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INTRODUCTION

The Food Safety Guidebook has been developed by Alberta Agriculture and Rural Development to assist you in developing a food safety system. This guidebook is designed to take you through the steps necessary to develop an effective food safety system specific to your food-processing operation.

This guidebook contains basic food safety system information that you may adapt and modify to fit your facility's special needs. You can use all the suggestions or just parts found in each chapter.

A successful food safety system requires understanding and commitment by your entire staff. This guidebook will help ensure that you and your employees have a complete understanding of the requirements of an effective food safety system and of everyone's role in ensuring its success.

It is recommended that you consult with someone with the necessary food safety knowledge when developing your HACCP system. You or a member of your staff may have the required education or experience, or you can work with a food safety consultant who can provide advice, direction and expertise on developing and implementing a HACCP system.

To help make this guidebook more useful, we have developed a few visual symbols.

- Chapter Symbol – To help you to find your way more easily through the manual, we have provided pointers showing where in the publication you can find more information.

- Website Symbol – Other outside resources, including websites, can be helpful when developing a food safety system. This symbol can direct you to websites worldwide that can offer further information or resources.

- Forms Symbol – To help you implement a food safety system, we have developed a series of forms that you can use. This symbol points you to these form.

Here are some government website addresses for food safety regulatory information:

- ODEX Alimentarius www.codexalimentarius.net
- Agriculture and Agri-Food Canada www.agr.ca
- Canadian Food Inspection Agency www.inspection.gc.ca
- Health Canada www.hc-sc.gc.ca
- Canada Food and Drugs Act Phone (613) 957-4222 or visit http://lois.justice.gc.ca/en/F-27
- Alberta Health and Wellness www.health.gov.ab.ca

Disclaimer

While Alberta Agriculture and Rural Development has produced this guidebook, it does not guarantee that the information or materials provided will identify all the potential risks and all measures that may be required to eliminate or manage the food safety risks associated with your food production facility. You are not required to use all materials contained within. Risk management is the responsibility of the food processor, and therefore it will be your responsibility to determine your facilities needs.

This guidebook has been developed to assist Alberta food processors in developing and implementing their own food safety systems. Government regulations and their requirements take precedence over all information contained in this manual. It is the responsibility of the food processor to determine which regulations apply to the food products they are producing and to meet these regulations before implementing any changes within their facility structure or processes.

Chapter 1

FOOD SAFETY SYSTEMS

1.0 FOOD SAFETY SYSTEMS

1.1 Parts of a Food Safety System

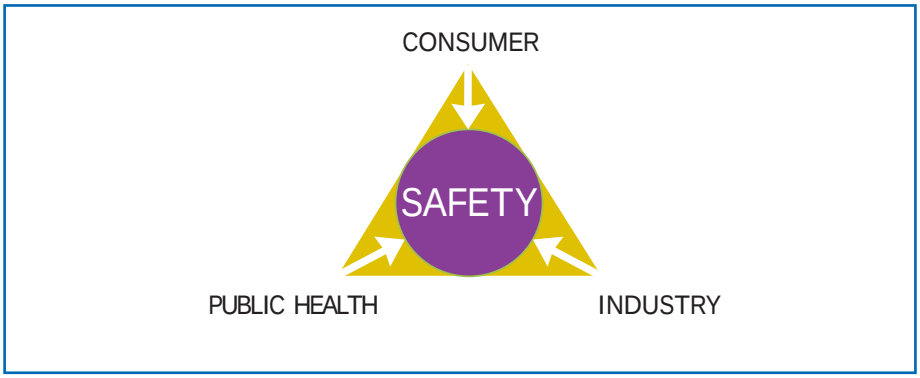
2.0 HACCP

3.0 SOURCES OF INFORMATION

1.0 FOOD SAFETY SYSTEMS

Food safety is driven by consumers, industry and public health.

The need for food safety is driven by consumers, the food industry and public health agencies. Food processors have an obligation to ensure they produce the safest food possible.



The best way to ensure that the food you produce is safe is to develop a food safety system.

Mishandling and/or misuse can make even the safest ingredients unsafe. To produce safe food, processors must follow specific steps and procedures throughout the entire production process.

Safe food usually becomes unsafe by accident. This is important to keep in mind even if the facility has never been involved in a food safety issue or recall.

Many people become sick or injured from unsafe food each year. A food safety incident connected to the facility could cause significant costs through recalls, negative publicity, loss of customers, loss of credibility and lawsuits.

1.1 Parts of a Food Safety System

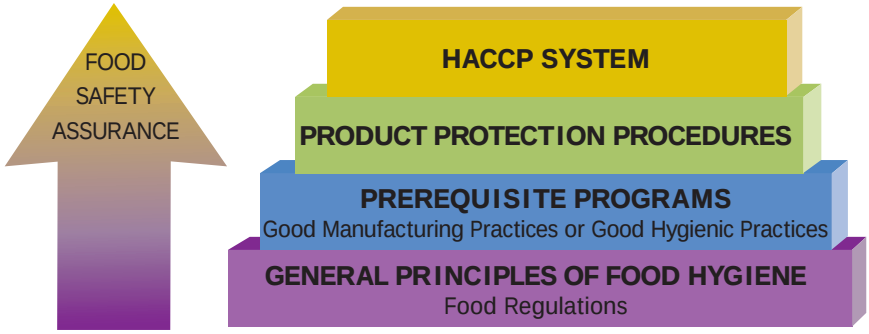
In the past, three types of food safety measures were used:

- Activities required by regulation. Regulatory requirements are the basic minimum legal requirements that all food processors must follow.
- Activities stated in the codes of Good Manufacturing Practices (GMP) or Good Hygienic Practices (GHP). These activities relate to processing, transportation, etc.
- Activities performed to verify the food's safety after it is produced (e.g. end product testing).

Food regulations are the foundation of all food safety systems.

As seen in Figure 1, food regulations are the foundation for a successful food safety system. These regulations are further enhanced by GMP or GHP, but these practices alone are not enough. These measures rely on a snapshot inspection of the processing facility and not ongoing activities.

Figure 1



In order to increase food safety assurance, a facility's GMP or GHP programs need to be further supported. This is to ensure that all potential hazards to the food and production process are identified and controlled.

End product testing may provide some added assurances to consumers but can be costly and time consuming. End product testing has also been proven to be less reliable than a well implemented, documented and maintained food safety system. Today's approach to food safety combines compliance with a number of approaches including food safety regulations, GMP, GHP, and the use of an appropriate HACCP system.

Developing a successful food safety system requires a solid understanding of:

- Food safety principles;
- Hazards associated with the facility's products;
- The steps required to prevent those hazards;
- Regulatory requirements for the product; and
- What makes a food safety system auditable and verifiable.

A facility is responsible for knowing all necessary regulations and laws as they relate to the company's product or process. These requirements may include but are not limited to:

Alberta Food Regulation
http://www.canlii.org/ab/laws/regu/2006r.31/20061113/whole.html

Alberta Food and Retail Services Code
http://www.health.gov.ab.ca/professionals/foodcode.html

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

Consumer Packaging and Labeling Act
http://laws.justice.gc.ca/en/C-38/C.R.C.-c.417/index.html

Commodity Specific Acts and Regulations
http://www.inspection.gc.ca/english/reg/rege.shtml

A facility's food safety system must meet all regulatory and legislative requirements, and also be auditable.

Alberta Agriculture and Rural Development has a list of Alberta food safety consultants. For contact information, visit http://www.agric.gov.av.ca/app68/agriprocessors?cat1=Consultants#30829

2.0 HACCP

HACCP is internationally accepted as one of the most effective approaches to safe food production. HACCP (pronounced HAS-sip) stands for Hazard Analysis Critical Control Point. It is a proactive and prevention based system.

HACCP complements regulatory compliance and GMP.

HACCP helps facilities take food safety to the next level. It complements regulatory compliance and GMP, and provides additional assurances. Rather than relying on end product testing to detect failures, HACCP applies control measures at identified stages of the production process. This serves to prevent, reduce or eliminate hazards before they occur. When well implemented, HACCP will meet the requirements of an effective food safety system.

Chapter 2: HACCP Systems Explained provides an overview of HACCP and its processes. It explains the basic provisions needed to ensure an effective and successful HACCP plan.

A HACCP system includes both prerequisite, or underlying programs and also HACCP plans. Prerequisite programs are the foundation of a HACCP system and include the procedures and practices that provide the basic environmental and operational conditions needed to produce safe foods. Once a facility documents and implements these environmental controls, it can begin the development of HACCP plans.

HACCP plans outline how the hazards associated with incoming materials (ingredients) and process steps are controlled. They also identify the processes that are critical to ensuring food safety (e.g. the critical control points).

Prerequisite programs + HACCP plans = HACCP system.

A facility must develop, implement and maintain both prerequisite programs and HACCP plans when implementing an effective HACCP system.

3.0 SOURCES OF INFORMATION:

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Chapter 2
HACCP SYSTEMS EXPLAINED

1.0 WHAT IS HACCP?

2.0 FOOD SAFETY HAZARDS
- 2.1 Assessing Hazards
- 2.2 Cross-contamination

3.0 REQUIREMENTS FOR A HACCP SYSTEM
- 3.1 Management Commitment
- 3.2 Selecting the HACCP Team
- 3.3 The HACCP Coordinator
- 3.4 HACCP Training

4.0 COMPONENTS OF A HACCP SYSTEM
- 4.1 Prerequisite Programs
- 4.2 HACCP Plans

5.0 SOURCES OF INFORMATION

Food safety begins with effective controls and practices during farm production. It continues through processing, distribution, retailing and consumer handling. Thousands of operations around the world use HACCP-based food safety programs in various stages of food production.

