit a written notice to the CFIA (Area FSEP/HACCP Coordinator) indicating that the self-evaluation has been completed, in order to initiate the review of the written HACCP system. The establishment must have corrected any deficiencies identified during the internal audit (e.g. construction or ventilation concerns, etc.) or provided a plan of action to address such deficiencies.

2.4 The establishment submits a documentation package

The establishment must provide the Agency with a documentation package that includes the following information (see Chapter 2 for details on each item). This package may accompany the letter of commitment.

1) *HACCP coordinator and team members*
   A list of names and titles for the HACCP coordinator and/or the designated on-site liaison person and for the other team members (if applicable).

2) *Prerequisite programs*
   A complete description of the establishment's prerequisite programs.

   This section must address all criteria listed in Appendix II, FSEP Prerequisite Program Checklist and Appendix VI, Guideline for a Complete Written Program. If the company does not use the FSEP approach, it must cross-reference its written program with Appendix II to ensure that it meets all FSEP criteria.

3) *List of products*
   A list of all products that the establishment produces (including non-registered products and those in Risk Category III).

   The establishment may group similar products into one HACCP plan but must identify those that are grouped. If the establishment has used a generic model as a starting point for any of its HACCP plans, it must identify the model and the corresponding plan(s).

4) *HACCP plans*
HACCP plans for all processes and product lines in Risk Categories I and II. For each HACCP plan, the establishment must submit FSEP Forms 1 to 10 or equivalent documentation.

If the establishment has not used the FSEP approach for any of its HACCP plans, it must include the following information in its documentation package:

- Description of product or process type
- List of incoming materials
- Process flow diagram(s)
- Plant schematic diagram(s)
- Hazard identification and analysis
- Determination of Critical Control Point(s) using the Codex *Alimentarius* HACCP decision tree
- Critical limits
- Monitoring procedures
- Deviation procedures
- Verification procedures
- Record keeping procedures and samples of records

5) *Reassessment procedures for the HACCP system*
(See Chapter 2, Section 5 for details on developing reassessment procedures.)

The HACCP system reassessment procedures must include a description of how the establishment reassess its HACCP system. These procedures should include a regular review of the establishment's HACCP system in order to:

- accommodate changes to regulations, operations, processes, products, etc.; and
- ensure that existing controls continue to be effective in addressing all hazards.

2.5 The Agency reviews the establishment's written prerequisite program

The Agency's audit team reviews the establishment's written prerequisite program. The team assesses each of the six documented prerequisite programs to determine if they are complete and presented in a format that can be audited. The written program must include or refer to all pertinent supporting documentation (e.g. equipment manufacturers' calibration instructions).

To be considered "complete," a written program must:

1) Meet FSEP and regulatory requirements
2) Answer the following questions:
    - What procedures (monitoring, deviation and verification) are followed to reduce or control the hazard?
    - How are these procedures conducted?
    - How often are the procedures conducted?
    - Who is responsible for conducting the procedures?
    - What are the records that confirm adherence to the written program?
3) Demonstrate document control by requiring:
    - that the first page of each prerequisite program document be signed by the HACCP coordinator or designated individual; and
    - that all pages be dated.

The CFIA audit team uses the FSEP Prerequisite Program Checklist (Appendix II) to review the establishment's prerequisite programs.

During its review of the written prerequisite programs, the audit team generates an audit checklist for the prerequisite programs. After reviewing all of the written programs, the Agency will use this checklist during its regulatory system audits (Chapter 4) for the on-site review of the establishment's prerequisite programs.

If the establishment's written prerequisite programs need to be amended, the Agency will provide the establishment HACCP coordinator with a detailed list of the written programs' deficiencies. Once the establishment has amended its written programs to meet FSEP and program requirements, the written prerequisite programs will be considered complete and the Agency will begin reviewing the establishment's HACCP plans.

Please note: While prerequisite programs control the environment, Critical Control Points (CCPs) provide in-process controls. Prerequisite programs do not substitute for CCPs, as they do not provide full control over hazards identified in the process (as in cooking, for example).

2.6 The Agency reviews the establishment's written HACCP plan(s)

The Agency's audit team assesses each of the establishment's written HACCP plans to determine whether they are complete and presented in a format that can be audited.

The team evaluates the following for accuracy and completeness:

1) Product description(s)
2) List of ingredients
3) Incoming materials
4) Process flow diagram
5) Plant schematic
6) Products and processes (appropriately grouped and controlled following the appropriate generic model(s), if applicable)
7) Application of HACCP principles
8) Identification and analysis of hazards
   Please note: if the HACCP plan(s) do not address all hazards identified in the generic model, the establishment must provide documented support for its rationale.
9) Selection of CCPs
   Please note: if the CCPs differ from those identified in the generic model, the establishment must provide documented support for its rationale.
10) Critical limits.
    Please note: if the critical limits differ from those identified in the generic model, the establishment must provide documented support for its rationale.
11) Monitoring, deviation and verification procedures
12) Record keeping procedures

As well, the Agency audit team verifies that each HACCP plan meets the applicable regulatory requirements.

The CFIA audit team reviews the HACCP plan(s) using the FSEP/HACCP Plan Review and HACCP System Reassessment Checklist (Appendix IV).

During its review of the written HACCP plans, the audit team generates an audit checklist for the HACCP system. After reviewing all of the written programs, the Agency uses this checklist during its regulatory system audit (Chapter 4) for the on-site review of the establishment's Critical Control Points.

If the establishment's written HACCP plans need to be amended, the Agency will provide the establishment HACCP coordinator with a detailed list of the written program deficiencies. Once the establishment has

amended its written programs to meet FSEP and program requirements, the written HACCP plans will be considered complete and the Agency will begin reviewing the establishment's reassessment procedures for its HACCP system.

Each page of your HACCP plan(s) must be dated and signed by the HACCP coordinator or the designated on-site liaison person. The HACCP plan shall be dated and signed:

1) upon initial acceptance;
2) upon any modification; and
3) at least annually, upon reassessment.

2.7 The Agency reviews the establishment's written reassessment procedures for its HACCP system

In reviewing the establishment's procedures for reassessing its HACCP system, the audit team verifies that the reassessment procedures meet the guidelines described in Chapter 2, Section 5.

If the establishment's written reassessment procedures need to be amended, the Agency will provide the establishment HACCP coordinator with a detailed list of the written program deficiencies. Once the establishment has amended its written programs to meet FSEP requirements, the written reassessment procedures will be considered complete and the Agency will initiate regulatory system audits.

2.8 Regulatory System Audit(s) for Recognition of the HACCP System

Regulatory System Audit(s) determine whether the HACCP system has been implemented as described and is effective. The audit(s) are initiated only after the Agency's team has deemed the establishment's written HACCP system complete.

Prior to recognizing an establishment, the Agency must:

- Complete a minimum of two Regulatory System Audits
- Confirm that all CARs for non-conformities are either closed or have an acceptable action plan in place
- Confirm that all Corrective Action Requests (CARs) for major non-conformities are closed.

The first Regulatory System Audit must take place soon (ideally, within one month) after the Agency completes it's review of the written HACCP system. The second Regulatory System Audit should take place approximately one month following the completion of the first audit.

The following conditions apply to Regulatory System Audits conducted for recognition purposes:

1) The audit team must include the responsible inspector
2) The audit scope includes (see Chapter 4):

    - Outstanding Corrective Action Requests (CARs), as required
    - Log Book
    - CCPs
    - Prerequisite Program Sub-elements.

The audit team selects CCPs and prerequisite program sub-elements to review as per Chapter 4, Section 6.2. However, the audit team must cover the following sub-elements prior to granting recognition:

- Sub-element A 2.1 Design, Construction and Maintenance
- Sub-element E 1.1 Sanitation Program
- Sub-element F 1.1 Recall Program

At the conclusion of the Regulatory System Audit, the audit team provides a written audit report to the establishment's management representatives. With it's report, the team includes Corrective Action Requests (CARs) issued as a result of the audit. An establishment may request a review of the results of a Regulatory System Audit (see Chapter four, Section 4).

If a major non-conformity is identified, it must be closed prior to the second Regulatory System Audit being conducted to ensure that the integrity of the HACCP system has not been compromised.

If a major non-conformity is identified during the second Regulatory System Audit, but can be closed, the establishment is granted FSEP/HACCP recognition. If the major non- conformity cannot be closed, another Regulatory System Audit must be conducted to ensure that the integrity of the HACCP system has not been compromised. If the major non-conformity cannot be closed as a result of the third Regulatory System Audit or an additional major non-conformity is identified, the Area FSEP/HACCP Coordinator issues a notification letter to the establishment. This letter indicates actions the establishment's management must take to correct the non-conformity(ies) in order to be granted FSEP/HACCP recognition. Failure to make these corrections would terminate the recognition process.

Once all the conditions for recognition have been met, the Agency Recognition Team Leader completes the FSEP Recognition Tracking Form (Appendix I) recommending recognition, and forwards the form to the Area FSEP/HACCP Coordinator.