This chapter gives an overview of HACCP and explains the basic requirements to set up and maintain an effective and successful HACCP system.

Consumer awareness of food safety and changing regulations are good reasons to adopt a food safety system such as HACCP.

1.0 WHAT IS HACCP?

HACCP (pronounced 'HAS-sip') stands for Hazard Analysis Critical Control Point. HACCP is an internationally recognized, science-based food safety system that focuses on preventing, eliminating and reducing hazards. It differs fundamentally from any inspection-based system because it identifies and deals with hazards before an incident occurs.

HACCP **is:**

- Recognized as the best way to eliminate, reduce or control hazards in a food handling or processing environment;
- Developed and maintained by individual processors to control their particular food safety environment; and
- Suitable for use in various food processing and handling facilities because the same HACCP principles apply whatever the location or food process.

HACCP **is not:**

- A quality control program. Although HACCP principles can be adapted to deal with quality control issues, this program is not intended to address quality control;
- A government controlled program. HACCP must be 100 percent owned and controlled by the processor;
- Maintenance free. Unlike inspection programs and other food safety control methods, HACCP is not a snapshot effort to deal with production processes. HACCP systems change continually and grow with a facility as it is developed and maintained; and

- A guarantee of food safety. Every step during the process from 'farm-to-fork' provides another opportunity for contamination of product. A well-designed HACCP system improves the chances that any hazards introduced in previous stages of the process will be detected.

HACCP first identifies potential food safety problems and then determines the best way to prevent, reduce or eliminate them. All potential hazards are considered ahead of time. These are designed out of the production process. Safety is built-in.

2.0 FOOD SAFETY HAZARDS

Some sources of food safety hazards include:

- *Facility environment*
- *Improper handling*
- *Unsanitary equipment*
- *Poor employee practices*
- *Raw materials or ingredients*

Hazards are defined as situations with the potential to cause an injury or illness in consumers. The four classes of hazards most commonly associated with food safety are:

- Allergenic
- Biological
- Chemical
- Physical

These hazards may exist in raw materials or be introduced at any stage during the manufacturing process.

Allergenic Hazards

Allergenic hazards are proteins that can cause an allergic response in sensitive individuals. Symptoms of an allergic reaction could include a runny nose, watery and/or itchy eyes, a rash, wheezing, respiratory distress or even death.

In Canada, the Canadian Food Inspection Agency (CFIA) regognizes 10 priority allergens known to cause life threatening reactions:

1. Egg
2. Peanut
3. Sulphites
4. Fish and shellfish
5. Milk
6. Wheat
7. Tree nuts
8. Sesame seeds
9. Soy
10. Mustard

Biological Hazards

A biological hazard is any danger to food safety caused by contamination with microorganisms. This type of hazard includes disease causing bacteria, viruses (e.g. Hepatitis A), parasites (e.g. Trichinella or Cryptosporidium), and moulds.

Chemical Hazards

Chemicals that can contaminate food products include:

- Naturally occurring toxins (e.g. alkaloids in potatoes, toxic wild mushrooms or aflatoxin in peanuts);
- Normally added ingredients (e.g. sodium nitrite can be toxic if added in high enough levels); and
- Unintentionally added hazards (e.g. pesticides used to treat insect infestations or cleaning chemicals that may not have been safely rinsed from equipment).

Physical Hazards

Physical hazards are any foreign materials not normally found in food (e.g. rocks, broken glass, metal fragments or bone pieces).

2.1 Assessing Hazards

Some hazardous agents are more dangerous than others. There are significant differences in severity depending on the type of hazard and who is consuming it.

It is the processor's responsibility to know the acceptable levels related of all types of standards. Some examples include the standard temperature that food can be safely stored or cooked to prevent the growth of microorganisms or the amount of normally added ingredients such as nitrates.

Some standards apply to the shelf life of ingredients, after which they are no longer safe to use in food. Each process will involve standards of handling and hygiene. It is the processor's responsibility to know all standards and to ensure they are understood and used by employees.

For more information on Assessing Hazards, see Appendix D: Food Safety Risk Analysis.

2.2 Cross-contamination

Product and employee flow are major considerations in controlling cross-contamination.

Cross-contamination occurs when micro-organisms, allergens, foreign matter or chemicals are transferred unintentionally from one food or surface to another.

It is important that a HACCP plan clearly indicates the actual movement of employees. It must also indicate the flow of goods and process steps for each product. Because employees do not always follow formal processes, it is important to observe what actually happens in daily operations. This information is then analyzed to identify situations where cross-contamination might occur.

3.0 REQUIREMENTS FOR A HACCP SYSTEM

Developing, starting, working and maintaining a HACCP system requires dedication, commitment and resources. Implementing HACCP is not an overnight process or a one-time effort.

The following steps will help to design and implement a HACCP system:

1. Obtain management commitment;
2. Assemble the HACCP team and assign a HACCP coordinator;
3. Train managers, frontline staff and the HACCP coordinator;
4. Develop or revise and implement prerequisite programs (see Chapters 4 to 13);
5. Develop or revise and implement HACCP plans (see Chapter 14: Developing a HACCP Plan); and
6. Maintain the HACCP system by reviewing, verifying and validating once a year (see Chapter 15: Maintenance of HACCP).

3.1 Management Commitment

Management commitment is key to a successful food safety system. Management commitment ensures that a food safety system is as much a part of daily business as maintaining sales and reducing costs.

A strong HACCP system that's developed and implemented effectively helps in maintaining sales and reducing costs.

Even if management only plays a supporting role in the food safety system, management commitment must be visible to all employees.

Management commitment can be shown by:

- Promoting HACCP activities at internal meetings;
- Posting signs indicating in-house HACCP policies;
- Posting a sign indicating management commitment to HACCP;
- Supplying adequate resources for HACCP development, implementation and food safety training;
- Regular review of HACCP materials and progress reports;
- Regular attendance by management at HACCP training sessions; and
- Standardizing and enforcing disciplinary actions for employees who don't meet their HACCP responsibilities.

Send a clear message that management is involved and that it cares about the success of the program.

For HACCP to be successful, the entire food production team must work together. They must develop and maintain the system. Lack of management commitment is one of the most common reasons for failure of a HACCP system.

3.2 Selecting the HACCP team

A HACCP team explores options and makes recommendations during the development and maintenance stages of a HACCP system. The HACCP team should involve people from across the organization including:

- Production
- Sales
- Sanitation
- Maintenance
- Shipping and Receiving
- Quality Control
- Management

Development of a HACCP system should involve people who can put the policies and activities in place in their respective areas.

Involve people who will be responsible for developing or changing HACCP policies in their respective areas. They will have the best understanding of how changes will affect daily operations in that area.

Involve employees and management who have varied skills and experience. Make sure they can:

- Identify hazards;
- Determine critical control points (CCPs);
- Monitor CCPs;
- Verify operations at CCPs; and
- Examine samples and perform verification procedures.

Everybody on the team should have a basic understanding of:

- Technology and equipment used on the processing lines;
- Practical aspects of food operations;
- Flow and technology of processes;

- Applied aspects of food microbiology; and
- HACCP principles and techniques.

The size of the HACCP team will vary depending on the size and complexity of the food production process. At minimum, the HACCP team must consist of at least one person who is thoroughly familiar with all aspects of the facility and its products.

3.3 The HACCP Coordinator

The HACCP coordinator leads the development and maintenance of the HACCP system. A HACCP coordinator organizes the information provided from the HACCP team into a workable system.

The HACCP coordinator must have a solid understanding of HACCP systems. They must have working knowledge of the facility and its processes. They must also be able to make decisions based on science.

The coordinator is not necessarily the person who does the work related to putting together the HACCP system. The expertise of an independent consultant may be needed to make sure that hazards are addressed (e.g. an expert in public health risk associated with the product/process).

3.4 HACCP Training

HACCP training is required for managers, personnel and the HACCP coordinator. The level of HACCP understanding and knowledge required for each person depends on their role and responsibility:

Manager Training

- Importance of their role in HACCP;
- Benefits and costs of HACCP;
- Need for consistent and obvious management commitment; and
- Resources needed for HACCP system development and certification.

Personnel Training

- Importance of food safety to the business, consumers and employees;
- Good Manufacturing Practices (GMP) and policies;
- Staff roles and responsibilities in the HACCP system;
- Importance of control measures; and
- How to perform specific tasks related to the HACCP system (e.g. monitoring, taking corrective actions, record keeping).

HACCP Coordinator / HACCP Team Training

- Food safety hazards common to products and processes;
- Regulatory requirements needed and the purpose of prerequisite programs;
- HACCP principles (including hazard analysis and determination of critical limits);
- Record keeping, understanding of audits and internal audits including concepts of monitoring, corrective actions and verification;
- Resources needed for ongoing HACCP activities and certification including processes for certification, recognition and maintenance of the HACCP system.

Sources for HACCP training and information include:

- Taking Food safety and HACCP related courses;
- Applying food processing environment experience;
- Researching regulatory requirements;
- Researching specific topics (e.g. reading scientific literature);
- Communicating with appropriate experts (e.g. sanitation company, government authorities); and
- Hiring HACCP trainers or consultants.