2.9 The Agency issues official notification recognizing the company's FSEP/HACCP status

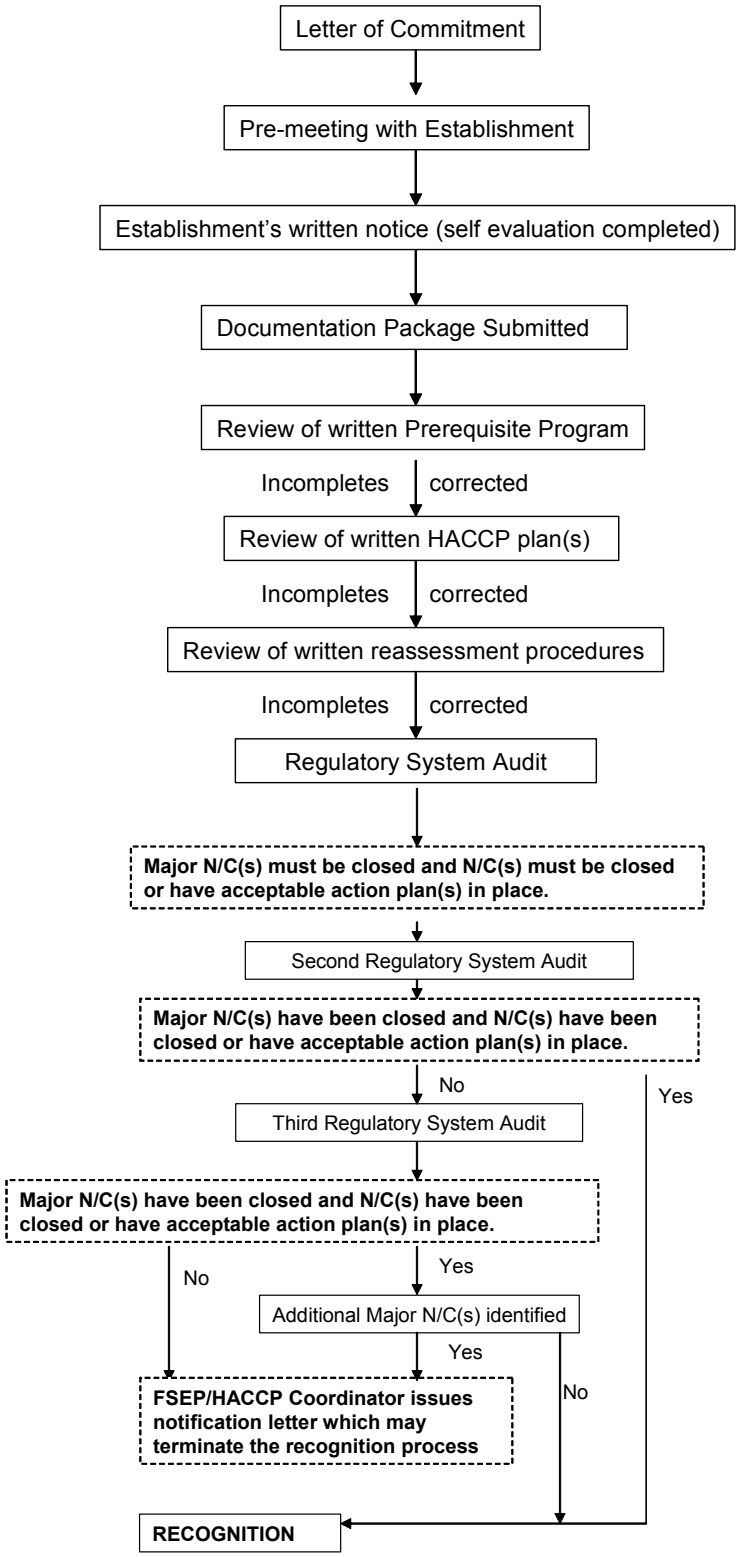
The FSEP/HACCP Coordinator reviews and signs Appendix I and forwards a copy to the appropriate Headquarters Program Chief. The Area Coordinator issues a written notice and a CFIA recognition certificate to the establishment's management. The Agency stamps, initials and dates all pages of the HACCP plan(s) and the first page of the prerequisite programs.

The CFIA maintains on file the following information related to the establishment:

- letter of commitment
- list of establishment HACCP team members
- list of products
- CFIA appendices
- CARs, if applicable
- regulatory system audit documentation

The Agency returns all other documents submitted by the establishment.

Figure 1. Recognition flowchart



Chapter 4: Regulatory System Audit

Section 1 – Background

The CFIA (the Agency) conducts regulatory system audits to verify that an establishment's HACCP system, including its prerequisite programs, HACCP plans and reassessment procedures, is implemented as described and is continuously effective. These audits are consistent with the International Organization for Standardization (ISO) approach to auditing: "a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives."

Regulatory system audits may be unannounced. However, notice of an audit may be given to an establishment to confirm its continued operation and/or the availability of company staff.

Auditors conduct a partial review of the company's HACCP system. Their objective is to confirm that:

- written procedures are up-to-date and continue to meet commodity program and FSEP requirements; and
- the HACCP system is being implemented as described and is effective.

Members of the CFIA audit team must have commodity-specific knowledge in order to identify deviations, assess their impact on food safety and take compliance action if the applicable acts and regulations are not being complied with.

Section 2 – Frequency of audits

Audit frequency for any establishment is determined by the risk category of its products and/or its manufacturing processes.

In the event that an establishment's products fall into more than one risk category, the higher risk category (e.g. Category I) must always determine the frequency of audits.

2.1 Risk categories

Risk categories are determined on the basis on a multitude of factors. The following examples are not comprehensive. If you are not sure which category applies to your company's products or processes, contact your Area FSEP/HACCP Coordinator.

2.1.1 Category I

Category I products or processes may involve **any** of the following, among other criteria:

- The process requires a number of possibly complex control procedures to ensure product safety.
- The process involves a kill step to eliminate microbial contaminants, or another step to reduce them to an acceptable level.
- The production involves a complex recipe. It may involve the use of chemical hazards (e.g. nitrates) or involve a product that addresses serious nutritional concerns.
- Raw material procurement is a critical step. Well-defined hazards can be controlled through incoming raw material (e.g. aflatoxin in nuts).
- Hazards are inherent to the processes, and the products are considered ready to eat, without further processing by the consumer.
- Similar products have been responsible for serious outbreaks of food-borne illness.
- Loss of control within these establishments could result in a significantly high health risk.

Category I includes the following processes, among others:

- Pasteurization, heat treating, drying, freezing (e.g. dairy products, processed egg)
- Thermal processing (e.g. low-acid canned foods)
- Aseptic processing (e.g. aseptically-packaged low-acid foods)
- Cooking or drying (e.g. ready-to-eat meat and dairy products)
- Fermentation or acidification (e.g. meat and dairy products, other acidified or fermented low-acid foods)
- Grinding (e.g. meat)
- Slaughtering

2.1.2 Category II

Products in Category II pose a lower risk than those in Category I. They have inherent hazards, but the processing controls are not designed to eliminate these hazards. The process does not

generally involve a kill step. Rather, the controls (such as proper sanitation and temperature control) are meant to prevent an increase to existing biological, chemical or physical hazards.

The inherent qualities of the raw product entering the establishment are an important factor.

Most products in Category II will be further processed by the consumer, who may need to follow specific handling and storage instructions. While it is necessary to minimize these risks, deviations will only moderately increase the health risks associated with the final product.

Category II includes the following processes, among others:

- Washing, grading, packing (e.g. shell eggs)
- Fresh cutting, modified atmosphere packaging (e.g. vegetables)
- Freezing (e.g. vegetables)
- Cutting (e.g. butter, cheese)
- Cold packing (e.g. cheese)

2.1.3 Category III

Products in Category III do not pose significant health hazards on their own, and the processing and other activities to which they are exposed represent little or no additional risk. Products may be ready to eat or they may be further processed by the consumer prior to consumption.

Category III includes the following processes, among others:

- Thermal processing or aseptic processing (e.g. high-acid foods)
- Maple products processing (includes maple syrup producers and processors)
- Honey processing
- Freezing, drying, packaging (e.g. fruits)
- Drying, packaging (e.g. vegetables)
- Registered storages (e.g. dry storages, freezer storages)

2.1.4 Audit frequencies

For each risk category, the audit frequencies are as follows:

Risk category	Audit frequency
I	One audit per quarter
II	One audit per six months
III	One audit per year

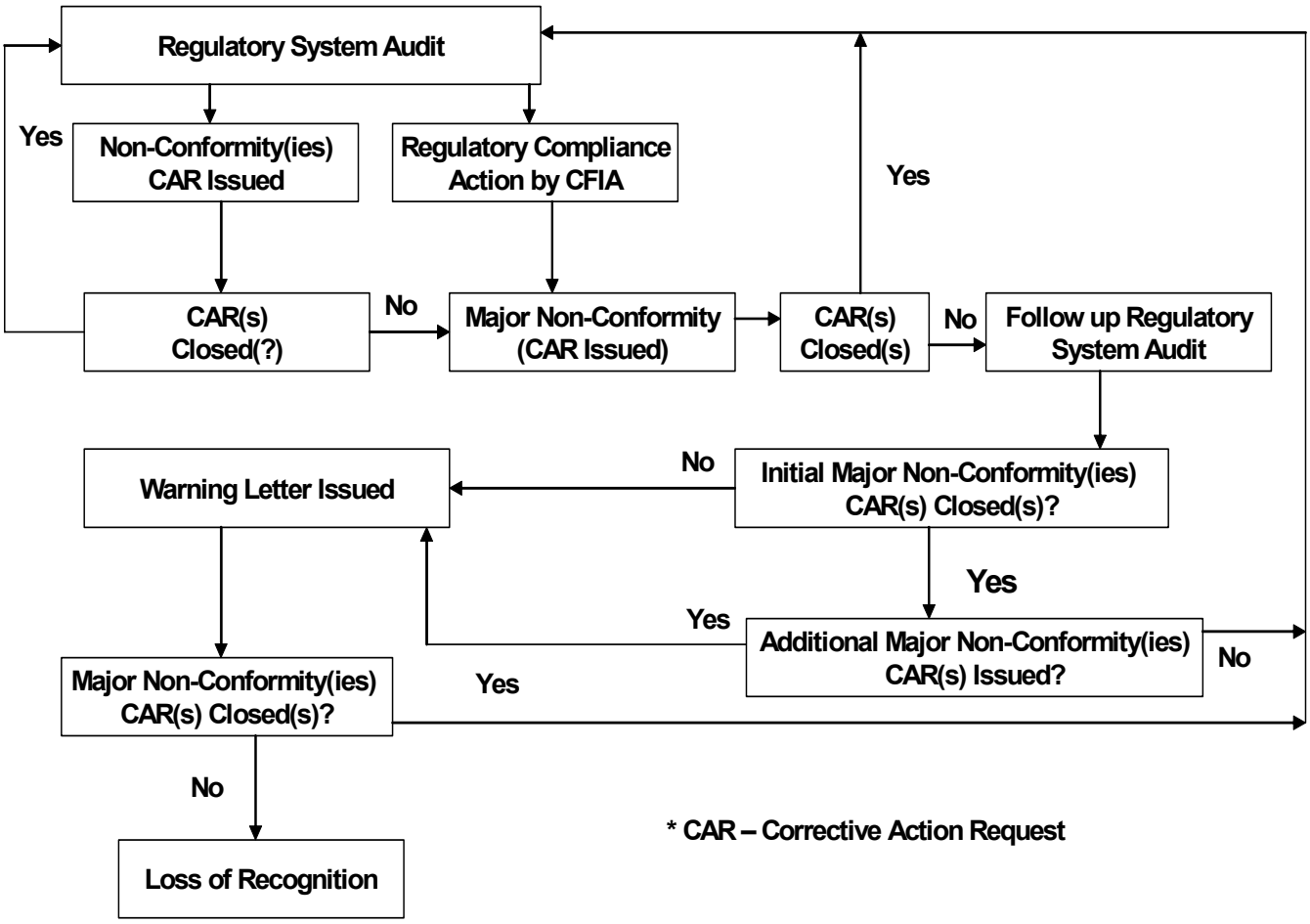
2.2 Non-Conformity Flow Diagram

The Non-Conformity Flow Diagram (see Figure 1) illustrates the steps that the Agency will take when a non-conformity is identified in a regulatory system audit. The steps include the following:

- A follow-up evaluation of corrective actions to close the CAR associated with the non-conformity or non-conformities.
- If the non-conformity cannot be closed a major CAR is issued.
- If the major non-conformity cannot be closed a follow-up regulatory system audit is performed as soon as possible.
- If the initial major non-conformity cannot be closed during the follow-up regulatory system audit or if another CAR is issued for a major non-conformity a warning letter is issued. This letter must be completed and signed by the Area FSEP/HACCP Coordinator.
- If the major non-conformity cannot be closed, the establishment will lose FSEP/HACCP recognition.