4.0 COMPONENTS OF A HACCP SYSTEM

A HACCP system includes putting together and using both prerequisite programs and a HACCP plan.

Prerequisite Programs + HACCP Plan = HACCP System

4.1 Prerequisite Programs

Most of the hazards that can be identified in a food processing operation are somewhat similar. They could happen at any stage of the process (e.g. contaminated blades, glass, pests, poor personal hygiene, etc.). These hazards are controlled by prerequisite programs.

Prerequisite programs are the foundation of any HACCP system. They are the standard operating procedures (SOPs) and environmental conditions necessary for safe food production and packaging and found in any comprehensive food safety system. Prerequisite programs control the facility, environment, staff and materials.

Prerequisite programs (PRP) are called Good Manufacturing Procedures (GMP) or Good Hygienic Practices (GHP) in the United States. They are called Standard Operating Procedures (SOPs) in many other countries.

Prerequisite programs must be complete. They must provide all the information that is needed to ensure a safe environment to produce food. All employees should understand the importance of these programs and be fully committed to following food safety policies and procedures.

Prerequisite programs with trusted controls will reduce the critical control points (CCP) needed in a HACCP system. Reducing the number of critical control points needed lets processors focus on where food safety is most likely threatened.

HACCP plans should not control hazards that are normally controlled through the prerequisite programs. This guidebook groups the required procedures in eight prerequisite programs:

- Premises;
- Transportation and Storage;
- Equipment;
- Personnel/Training;
- Sanitation and Pest Control;
- Recall;
- Allergen Control; and
- Supplier Food Safety Assurance.

4.2 HACCP Plans

A critical control point (CCP) is a point, process step or procedure where a control increases food safety. A CCP is used for preventing a food safety hazard, eliminating it, or reducing it to an acceptable level (e.g. cooking).

HACCP plans outline how food safety hazards connected with ingredients and process steps are controlled. HACCP plans identify the critical control points (CCPs) in the manufacturing process and identify how to control CCPs to ensure safe food production.

A HACCP plan controls hazards directly related to the food product, ingredients or the process. The plan identifies steps to control, eliminate, or reduce food safety hazards to an acceptable level. It's important to have fully functioning, effective prerequisite programs running before putting together a HACCP plan.

For more information about developing a HACCP plan, see Chapter 14: Developing and Implementing A HACCP Plan..

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Chapter 3
DOCUMENTATION AND RECORD KEEPING

1.0 DOCUMENTS AND RECORDS

2.0 DOCUMENTING HACCP PLANS

3.0 CREATING AN AUDITABLE PROGRAM
- 3.1 Document and Record Control

4.0 DOCUMENTATION SYSTEM FORMATS
- 4.1 Monitoring or Activity Section
- 4.2 Deviation Procedures and Corrective Actions
- 4.3 Verification Procedures

5.0 SOURCES OF INFORMATION

This chapter explains the importance of documents and record keeping. It also shows how they differ and recommends the best approaches for developing written programs.

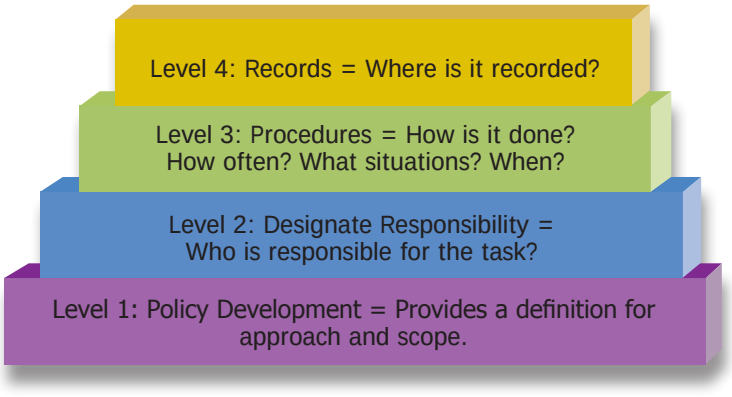
It is important to have standards, policies, and procedures written in simple, clear language to help employees with their job. Written instructions are very useful and assists in learning and often leads to employees bringing up good questions to help continually improve a system! Good documentation lets employees quickly double check their own work, without necessarily having to rely on others.

Documentation will:

- Prove that programs are effective and being completed as written;
- Demonstrate due diligence;
- Meet requirements for third party customer assessments/audits;
- Meet regulatory requirements; and
- Establish a paper trail to improve the current food safety program.

A facility may already have programs or activities in place. Processors should document and keep records of these programs. These can be used to prove that safety actions are taking place.

To develop a documentation system, it's important to break it into stages or levels. Each level expands to create a complete program and compares to one step in the development process.



1.0 DOCUMENTS AND RECORDS

It is important to understand the difference between a document and a record.

Documents	Records
• *Permanent* • *Describe facility policies and work instructions (Level 1, 2, and 3)* • *Define systems, processes and procedures*	• *Filled in as activity occurs (Level 4)* • *Provide proof that policies were followed or activities performed* • *Demonstrate processes and procedures are being conducted as required*

Records help provide proof that staff members complete necessary activities and that these activities are performed effectively.

Document and record all processes and activities. These documents and records should be stored in official files and remain accessible to staff who need them. Base the documents on the prerequisite programs and on the product protection or HACCP plan. If documents are already being kept, review them to make sure they are complete and that they follow the necessary standards.

Follow these three general principles to develop records and documents:

1. Keep it short and simple. Use bullet points and flow diagrams instead of long sentences and lengthy paragraphs.
2. Clarity is important. Step-by-step instructions are easily understood.
3. Use a standardized, consistent format. Although different programs may need different documents and records, using a similar approach will help staff learn quickly.

Let staff know that attempts to falsify records are easily detected. Auditors are trained to look for signs of fraud that can include records completed in the same increasingly messy handwriting and using the same pen.

Patterns or trends observed in records can be used as a basis for future food safety decisions.

Checking records regularly helps ensure that employees are completingtheir assigned activities. It helps to make sure that records are being filled out honestly and with all the information needed. Records are an important tool for analyzing and improving food safety. False records will not help improve the system or help you reach your goal of improved food safety!

Sample forms of records are included at the end of many chapters in this guidebook. Processors can use them as they are, or change them to meet a facility's specific needs.

At the very least, it is important that records include:

- **Who** is responsible for a specific duty;
- **How** they are to perform the duty;
- **When** they are to perform the duty;
- Spaces for the **date** and **initials** of the person who is responsible for the record(s); and
- Spaces for stating **deviation findings** (unusual situations or results outside of acceptable limits), and the **actions** taken to that fix that issue.

2.0 DOCUMENTING HACCP PLANS

HACCP plans provide the documents and records needed to make sure that the HACCP system is being followed at each critical control point. HACCP records differ slightly from prerequisite program records.

HACCP records provide a historical report of the following:

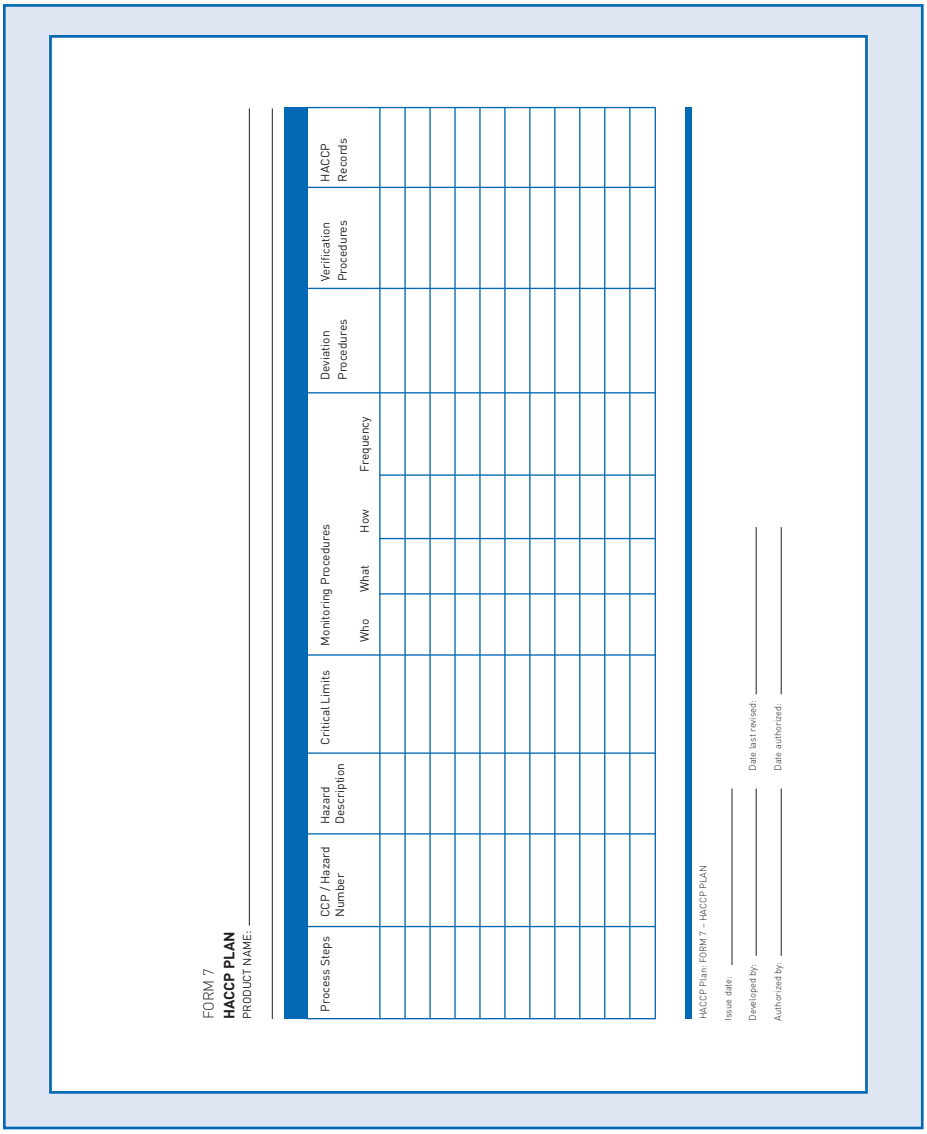
- Process;
- Monitoring procedures;
- Deviations; and
- Corrective actions taken at each critical control point (CCP).