The follow-up regulatory system audit is an additional audit conducted when the integrity of the HACCP system is in question. Its scope resembles that of a planned regulatory system audit, but the audit team may target specific CCPs, prerequisite program sub-elements or HACCP reassessment procedures.

Figure 1. Non-Conformity Flow Diagram



Section 3 – Request for review

An establishment may request a review of the results of a regulatory system audit within 30 days of receiving a Corrective Action Request (CAR). The company must submit its reasons, in writing, to the Area FSEP/HACCP Coordinator. The Area FSEP/HACCP Coordinator may contact the appropriate CFIA authorities (National FSEP/HACCP Coordinator, Program Chief) for the decision process. A decision, in writing, is forwarded back to the establishment with a copy sent to the National FSEP/HACCP Coordinator. If the company is not satisfied with the decision, it may contact its national association, which may further discuss the decision with the Agency's National Program Manager for that commodity.

Section 4 – Review of new HACCP plans

When an establishment adds a new HACCP plan to its system, the CFIA Audit team must conduct a review similar to that performed during the initial recognition process (by completing Appendix IV). Before commencing the new processes, the company must develop and implement its new HACCP plan fully, identify the plan in its log book and notify the CFIA.

Section 5 – Changes to a HACCP system

When an establishment changes its recognized HACCP system (e.g. removes a CCP), it must enter the changes in the company log book and support them with scientific data. This data must be available for future review by the CFIA.

Section 6 – Conducting a regulatory system audit

For each regulatory system audit, the Agency performs the following:

- preparing for the audit
- establishing the audit scope
- holding an opening meeting
- gathering information
- holding private meeting(s)
- developing the audit report
- holding a closing meeting
- conducting follow-up activities

6.1 Preparing for the audit

Prior to conducting an audit, the Agency:

- sets the language of the audit;
- identifies the members of the audit team;
- identifies the reference documents;
- sets the date of the audit (the establishment may or may not be notified in advance);
- determines the expected duration of the audit;
- determines the audit scope.

6.2 Establishing the audit scope

The audit scope includes tasks associated with the following:

- outstanding Corrective Action Requests (CARs), if applicable
- log book entries
- CCP(s)
- prerequisite program sub-elements
- HACCP system review tasks

The audit scope may be influenced by factors such as the results of previous audits (e.g. outstanding CARs, audit reports and audit observations), previous inspection results, food safety complaints and other relevant information.

6.2.1 FSEP Audit Scope Worksheet (Appendix VI)

The audit team uses the FSEP Audit Scope Worksheet (Appendix VI) when compiling tasks for the audit. Once complete, this worksheet summarizes the scope of the audit. The purpose of this worksheet is to list the selected tasks in the order in which they will be evaluated.

6.2.2 Order of selected tasks

The tasks are to be listed and audited in the order presented below.

6.2.2.1 Outstanding CARs

Outstanding Corrective Action Requests (CARs) are those CARs that were generated in previous regulatory system audits, for which the completion date has passed, and that have not been closed.

The auditors' first task is to review outstanding CARs. The audit team will evaluate the company's corrective action(s), and may also need to review the written program, in order to determine whether to close each outstanding CAR. The team documents the results of this review on Part C.2 of the CAR form.

6.2.2.2 Log book review

The auditors' second task is to review the company's record (log book) of changes to its processes or HACCP system. On the FSEP Audit Scope Worksheet, the auditors list changes noted in the log, as described below. The auditors will normally review only the revised description in the written program and the implementation of the change in the plant. The auditors will not normally review the entire sub-element or CCP affiliated with the change.

Any log book entries that coincide with CCP(s) or sub-element(s) already selected by the team for review are not listed on the audit scope worksheet. The auditors will evaluate these changes during their review of the related CCP(s) or sub-element(s).

Log book entries related to outstanding CARs are not listed on the worksheet. The auditors will evaluate these changes during their review of the outstanding CAR(s).

Any log book entries associated with new HACCP plans are listed on the Audit Scope Worksheet. The auditors will evaluate them using Appendix IV.

The audit team will select a minimum of two entries that have the greatest impact on food safety or the HACCP system. If no entries have a significant impact on food safety or the HACCP system, the team will not select any for review.

During its log book review, if the audit team determines that the company has not amended its HACCP system appropriately, the team may add the task of reviewing the establishment's reassessment procedures to the FSEP Audit Scope Worksheet.

After completing the review of the log book, the auditor underlines the last entry in the log book (to indicate the point at which the review terminated), enters the review date and signs his or her name.

6.2.2.3 Critical Control Points (CCPs)

The auditors choose to review a certain number of CCPs based on the total number of recognized CCPs. CCPs are randomly selected from among the operating CCPs, if possible. The audit team may, however, target specific CCPs if necessary.

The following guide is used to determine the number of CCPs selected for review:

- 1 recognized CCP: audit the CCP
- 2–8 recognized CCPs: randomly select 2 CCPs
- 9–15 recognized CCPs: randomly select 3 CCPs
- 16–25 recognized CCPs: randomly select 5 CCPs
- 26–50 recognized CCPs: randomly select 8 CCPs
- 51–99 recognized CCPs: randomly select 13 CCPs
- If 100 CCPs or more are recognized, the audit team will consult with the Area FSEP/HACCP Coordinator for instructions on selecting CCPs.

If there are not enough recognized CCPs operating at the time of the audit, the audit team will review the records and interview the personnel responsible for the selected non-operating CCPs, if possible.

6.2.2.4 Prerequisite program sub-elements

Prerequisite program sub-elements have been grouped according to their impact on food safety (see Table 1), with Group 1 having the most impact and Group 3 having the least. The auditors will select the prerequisite program sub-elements to be audited according to the following guide:

- Group 1 sub-elements: randomly select 2
- Group 2 sub-elements: randomly select 2
- Group 3 sub-elements: randomly select 2, once per year.

While the selections are normally random, the audit team may target specific sub-elements as necessary.

The following guidelines will be utilized by the auditor during the evaluation process:

C 1.2 Equipment Maintenance and Calibration – Select a maximum of two pieces of equipment for general maintenance and two for calibration as identified in the company's written program (e.g. the whole pasteurizer or its individual parts [plates, pumps, recording thermometers, etc.]) and not selected from the previous audit.

E 1.1 Sanitation Program – Select one room or area and select a sample of the equipment located in that room or area.

Table 1. Grouping of prerequisite program sub-elements

Group 1	Group 2	Group 3
Premises: A 4.1 Water/Ice/Steam **Transportation, Receiving and Storage:** B 1.2 Temperature Control B 2.1 Incoming Material B 2.3 Finished Product Storage **Equipment:** C 1.2 Equipment Maintenance and Calibration **Personnel:** D 2.1 Cleanliness and Conduct **Sanitation and Pest Control:** E 1.1 Sanitation Program	**Premises:** A 2.1 Design, Construction and Maintenance A 2.2 Lighting A 2.3 Ventilation A 2.5 Inedible Area **Transportation, Receiving and Storage:** B 1.1 Food Carriers B 2.2 NFC Receiving and Storage **Equipment:** C 1.1 Design and Installation **Personnel:** D 1.1 General Food Hygiene Training D 1.2 Technical Training **Sanitation and Pest Control:** E 2.1 Pest Control Program	**Premises:** A 1.1 Outside Property and Building A 2.4 Waste Disposal A 3.1 Employees' Facilities A 3.2 Equipment Cleaning and Sanitizing Facilities **Personnel:** D 2.2 Communicable Diseases/Injuries **Recall:** F 1.1 Program F 1.2 Product Code Identification and Distribution Details

6.2.2.5 HACCP system review tasks

The audit team members must audit, at a minimum of once per year, each item listed in the following task list for HACCP system review. These items may be audited separately over the year. The criteria to be evaluated appears in parentheses below. The auditors record the results of their review on the FSEP Regulatory System Audit Worksheet (Appendix VI).

The HACCP system review consists of the following:

a. Review Task 1

- Review label against product description (Appendix IV, task 1.9)
- Review formulation against product description (Appendix IV, task 1.10)
- Review labels and formulation against incoming ingredients (Appendix IV, task 2.4)
- Conduct on-site verification of formulation (Appendix IV, task 2.5)

b. Review Task 2
Conduct on-site verification of process flow diagram (Appendix IV, task 3.4)

c. Review Task 3
Conduct on-site verification of plant schematic (Appendix IV, task 4.4)

d. Review Task 4
Review the establishment's written procedures for its reassessment of the HACCP system (Chapter 2, Section 5) and the on-site evaluation of the implementation of these procedures

6.3 Holding an opening meeting

The purpose of the opening meeting is to:

- introduce the members of the audit team to the management representatives;
- establish official communication links between the auditor and the establishment's representative (e.g. HACCP coordinator);
- confirm that the needed resources and facilities are available;

- confirm the time and date of the closing meeting and any necessary interim meetings;
- obtain the company's written prerequisite programs and HACCP plans;
- confirm which CCPs are operating;
- obtain access to the company's log book;
- discuss previous audit findings (e.g. outstanding CARs); and
- finalize the audit scope.

6.4 Gathering information

Prior to conducting its on-site audit, the audit team evaluates the company's written programs to ensure that they are complete. During this review, the team develops or updates its FSEP checklists (Appendix II or IV) for the prerequisite program and HACCP plan.

When an establishment has developed written procedures that exceed regulatory requirements, the audit team evaluates the written program on the basis of the higher standard.

If the auditors determine that the company's written procedures are incomplete, they note this deficiency on the FSEP Audit Worksheet. Once the establishment has amended its written program(s), the audit team reviews the amended version to ensure that it is complete. Only then will the team conduct the on-site evaluation of that selected task. If the written program cannot be amended during the audit, the auditors may select another task to evaluate. They note the incomplete sub-element or CCP in their audit report. This task will then be selected in the next regulatory system audit.

The audit team uses the checklists found in Appendix II and Appendix IV while reviewing records and conducting an on-site evaluation of CCPs and prerequisite programs.

The audit team gathers information to ensure that the company's HACCP system is effective in meeting food safety objectives. It gathers objective evidence to confirm that the procedures, documents and other information describing the HACCP system:

- are implemented as described;
- are up to date; and
- continue to meet commodity and FSEP program requirements.

Objective evidence is collected by conducting the following activities.

6.4.1 Record review

The audit team examines company records (e.g. monitoring, deviation and verification records) to confirm that they have been completed and filed as indicated in the written procedures.

6.4.2 On-site evaluation

The on-site evaluation may include two components:

- Interviewing designated personnel responsible for carrying out activities outlined in the written program. The interview should confirm that these employees have access to, understand and are using the current written procedures.

- Visually confirming the information gathered through the above interviews, by observing on-site activities and/or environmental conditions in the establishment.

Should the auditors find objective evidence that is not in the audit scope, they may add the associated audit task to the audit scope or note those observations in the audit report. This audit task would then be selected in the next regulatory system audit.