These records can take a variety of forms (e.g. processing charts, checklists, written records, computerized records, etc.). HACCP records can help to trace a product or troubleshoot a problem. It's critical that a facility make sure HACCP records are up to date, complete and accurate.

Most of the record keeping will be noted on a CCP record. Procedures, responsibilities and activities related to these control points will be stated on HACCP Form 7 below. Monitoring results are usually recorded at the same time that deviations and corrective actions occur.

All HACCP documentation should include a report of who recorded, reviewed and approved the information.

HACCP Form 7: The HACCP Plan



FORM 7
HACCP PLAN
PRODUCT NAME: _____

Process Steps	CCP / Hazard Number	Hazard Description	Critical Limits	Monitoring Procedures				Deviation Procedures	Verification Procedures	HACCP Records
				Who	What	How	Frequency			

HACCP Plan: FORM 7 – HACCP PLAN

Issue date: _____ Date last revised: _____

Developed by: _____ Date authorized: _____

Authorized by: _____

HACCP Form 7 is used to document the procedures and activities associated with each critical control point. Each column breaks down the monitoring, deviation, verification, and record keeping required at each CCP. It breaks these into manageable pieces.

The following describes how to fill in each column.

Column 1. Process Step or Incoming Material – Enter in a description of each processing step or incoming material that has a CCP (as identified on HACCP Form 5 – Processing Steps, or on HACCP Form 5 – Incoming Materials).

Column 2. CCP Hazard Number – The number given to each CCP is transferred into this column to make sure they correspond.

Column 3. Hazard Description – This column identifies the type of hazard that this CCP addresses.

Column 4. Critical Limits – This column identifies the standards that the product should be safely produced on. These standards must be clearly defined, objective and measurable.

Column 5. Monitoring Procedures – This column is broken down into four to identify monitoring procedures and how they will be used on the production floor. Monitoring procedures need to indicate:

i. **Who** will perform the task (recorded in WHO column);
ii. **What** will be monitored (recorded in WHAT column);
iii. **How** it will be monitored (recorded in HOW column); and
iv. **Frequency** it will be monitored (recorded in FREQUENCY column).

Column 6. Deviation Procedures – This column is used to record deviation procedures and also to refer to documents that contain deviation procedure instructions. Deviation procedures need to indicate:

i. **Who** will perform the task;
ii. **What** the task is;
iii. **How** the task is to be performed;
iv. **Where** this information will be recorded; and
v. **Cause** of the deviation (if known).

Column 7. Verification Procedures – This column may be used to record verification or can to refer to the documents that contain verification procedures. Verification procedures need to indicate:

i. **Who** is responsible for the activity;
ii. **What** is being tested or examined;
iii. **Why** this is being tested or examined;
iv. **How** is the activity being carried out;
v. **When** is the activity done (e.g. frequency); and
vi. **Where** the results or information are recorded.

Column 8. HACCP Records – This is a list of all documents and records connected with each CCP. State where each record can be found to assist facility employees.

3.0 CREATING AN AUDITABLE PROGRAM

An auditable program must have controlled documents and records. The main focus of an audit is the review of documents and records, but an auditor will also review procedures.

Figure 2: Components of an Auditable Program

The Components of an Auditable Written Program

1. **Developing the program**: Creating a written documentation of who performs each task, what and how is it being done and how often. The written program includes any regulatory requirements (e.g. temperature controls) relating to the operation.
2. **Implementing the program**: Creating records of activities.
3. **Proving it**: By maintaining documentation and records that demonstrate development and implementation.

3.1 Document and Record Control

A controlled document or record must contain the following:

- Title
- Creation/revision date
- Page number
- Prepared by/issued by
- Approved date
- Approval signature

By including this information on each page a facility will be able to maintain control of the document or record. Include this information either in the header (top of the page), footer (bottom of the page) or in a combination of the two.

Controlled documentation also ensures that when the system is revised or updated, processors will use only the most up-to-date documents or records. This also helps processors make sure that changes are not made to the system without proper knowledge and approval.

Figure 3: Example of Document Control

Document Title	
Prepared By:	Date Issued:
Revised By:	Date Revised:
Approved By:	Page # of #

Although outdated documents and records should be kept for reference and auditing, remove outdated information from circulation to avoid confusion.

A Revision Log is a list of changes made to each document or record and helps to track the change, the date of the change, who made the change, and why the change was made. This process helps eliminate unnecessary changes to documents and records.

For an example of a revision log, see form HACCP Revision Log in Chapter 15.

4.0 DOCUMENTATION SYSTEM FORMATS

There is more than one correct format for a documentation system, but it must include all necessary information and be easy to read and understand.

Figure 5: Information to Include

Description of Activities and Qualifiers

Who: Identifies the person or position responsible for carrying out the activities.

What/How: Describes what is done and provides instruction (monitoring procedures) on how it's done. Includes:

- Duties and how they are completed;
- Acceptable and unacceptable standards/limits (if applicable);
- Records to be completed and how they are completed; and
- References to other bullet points and/or manuals.

When: Describes how often (frequency) the monitoring procedure is done.

Records: Describes what records are kept and where they are located.

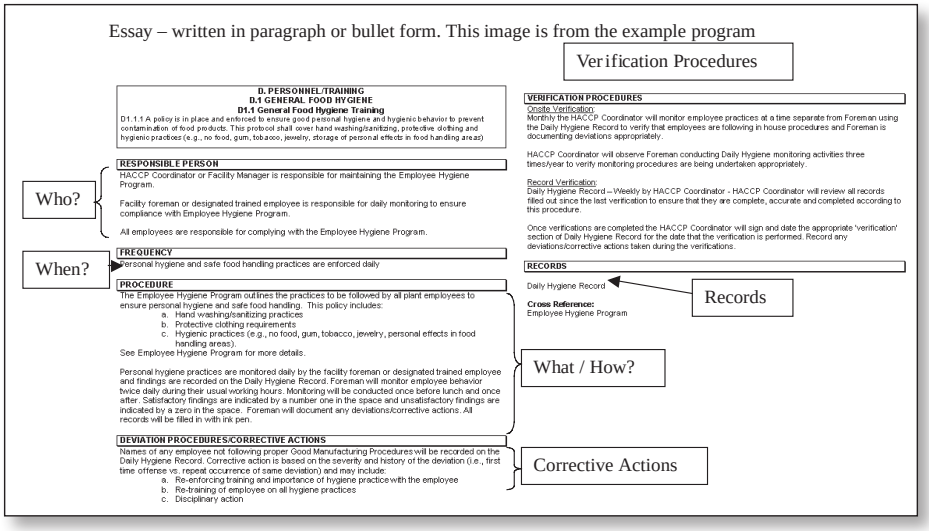
Deviation and Corrective Action Procedures: In the event that a deviation from normal occurs (e.g. outside of the acceptable limits), the corrective action procedure describes the actions to be taken to correct the deviation. It includes who, what, how and a record description.

Verification Procedures: Verification procedures ensure that the monitoring procedures have been performed correctly. This involves a different person/position than the who in the monitoring procedure. Verification procedures also include who, what, how and a record description.

Three formats for a written program are essay, matrix, or combination.

Processors can use one of three formats for formal documentation: essay, matrix or a combination of the two.

1. Essay – written in paragraph or bullet form.



2. Matrix - a simple chart. This is an ideal format to use when the information can be recorded in a limited space.

	Monitoring or Activity	Deviation Procedures	Verification Procedures
Who			
What/How			
When			
Records			

3. Essay/Matrix Combination – a chart filled in using paragraphs or bullets to provide the detail. This is the best format to use if program descriptions (what/how) require more explanation.

4.1 Monitoring or Activity Section

It is important that all procedures or instructions are simple and direct.

Activities identified in this section can vary from cleaning procedures to training instructions. The information must be simple, direct and explained clearly. Any employee reading this section should understand exactly how to perform the described duties.

Use the ‘Monitoring or Activity’ section to report the regular measuring and reporting of values of your steps or activities. These values are used to determine whether a situation is under control. Monitoring works best if performed continually. However, if this is not possible, develop procedures based on the most effective timing of these activities in the facility.