The audit team documents its objective evidence on the FSEP Audit Worksheet (Appendix VI) and communicates this evidence to representatives of the establishment during the audit. One or more company representatives should be available to accompany the audit team members during their gathering of objective evidence. If company staff cannot be present, the audit will continue.

6.5 Holding a private meeting

The audit team discusses its objective evidence in a private meeting. The team assesses the evidence to determine whether each item:

- conforms to the appropriate criteria
- warrants an audit observation
- constitutes a non-conformity (Figure 2)
- constitutes a major non-conformity (Figure 2)

During the private meeting, the auditors may seek advice from other experts to help them assess the objective evidence (e.g. CFIA commodity specialists, FSEP/HACCP specialists).

6.5.1 Evaluating objective evidence

In assessing the objective evidence, the audit team determines whether any existing conditions put food safety at risk. If a food safety issue is identified and the establishment does not initiate immediate corrective action (e.g. hold products or initiate recall procedures), the audit team will take regulatory compliance action to control the food safety issue. If the auditors take regulatory compliance action, they will also generate a CAR indicating that a major non-conformity has occurred (Chapter 4, Section 6.5.1.3, Figure 2).

6.5.1.1 Audit observation

An audit observation is a deviation that is identified during an audit but has no impact on the integrity of the HACCP system and does not requiring a written action plan (e.g. a signature missing on one record). The auditor may note these as “audit observations” on the audit report. If similar observations were noted on past audit reports, the audit team may decide to rate this observation as a non-conformity.

6.5.1.2 Non-conformity

A non-conformity is a deviation identified during an audit that impacts on the integrity of the HACCP system and necessitates a written corrective action plan (e.g. the written program continues to control the sub-element effectively).
Non-conformities may occur within:

- the sub-element of a prerequisite program;
- a CCP of the HACCP plan; or
- the HACCP system reassessment procedures.

For each non-conformity, the Agency requires a written corrective action plan from the establishment.

6.5.1.3 Major non-conformity

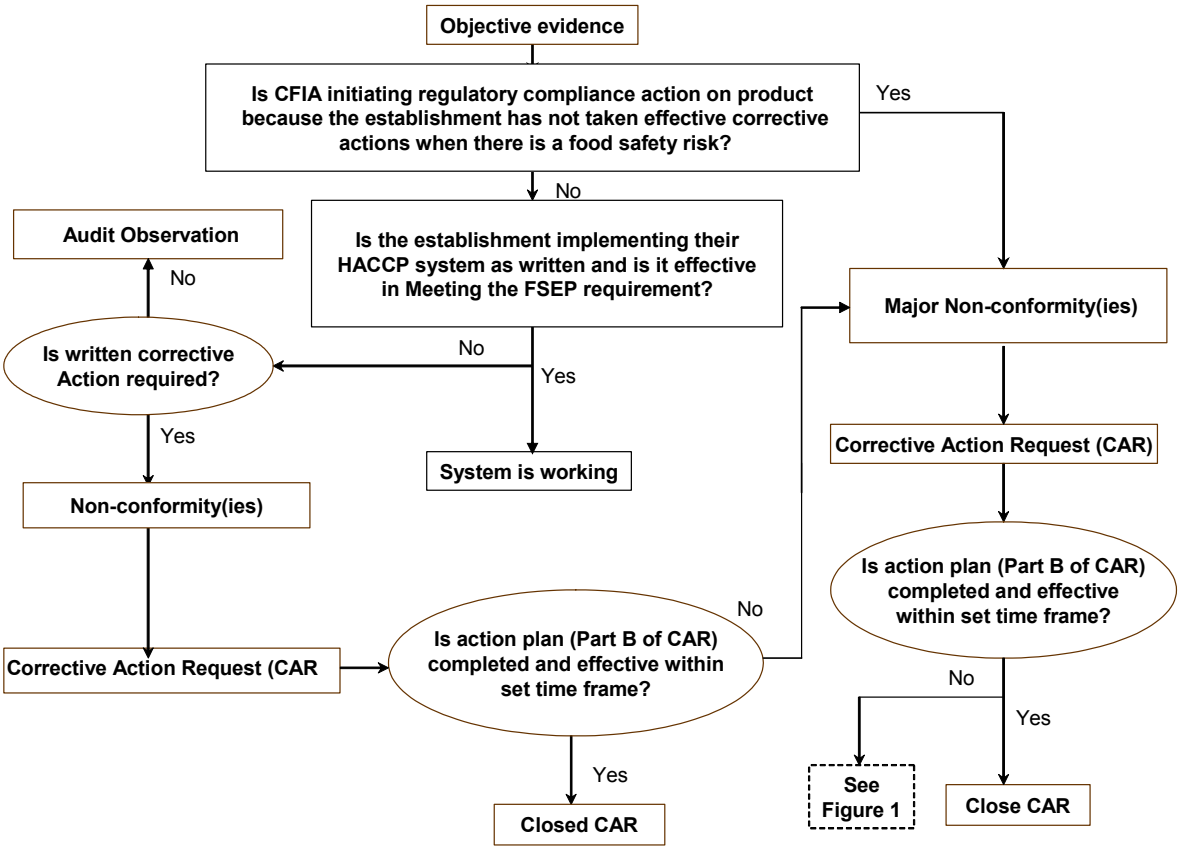
A major non-conformity is identified when the following are observed:

- An incident putting food safety at risk, where the establishment has not taken effective corrective action and the CFIA takes regulatory compliance action on the product.