4.2 Deviation Procedures and Corrective Actions

Although it may be easy to recognize when problems exist in a facility, it can be challenging to make sure that these situations are reported. It may also be challenging to make sure that corrective actions are taken and reported. Completing records of the corrective actions is important for the following reasons:

- Assists the company to prove due diligence;
- Demonstrates a commitment to problem solving and the management of food safety issues;
- May lead to improved employee performance;
- Reduces unproductive, repetitive activities; and
- May reduce costs by revealing what activities aren’t working.

It’s important that corrective actions are reported in full each time there is a deviation or a change outside the acceptable limits in the food safety system. Complete documentation should include:

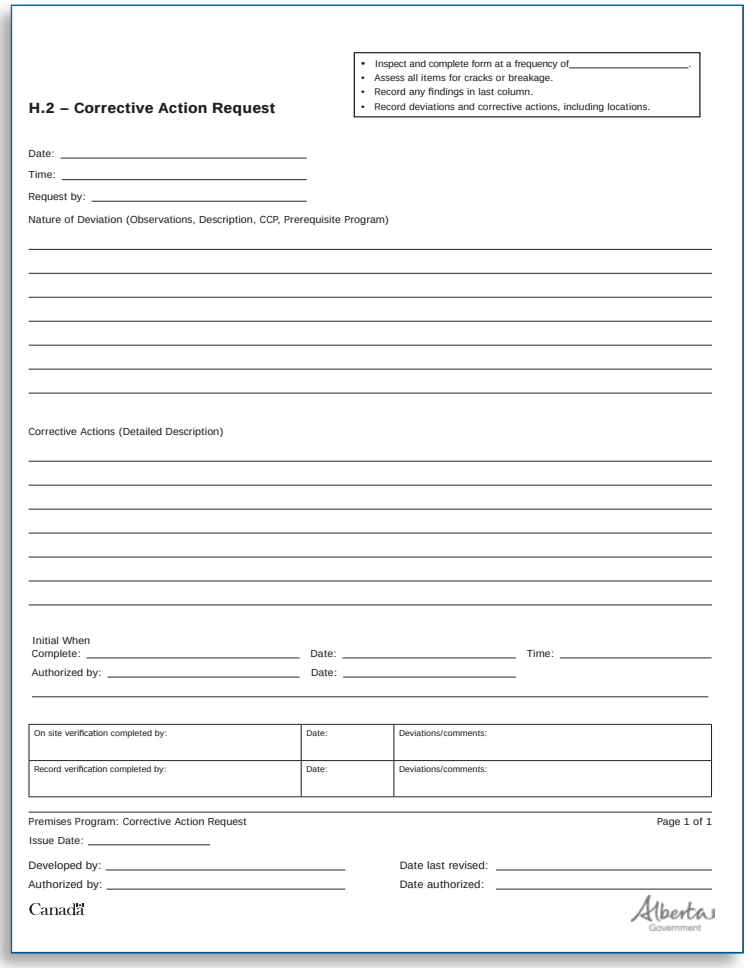
- The date and time the deviation was observed;
- Nature of the deviation;
- Whether product or food contact surfaces are affected;
- What corrective actions are to be taken;
- The timeframe for completion of corrective actions;
- Signature of responsible employee; and
- Verification date, time and signature indicating that the activity was completed satisfactorily.

Below are some examples of poor and appropriate corrective action reports.

Observations	Poor Corrective Action Reported	Appropriate Corrective Action Reported
No paper towel in restroom	Paper needs restocking	Restocked paper towel and directed sanitation employee to re-stock restroom daily/more frequently.
Transport carrier has dirt build-up inside	Trailer needs sweeping	Truck driver swept trailer – was clean before boxes were loaded.
Raw materials spilled on floor	Floor needs cleaning	Sanitation crew cleaned floor and disposed of spilled material – no other product was affected.
Soda cans and food items observed in production area	Soda cans and food need to be removed from production area	Food and soda cans disposed of – no product or equipment was affected. Informed staff that food items are not allowed in production areas. Disciplinary action for violators documented in personnel files.

Corrective actions are determined by processors. Processors may report corrective actions directly onto associated records, provided there is enough space to report all the necessary information. Another option is to create a Corrective Action Request form as shown in Figure 6.

Figure 6: Corrective Action Request



- Inspect and complete form at a frequency of_____.
- Assess all items for cracks or breakage.
- Record any findings in last column.
- Record deviations and corrective actions, including locations.

H.2 – Corrective Action Request

Date: _____

Time: _____

Request by: _____

Nature of Deviation (Observations, Description, CCP, Prerequisite Program)

_____

_____

_____

_____

_____

_____

_____

Corrective Actions (Detailed Description)

_____

_____

_____

_____

_____

_____

_____

Initial When Complete: _____ Date: _____ Time: _____

Authorized by: _____ Date: _____

_____

On site verification completed by:	Date:	Deviations/comments:
Record verification completed by:	Date:	Deviations/comments:

Premises Program: Corrective Action Request Page 1 of 1

Issue Date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Canada Alberta Government

Blank copies of the Corrective Action Request form can be kept in key areas of the facility. They can be attached to or stored with the related monitoring record.

Deviation and corrective action procedures should be included for each relevant prerequisite program bullet and critical control point. These procedures should identify the most common deviations and examples of useful corrective actions for each. These procedures should also explain how and where to document this information.

4.3 Verification Procedures

Verification involves the methods, procedures, tests or other forms of evaluation used to check that a written program is being followed. Verification ensures that:

- Activities are performed according to procedures;
- Activities are performed at the correct times / frequencies;
- Effective corrective actions are recorded for any deviations; and
- Records are completed accurately and at the correct frequency.

Verification includes:

- Checking system conformity;
- Matching performance to records; and
- Confirming the effectiveness of the system.

Note: All process changes require a verification of the system.

Think of verification as "checking the checker."

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Chapter 4
DEVELOPING A PREMISES PROGRAM

1.0 CONSIDERATIONS

2.0 SANITARY FACILITY DESIGN

3.0 EXTERIOR ENVIRONMENT AND BUILDING
- 3.1 Facility Location
- 3.2 The Building Exterior

4.0 INTERIOR ENVIRONMENT AND BUILDING
- 4.1 Proper Ventilation Systems
- 4.2 Loading Docks and Receiving Bays
- 4.3 Doors
- 4.4 Windows
- 4.5 Floors
- 4.6 Walls
- 4.7 Ceilings and Overhead Structures
- 4.8 Lighting
- 4.9 Glass and Brittle Plastics
- 4.10 Process and Product Flow
- 4.11 Employee Facilities
- 4.12 Equipment
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5.0 WASTE DISPOSAL
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6.0 WATER, ICE AND STEAM
- 6.1 Water Testing and Potability
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7.0 PREVENTATIVE MAINTENANCE

8.0 PREMISES FORM TEMPLATES

9.0 SOURCES OF INFORMATION

The premises are generally known as the interior and exterior building and also include the surrounding areas not directly connected with food production and storage.

Facilities are areas directly involved with the production of food products. This includes processing equipment and storage areas.

In this chapter, the terms ‘premises’ and ‘facilities’ are used interchangeably because a premises program should include both these areas.

All food processors need to meet the requirements of the laws and regulations related to their production. This includes both their processing license and the products they produce. This is why it’s important to consult the municipal, provincial and federal regulatory agencies when designing or renovating a food processing facility.

Contact Alberta Agriculture and Rural Development, the regional healthy authority or the Canadian Food Inspection Agency to learn more about the necessary legal acts and regulations.

The Alberta Food Regulation states:

> “A person must not construct or make alterations to a food establishment unless plans and specifications for the construction or alterations have been approved by the executive officer of the health region.”

This regulation ensures the safety of products both during and after construction or renovation.

When building or renovating a food processing facility, follow municipal building codes and bylaws.

1.0 CONSIDERATIONS

Consider the following elements when designing, constructing and maintaining a food processing facility:

- Receiving
- Raw materials storage
- Processing area
- Finished product storage
- Quality control laboratory
- Mechanical room
- Maintenance/workshop
- Lunchroom
- Washrooms (with shower and lockers where applicable)
- Offices
- Waste disposal
- Construction materials

The food processing facility should always be designed and constructed with food safety in mind.

Facility design determines employee flow, which in turn will determine opportunities for the contamination of food. A good facility design will minimize the chance for contamination.

Elements that can influence maintaining a hygienic and pest-free environment include:

- Sufficient space in production areas for equipment, employees, materials and cleaning;
- An appropriate amount of hand wash/sanitizing and utensil cleaning stations;
- Waste disposal facilities located both inside and outside the facility;
- Appropriate water and waste treatment needs;
- A suitable employee training area; and
- An effective sanitation department and material storage.

A food processing facility should be designed and constructed to produce safe food. It should have enough space to carry out necessary activities while providing good lighting and ventilation. It is important to keep pests out and make sure that dust, dirt, odours, smoke and other contaminants are kept out of food production and storage areas.

2.0 SANITARY FACILITY DESIGN

The objective of sanitary plant design is to control food safety hazards.

Sanitary facility design aims to reduce the risk of contaminating food products by controlling allergenic, chemical, microbiological and physical hazards. Different methods are used to control each of these hazards. For example, a significant difference between allergenic and microbiological hazard control is the use of heat. While microbes can be partially controlled by hot water, heat will not remove or destroy allergens. These proteins must be removed by scrubbing, using detergents, or, in the case of dry cleaning, by an effective vacuum system.

See Form A.2: Change Control Checklist, and Form C.8: Sanitary Design Checklist.