- Failure to implement effective corrective action from a previously identified non-conformity.

For each major non-conformity, the Agency requires a written corrective action plan from the establishment.

Figure 2. Evaluation of objective evidence diagram



6.5.2 Corrective Action Request (CAR)

When a non-conformity is identified during a regulatory system audit, the auditors complete a CAR form describing:

- the non-conformity;
- the company's written corrective action plan; and
- subsequent follow-up observations by the Agency.

Each CAR is numbered using the establishment registration number followed by the year and the consecutive CAR number (e.g. 111-2005-01).

The CAR form is divided into three parts as follows (Appendix VI).

6.5.2.1 Part A: Description of Non-Conformity

Part A of the CAR form is completed by the audit team. The information must include the following:

a) a description of the non-conformity (include objective evidence);
b) a reference to the establishment's procedures associated with the non-conformity;
c) the auditor's name and signature and the date on which the CAR was issued;
d) the target date for the establishment to submit Part B, if required; and
e) the signature of the establishment's representative acknowledging receipt of the CAR.

Note: The original signed CAR should be kept by the auditor and a photocopy of the CAR is given to the establishment

6.5.2.2 Part B: Corrective Action

Part B is completed by the establishment. The information must include details of the corrective action(s) and preventative measure(s) that it has taken to address the non-conformity identified in Part A.

If the establishment does not submit Part B to the audit team at the time the CAR is presented, the establishment must submit Part B by the date indicated in Part A, "date for submission of corrective action."

The establishment's representative must sign and date Part B of the CAR and submit it to the audit team, who will determine if it is acceptable (Appendix VI, Corrective Action Request Guidelines).

The establishment must identify the date by which it will complete its corrective action(s). It is the responsibility of the establishment to ensure that its corrective action(s) are implemented effectively by the date that it has indicated.

For major non-conformities, an action plan is to be requested from the operator within 24 hours, including implementation of immediate appropriate corrective actions, and up to 10 days for implementation of preventative measures.

For all other non-conformities, an action plan is to be requested from the operator within 10 days. The operator has up to 60 days for implementation of corrective actions, including preventative measures.

The Agency may grant an extension to the agreed "date for completion of corrective action" under the following circumstances:

- Food safety is not compromised.
- The establishment will not meet its "date for completion of corrective action" due to reasons beyond its control (e.g. a part is on back order).

Please note: If the above criteria apply, it is the establishment's responsibility to contact the CFIA prior to the current completion date indicated in Part B in order to request an extension. If the extension is granted, the new date is entered in Part B of the CAR form and initialled by the auditor.

6.5.2.3 Part C: CFIA Assessment and Follow-up

The auditor completes Part C.1 while reviewing the corrective action plan submitted by the establishment (Part B). If the corrective action plan (Part B) is acceptable, the auditor signs and dates Part C.1. If the corrective action is not acceptable, the auditor returns the CAR form to the establishment's representative for correction.

The auditor completes Part C.2 whenever a follow-up review is conducted at the establishment to determine whether corrective actions have been implemented effectively. If the auditor finds that corrective actions have been implemented effectively, the auditor signs and dates the CAR and closes it. If the corrective actions have not been implemented effectively, the CAR remains open and the following actions are taken:

- For a non-conformity: a major CAR is issued
- For a major non-conformity: a follow-up regulatory system audit is scheduled, as indicated in the Non-Conformity Flow Diagram (Section 2.2, Figure 1)

6.6 FSEP Audit Report

The FSEP Audit Report (Appendix VI) is completed by the audit team. It includes the following information:

- scope of the audit
- name(s) of the audit team member(s)
- name(s) of the company representative(s)
- reference documents used (e.g. prerequisite programs, HACCP plans, standard operating procedures (SOPs), etc.)
- audit findings
- CAR information (attach CAR form(s))
- conclusions (overall comments on the results of the audit)

The audit report, including any applicable CARs, must be provided to the establishment's management with a copy sent to the Agency inspector responsible for follow-up action. The audit report is also copied to the Agency's Area FSEP/HACCP Coordinator and HQ Program Chief.

6.7 Closing meeting

The audit team conducts a closing meeting with management representatives (e.g. HACCP coordinator, plant manager, plant supervisor, etc.). At this meeting, the auditors present the company representatives with the audit report and any CARs. The auditors review the results of their audit and clarify their audit findings. At this time, the establishment is expected to provide target dates for completing any necessary corrective actions.

6.8 Conducting follow-up

All CARs are followed up on by the auditor or the responsible inspector. The auditor reviews all written corrective action plans submitted by the company and determines whether they are acceptable. Part C.1 of the CAR is completed at this time.

After the "date for completion of corrective action" has passed, the auditor and/or inspector follows up at the establishment in the presence of the company representative to ensure that the corrective actions have been completed as described and are effective. The follow-up to the non-conformity may be performed during the subsequent audit, or sooner, if required.

A follow-up to a non-conformity must be performed as soon as possible after the date for completion of corrective action identified in Part B of the CAR form.

When the auditor and/or inspector determines that the corrective action is completed and effective, Part C.2 of the CAR is completed and the CAR is closed.

If the action plan has not been effectively implemented and the CAR cannot be closed, the CFIA will take action as per the Non-Conformity Flow Diagram (Section 2.2, Figure 1).

Section 7 – Loss of recognition

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

When an establishment loses recognition, the Area Executive Director sends a letter to the company's management, with a copy to the Agency's Program Chief, informing it 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, it must begin the process by re-submitting a letter of commitment and following the steps outlined in Chapter 3.