The American Meat Institute's Equipment Design Task Force has developed ten principles of sanitary design for food production facilities. The task force created the list with input from meat and poultry processing facilities, as well as from equipment manufacturers. It also had input from certifying organizations and government officials. Although developed for the meat industry, these principles can be applied to any production environment.

Ten Principles of Sanitary Design

1. **Equipment and premises should be designed so that all components can be cleaned to a microbiological level.** Make sure that equipment, walls, ceilings and floors are designed and built with materials that are durable. Make sure these materials are smooth, cleanable and suitable for production conditions.
2. **Equipment and premises should be designed with compatible materials.**

   Construction materials should match:

   - the product you are producing;
   - the production environment;
   - cleaning and sanitizing chemicals; and
   - cleaning and sanitizing methods.

All materials should be listed in the "Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products," published by the Canadian Food Inspection Agency. To use materials not listed, a 'Letter of No Objection' should be obtained from Health Canada.

3. **Equipment and premises should be designed so that they're easy to access for inspection, maintenance, cleaning and sanitation.** As part of the production and sanitation process make sure that microbial growth locations are designed out or managed. Access should not require tools.
4. **Equipment and premises should prevent product or liquid collection.** The floors should be sloped enough to let liquids drain to trapped outlets. All equipment should be self-draining. This prevents moisture from condensing or pooling into uncontrolled areas of microbial growth.
5. **Hollow areas should be hermetically sealed (watertight, airtight).** The term hermetically sealed is used to describe something that has an airtight and watertight seal. Hermetically sealing all hollows prevents the possible build-up of allergens, microbes or other hazards in hard-to-reach areas. Eliminate or permanently seal these areas wherever possible.
6. **Examine and eliminate any other possible recesses or nooks.** Equipment and premises should be free of recesses such as pits, cracks, corrosion, gaps, ledges and dead ends.
7. **Sanitary Operational Performance.** The facility should always operate without contributing to unsanitary conditions and cross-contamination hazards.
8. **Hygienic design of maintenance boxes/enclosures.** Design and install electrical boxes, equipment interfaces, control boxes, valve handles and other maintenance enclosures in the facility with safety in mind. Make sure the design prevents accumulation of hazards at these points.

9. **All facility systems must be hygienically compatible.** This means that the facility's design must include only compatible systems or systems that work well with each other. In no way should the design contribute to food safety hazards because certain systems are not compatible (e.g. electrical, water, air). The systems also must not interfere with each other.
10. **Validate all the premises controls through cleaning and sanitizing protocols.** Validation and verification procedures for the sanitation program help to assess the facility design and ensure that the manufacturing environment matches the production needs

See Chapter 8: Developing a Sanitation Program.

3-A Sanitary Standards, Inc. (3-A SSI) is another non-profit association that represents equipment manufacturers, processors and public health professionals. Over many years, this group has developed a long list of 3-A Sanitary Standards. It has also developed 3-A Accepted Practices. Both of these are used around the world for food processing equipment and systems.

For more information on 3-A SSI and its standards visit: http://www.3-a.org/.

3.0 EXTERIOR ENVIRONMENT AND BUILDING

To control all food safety hazards, be sure to think about the facility's exterior environment. Make sure that contaminants can't get inside. Consider how to repel insects, rodents, birds, and windborne microbes and dust. Design driveways, landscaping, access doors and ventilation systems to help keep out contaminants.

3.1 Facility Location

Keep in mind possible sources of contamination on and around the site. Be certain to minimize possible maintenance and food safety issues. When thinking about location, make sure that the building isn't close to any environmental contaminants.

Make sure that the land around the building is maintained to control sources of contamination. Remove debris and elements that might attract pests. This means removing things like long grass and other vegetation.

Possible contamination sources include:

- Birds
- Rodents
- Insects
- Paint
- Odours
- Moisture

Try to avoid placing a facility near high-risk neighbours including:

- Oil refineries
- Sanitary landfills
- Chemicals plants
- Coal yards
- Paper and steel mills

Remember that the area around a facility could create potential food safety hazards including smoke, sewage, dust, odours and plants.

Place the building at the highest elevation possible.

Place the building at the site's highest possible elevation. This will allow storm water to drain away from the building as storm water should be efficiently and entirely removed from the site. This is because standing water attracts insects and will then become a place with microbial and mould growth. Airborne spores from this growth can enter the facility.

Once the location for the facility is chosen, make sure that the roadways are well graded, compacted, dust proofed and drained. A minimum 18 inch growth-free zone around the building is recommended. This area should be covered with pea gravel or paved with asphalt or concrete. This controls plant growth and minimizes the amount of insects and animals attracted to the building.

A minimum 18 inch growth-free zone around the entire building is recommended.

It's important to have good site security. This helps to control traffic and safegaurds the activities, materials and equipment on the premises. If equipment must be stored outside, locate it away from walls. Also make sure it's off the ground to prevent forming sites that attract pests. Good storage practices also allow for better site inspection.

3.2 The Building Exterior

Construct and maintain the building exterior to keep any contaminants and pests from entering. This means that the facility should have:

- No unprotected openings;
- Air intakes that are well placed, covered and screened; and
- Well-maintained roof, walls and foundation to prevent leakage.

Design the building to prevent unwanted hazards from entering the facility.

See Form A.4: Exterior Inspection Record – Option 1, or Form A.5: Exterior Inspection Record B – Option 2.

4.0 INTERIOR ENVIRONMENT AND BUILDING

Careful thought should be given to designing the floors, walls, ceilings, equipment and ventilation systems inside the facility. Problems with the design and installation of the interior environment can reduce product safety. Some things to look out for include:

- Exposed fibre glass insulation;
- Unprotected glass (e.g. skylights, light fixtures);
- Flaking paint; and
- Rust that's directly over open production lines.

Any of these could cause contamination by foreign matter.

Examine the inside environment. Look at individual parts, as well as several parts together. This helps to make sure the parts combine to protect food product safety.

See Form A.8: Interior Facility Maintenance Inspection Record.

4.1 Proper Ventilation Systems

Allergens or other hazards that are easily airborne can contaminate nearby lines or other food contact surfaces.

Creating safe ventilation systems is very important in designing food processing facilities. This is because airborne allergens can be easily transferred from one area of a facility to another. If a product or its ingredients contain one or more allergens that are dusty or easily airborne, the escaping dust can contaminate nearby lines. It can also contaminate other food contact surfaces.

Positive air pressure in the processing / packaging departments minimizes the risk of allergen contamination by preventing the transmission of contaminated air. It prevents this in areas from the facility's raw material handling areas to finished product areas.

High filtration of incoming air also minimizes the risk of allergen contamination. Filters that are 95 percent efficient at 5 microns are recommended to maximize food safety. This level of filtration deals with dust particles carrying microbes. It also traps the allergens that can be found in recycled air.

It is important when designing the ventilation systems to consider the possible build up of condensation. Product contamination from too much condensation is a big concern in facilities with humid environments. Make sure to adjust ventilation systems to reduce condensation from forming.

See Form A.1: Air Flow Record, and Form A.13: Ventilation Inspection Record.

4.2 Loading Docks and Receiving Bays

Areas where trucks dock are important to sanitary design. This is because these areas are the frontline of defense in pest control programs. Some modern docks have seals. So when a truck backs up to the door, it creates positive pressure helping to minimize the entry of both pests and dust into the facility.

If seals are not used, it is recommended to use vertical lift dock doors or overhead rollup doors. These doors should have no housing, eliminating nesting places for various insects.

Monitor these doors routinely to check for insects. Keep birds from nesting and roosting in overhead canopies or roofs. Birds can easily enter the facility when dock doors are open and trucks aren't backed against the door, leaving a wide open space.

Birds can easily enter the facility while dock doors are open and no truck is in place.

Dock-leveler plates, which create a bridge between the dock and the truck, also have dead space to the outside. This space can let pests enter the facility. Make sure that the dock-leveler plates line up with brush seals. This discourages rodents from getting into the leveler pit and from entering through the space between the plate and the inside floor.

4.3 Doors

Doors are obvious entry points into the production areas of the facility. Install doors that are durable, washable, smooth and of non-absorbent materials. Avoid wooden doors because they absorb moisture that can allow microbial and mould growth.

4.4 Windows

Windows are another key sanitation and pest control hazard. Broken windows can easily result in glass contamination. They also provide entry points for pests.

If the facility must have windows, make sure that they can't be opened.

If the facility must have windows, make sure they can't be opened. This way, windows can let in light while repelling potential contaminants.

Maintaining window screens is time-consuming and costly, so avoid screened windows if possible. If the facility does have screens, make sure they fit tightly and are well maintained.

4.5 Floors

Floor contaminants can easily be splashed onto the equipment. They can also be tracked through a facility on footwear.

Floors must be able to withstand all kinds of abuse including mechanical stress, chemical spills and heat. In choosing floor materials, consider the equipment used, food production processes and sanitation procedures. Install smooth, non-absorbent and easy-to-clean floor coverings. Where it's needed, cover and seal floor joints. This prevents contamination and allows for easy cleaning.

Pitted floors cause microbial growth and therefore contamination. Tests show that severely damaged floors can be rinsed, foamed, rinsed again, then sanitized and still remain contaminated.

Having to use a lot of sanitizer can create its own hazards. Floor contaminants can easily be splashed onto clean equipment during sanitation. They can also be tracked throughout a facility on footwear.

4.6 Walls

Walls should be smooth and non-absorbent. This prevents microbial growth. It also prevents the absorption of dusty materials from ingredients containing allergens. The finish should reach from floor to ceiling and should be easy to clean.

Items hung on the walls should be included in scheduled maintenance, cleaning and sanitation programs.

4.7 Ceilings and Overhead Structures

Ceilings in production areas should prevent contaminants (e.g. dust, condensation, paint chips, etc.) from falling from the roof supports. Ceilings should also prevent contaminants from the underside of the roof from falling into the food production area or onto product.

False ceilings become great places for insects to live. They are a potential source of contamination.

Avoid false ceilings in a food processing environment. The area above these ceilings becomes a home for insects and can become a source of contamination.

If a facility needs a drop ceiling, consider creating another floor. However, if a drop ceiling is the best solution, make sure the hollow or suspended area allows access for cleaning, maintenance, service and inspection. This area should be included in the sanitation plan.

4.8 Lighting

Good lighting makes for better inspections and sanitation. Include production areas, hallways, storage areas, equipment rooms, bathrooms, etc.

Arrange lighting to reduce eye strain, to maintain or increase efficiency and to prevent errors during food preparation and processing. Inadequate lighting can harm production processes.

Make sure that lighting fixtures don't create a contamination risk. Use fixtures that don't leak, corrode, cause fires or electrical problems. Assume that fixtures may get knocked by accident. Also make sure that broken bulbs, glass and other material won't affect the production area.

See Form A.9: Lux Monitoring Record.

4.9 Glass and Brittle Plastics

Blunt force can break brittle plastics into pieces. This can be a food safety risk.

Have a policy to control contamination from glass and brittle/hard plastics. Things like thermometers, windows, sight glasses, light bulbs, gauge covers and chemical-testing glassware can create a high food safety risk.

An effective glass and brittle plastics control policy should:

- Identify all glass and brittle plastics in the facility and their locations;
- Eliminate these items whenever possible;
- Identify and use protective materials (e.g. light bulb covers);
- Include regular inspection schedules of all glass and brittle plastics (e.g. gauge covers, thermometers, windows, etc.);
- Create a plan to handle situations where breakage might occur (e.g. set up documentation and assign someone to receive and review reports); and
- Keep employees from bringing these materials into the facility.

Store glass and brittle plastics away from raw materials, packaging and production lines. If this isn't possible, make sure that clean-up procedures include checking the area. Make sure that all particles have been removed.

See Form A.6: Glass and Brittle Plastic Incident Report, and Form A.7: Glass and Brittle Plastic Inspection Record.

4.10 Process and Product Flow

Product flow is the way raw materials, ingredients, packaging and finished product move through a facility. Process flow refers to how the product is assembled. Equipment selection and layout design of the facility will depend on both product and process flow.

Poor product and process flow is a problem in older buildings where food safety wasn't considered during design.

To avoid costly mistakes, map both product and process flow. Analyze these maps for possible hazards and improvements. Do this before committing to any construction or renovation.

Segregation, or separation, is a major food safety consideration. Consider this during design and construction. Physical barriers provide the best separation. Design buildings and facilities to maximize hygienic operations. Design them to have a regulated process flow from the arrival of raw material to the shipping of finished product.

4.11 Employee Facilities

To keep employees from causing contamination, the facility should provide:

- ✓ Storage facilities for personal items;
- ✓ Areas for employee breaks and meals;
- ✓ Washrooms with adequate sinks and clothing hangers; and
- ✓ Hand wash sinks and hand dip stations.

Design employee facilities so they don't open right into production areas. This helps to make sure that no one enters production areas without protective clothing. Self-closing doors at entrances lower the risk of doors staying open for long periods.

To minimize contamination, use hand washing or dipping stations only for these purposes.

Make sure there are enough hand wash stations available. Put them in the following locations:

- ✓ At each work area, so that employees can wash whenever they become contaminated. If employees have to move far from their work area to reach a wash station, it increases the risk of cross-contamination.
- ✓ Near any toilets, so that staff can wash their hands immediately after using the restroom.

Hand sanitizer or dip stations shouldn't be used as a substitute for hand washing. However, these stations offer a way to remove microbial contamination from hands when it's not possible to have complete hand wash stations.

At hand dip stations, employees dip their hands into a sanitizing solution. They might also sanitize hands using an alcohol gel. This solution is not rinsed, but allowed to air dry. Always post instructions for the correct methods of hand cleaning and sanitizing.

If the facility uses hand dips or hand sanitizers, keep in mind:

- ALL employees and visitors are to use these stations consistently;
- These stations should be part of the facility's regular cleaning schedule; and
- Chemicals used at these stations must be listed on the Chemical Inventory Record and approved for use in food establishments.

Remember that if employee hands are contaminated with large amounts of solid materials, fat or other food residues, these disinfectant or sanitizing chemicals won't work properly. Using dip stations in these situations can lead to increased, rather than reduced, risk to the products.

4.12 Equipment

Sanitary design principles can help safeguard equipment from becoming a source of contamination.

Employees are less likely to clean and sanitize equipment effectively if it's difficult to clean.

Examples of good design principles are the American Meat Institute's (AMI) *"10 Principles of Sanitary Design,"* and the 3-A Sanitary Standards, Inc.'s comprehensive inventory of sanitary design standards.

To prevent microbial contamination and to help remove allergen residue between production runs, use equipment with food-contact surfaces that are:

- Non-absorbent
- Non-corrosive
- Non-reactive with the product
- Non-contaminating
- Cleanable

Purchase equipment without internal horizontal ledges. Don't purchase equipment that has hidden or hard-to-clean areas and don't use equipment that has recessed fasteners like Allen-head screws on horizontal surfaces.

The design shouldn't limit access to the interior of the equipment. This makes it hard to clean and sanitize.

For further information on setting up the equipment program, see Chapter 6: Developing an Equipment Program.

4.13 Sanitation Facilities

One of the best ways to control hazards in a facility is through sanitation and cleaning of both equipment and premises. Make sure that the facilities are made of corrosion resistant materials that can be cleaned easily.

One of the best ways to control hazards in a food processing facility is through sanitation and cleaning of both equipment and premises.

Also provide potable, or drinkable, water at a temperature suitable for the cleaning method and chemicals used.

Key areas of the in-house sanitation facilities include:

- Chemical storage areas
- Waste collection storage rooms
- Wash-down rooms
- Waste water treatment facilities (if the facility has them)

Make sure that these facilities are separated from food storage, production and packaging areas. Use physical barriers or significant space separation to do this.

Remember that most activities related to cleaning can release airborne particles, which can cause cross-contamination. Fine particles can travel far and also through ventilation systems.

For more information on facility sanitation, see Chapter 8: Developing a Sanitation Program.

5.0 WASTE DISPOSAL

5.1 Interior Waste Disposal

Policies and procedures to remove waste from the production area should be put in place. This reduces the risk of contamination. Also provide dedicated areas and equipment for storing waste and inedible material. Maintain food safety practices as these are removed from the premises.

Maintain all waste disposal areas in clean condition, including storage rooms used for inedible material. Include them in the preventative maintenance program.

Colour coding is an excellent way to identify waste containers.

Colour coding is an excellent way to identify waste containers. These containers should be leak proof and should be cleaned on a preset schedule. Where appropriate, cover them to prevent spills during transport. Avoid locating waste containers near any food product. Be careful of this in preparation, handling or storage areas.

See Form A.4: Waste Disposal Area Inspection Record.

5.2 Exterior Garbage Bins

Do not locate on-site garbage bins close to the production facility. Garbage bins are excellent breeding grounds for insects and can attract pests including rodents and birds.

Garbage bins soiled with food debris will attract pests.

Don't overstuff bins. If the area around the bin gets contaminated by spills or overflow, clean the area immediately. To limit pests getting into the garbage, make sure lids are closed securely. If the garbage bin is in a high-traffic area, keep it locked. This stops people from dropping contaminants in that might later be tracked into the facility.

Include outside garbage bins in the preventative maintenance, cleaning and sanitation programs.

5.3 Drainage and Sewage System

Floors must have sufficient slope to allow liquids to drain toward outlets with approved traps and vents. Standards may be applied differently in some facilities. There are some exceptions, however. For example, bakeries don't use water for cleaning so they don't need to address the risks of standing water on the production floor.

Any site with pooled water is a good location for a drain.

Install and maintain enough trapped drains in all wet processing or wash areas. When locating drains, think about potential discharge or overspill from processing. To minimize cross-contamination risks, make sure that overcharge goes directly into a conveniently located drain. Make sure it doesn't go onto the floor.

Equip each floor drain with a deep seal trap. Make sure it has the plumbing needed to prevent sewer back up and floor flooding. Regular inspection and cleaning of drains is important. Fit all drains with easily removable grates or covers.

Separate production drainage lines from sewage disposal lines. This makes sure that sewage doesn't pass directly over, or through, production areas. Ensure the production facility's plumbing is designed to prevent cross-connection between the sewage system and any other waste disposing system. As with drains, equip the sewage disposal system with backflow prevention devices.

6.0 WATER, ICE AND STEAM

Most food processing operations use a lot of water and it is important to be able to draw enough water and to treat the wastewater.

A reliable, potable water supply and sewage disposal system is very important.

If municipal wastewater handling is limited, a facility may have to treat its wastewater onsite. In some facilities, water must be stored to meet needs during water shortages. Storage and treatment facilities must therefore be designed, constructed and maintained to prevent contamination of water being stored or treated.

All water used in the production process must be potable. This is defined in Health Canada's Guidelines for Canadian Drinking Water Quality. Visit http://www.hc-sc.gc.ca/ewh-semt/water-eau/drink-potab/guide/index-eng.php

Any water treatment chemicals used must be listed in the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products*, published by the Canadian Food Inspection Agency (CFIA). The facility may need to get a 'Letter of No Objection' from Health Canada for a chemical not listed.

Monitor and control any chemical treatment. Make sure to use the recommended concentration and to prevent contamination.

6.1 Water Testing and Potability

Water, ice and steam are used as raw materials in many production processes. Ice that is used as an ingredient or that comes in direct contact with food must be made from potable water and protected from contamination.

Analyze water frequently to make sure it's potable (safe for human consumption).

Ice used in food processing should be handled as an incoming ingredient. It should be assessed under the incoming material control program. Ice produced on site should also be assessed.

Be sure to analyze water, ice and steam frequently to confirm potability. Some municipalities have regular water testing programs and may provide the plant with the results of the tests performed. This document can be used as a reference on the potability of the water the facility uses.

Processors producing high-risk products may need to test water daily. Those facilities producing a lower-risk product (e.g. bread) may need to test only monthly.

See Form A.15: Water and Ice Potability Testing Record.

Examples of Required Water, Ice and Steam Records

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

If a facility has its own water well and treatment system, develop an in-house program to regularly assess water. Don't forget to make sure it's potable.

All water used in a processing facility (water, ice or steam) must meet Health Canada's Guidelines for Drinking Water Quality.

Water, ice and steam potability records can include:

- Sampling site (specific tap, water source, etc.);
- Results of the tests;
- Individual or company responsible for analyzing the water; and
- Date of the test.

See Form A.3: Chlorine Testing Record, and A.16: Water and Ice Potability Record.

6.2 Recirculated Water Systems

Recirculated water is water that has been previously used, then recycled and treated in a facility. Many facilities use this method to reduce water costs.

Depending on the purpose for the recirculated water, make sure that the facility has an organized, in-house water treatment program. This program must include monitoring and testing to verify water safety.

Recirculated water must have a separate distribution or piping system. Be sure that this system is identified clearly. A separate distribution system reduces the likelihood of cross-contamination with potable water lines.

6.3 Water Storage Facilities

Water storage is used in the food industry to supply water when a regular source can't meet peak demands. Water storage facilities can be made from any material that can hold water, as long as the storage structure won't reduce water quality.

Materials used in water storage facilities should be listed in the *Reference Listing of Accepted Construction Materials*, *Packaging Materials and Non-Food Chemical Products*, published by the CFIA. If the material is not listed in this source, the facility must have a 'Letter of No Objection' from Health Canada.

Be sure to think about the following when either selecting or sizing a water storage facility:

- How long the storage facility is expected to meet demands;
- The total water demand during the period water must be stored; and
- The likelihood of materials used in the storage facility releasing toxic compounds into water.

Glass, metal and plastic are the most common materials used for water storage. Glass is not generally recommended because it can chip and plastic is problematic because it can be permeable (lets gases through).

Water storage tanks made from plastic must be located away from gasoline, pesticides or any other chemicals. These may contaminate the stored water.

If the facility uses stored water for sanitation or production processes, develop an in-house program to check the potability of stored water.

Sanitize or disinfect water being stored for long periods. Use the best quality water possible for storage.

Pre-used or secondhand water storage tanks and equipment are not recommended. However, if used, make sure they held only food products previously. Make sure all new or used water storage tanks and equipment are cleaned and sanitized thoroughly before use. Include water tanks used for long periods in the facility's master sanitation schedule.

7.0 PREVENTATIVE MAINTENANCE

Preventative maintenance refers to equipment maintenance and calibration (checking the equipment is accurate). It also refers to activities that maintain the facility and premises, and that help prevent contamination.

Preventative maintenance activities in the premises program may cover:

- Windows – to keep them in good condition with permanent seals or close fitting screens;
- Doors – to ensure they're self-closing and close fitting;
- Lighting – to make sure there's enough light for activities performed, and to make sure lighting isn't a potential source of contamination;
- Ventilation systems – to prevent steam, condensation or dust from collecting;
- Waste facilities and disposal processes – to make sure they don't become a source of contamination because of leakage, or backflow into potable water systems;
- Water, ice and steam systems – to ensure they're potable and capable of meeting the facility's needs; and
- Water storage or treatment facilities – to make sure they're in good working condition.

Preventative maintenance programs not only help maximize food safety, but they help operations run smoothly.

Preventative maintenance programs are also an excellent source of information. They help in making wise equipment purchases.

Further, documenting that the premises and facilities are well maintained helps the maintenance program to work better.

For more information about preventative maintenance, see Chapter 6: Developing An Equipment Program.

See Form A.10: Maintenance Requests Tracking Record, Form A.11: Preventative Maintenance Log, and Form A.12: Repair/Maintenance Request.

8.0 PREMISES FORM TEMPLATES

A.1 Air Flow Monitoring Record

A.2 Change Control Checklist

A.3 Chlorine Testing Record

A.4 Exterior Premises Inspection Record (Option 1)

A.5 Exterior Premises Inspection Record (Option 2)

A.6 Glass and Brittle Plastics Incident Report

A.7 Glass and Brittle Plastics Inspection Record

A.8 Interior Facility Maintenance Inspection

A.9 Lux Monitoring Record

A.10 Maintenance Requests Tracking Record

A.11 Preventative Maintenance Log

A.12 Repair/Maintenance Request

A.13 Ventilation Inspection Record

A.14 Waste Disposal Area Inspection Record

A.15 Water and Ice Potability Testing Record

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Chapter 5

DEVELOPING A TRANSPORTATION AND STORAGE PROGRAM

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A good transportation and storage program ensures that food safety is always maintained. This means making sure that all ingredients, packaging, incoming chemicals and finished products are received, handled, stored and shipped with safety in mind.

The transportation and storage program is a facility's first and last defense against product contamination. Food products and ingredients need to be protected from many hazards including:

- Temperature
- Humidity
- Dust
- Moisture
- Foreign odours
- Pests (rodents, birds and insects)

A good transportation and storage program makes important links in the food chain with suppliers, manufacturers and consumers.

Supplier Manufacturer Consumers

The Transportation and Storage Program requires that:

- Manufacturers prove that their carriers know how to handle food transportation;
- Carriers are inspected by manufacturers before shipping and receiving;
- Ingredients or products that need refrigeration are shipped at a standardized, safe temperature;
- Frozen ingredients or products are transported at a temperature that won't allow thawing;
- Incoming materials and finished products are handled in a 'first in, first out' (FIFO) basis; and
- Non-food chemicals are controlled and stored separately to prevent cross-contamination hazards.

1.0 RECEIVING

Only trained and experienced employees should be responsible for receiving incoming materials.

Receiving is the entry point for all product coming into the facility. If incoming ingredients and other materials don't meet food safety standards they can bring contamination. If these ingredients and materials aren't handled properly they can contaminate the finished product. Contamination is prevented by controlling items allowed into the facility.

Develop controls to make sure of the safety of all incoming materials. Include the following:

- Approved supplier lists (Form B.2: Approved Suppliers List);
- Incoming material specification sheets (Form H.5: Sample Product Specification – Black Pepper);
- Check the safety of the supplier (Form H.7: Supplier Approval Questionnaire);
- Inspect carrier procedures (Form B.10: Incoming or Outgoing Goods Carrier Inspection Report);
- Inspect incoming material (Form B.8: Goods Receiving Record Option 1); and
- Fill out receiving records (Form B.9: Goods Receiving Record Option 2, Form B.4: Bulk Receiving Record).

The first three controls mentioned are covered in the Supplier Food Safety Assurance Program (see Chapter 12: Supplier Food Safety Assurance).

Good communication with suppliers can increase confidence in the quality and safety of products being brought into the facility. But supplier controls are only the first step in controlling incoming materials.

Depending on the risks involved with each product, the incoming material procedures might also include:

- 
  Certificate of Analysis from the supplier (Form H.1: Certificate of Analysis);
- A visual inspection when received; and
- Analytical laboratory testing.

1.1 Receiving Facilities

To ensure the safety of incoming materials, make sure that the receiving area has good lighting. Also be sure that the area and equipment are clean and dry.

Receiving staff must have easy access to the following:

- Labels
- Tape
- Permanent markers
- Thermometers
- Detergents
- Sanitizers
- Blank document forms

If a bulk dump tank is used for incoming materials, it is recommended to install a fixed wall with a pass-through. This is a safer way of moving product from outside to inside the facility and reduces the chances of water moisture, or aerosols in the air, from contaminating the processing area.

1.2 Carrier Inspection

The first step in receiving incoming raw materials, products and chemicals is to inspect the carrier (trailer, boxcar, container or other means of transport).

See Form B.10: Incoming or Outgoing Goods Carrier Inspection.

Take photographs of all rejected carriers to support the report. These photos can also be used as a training resource for staff.

Inspect the carrier carefully *before* unloading any materials. Look for cleanliness, the condition of the vehicle, and signs of recent damage. Any of these signs could mean there are problems with the materials.

After inspecting the carrier, check the condition of the entire load inside the carrier. If any materials are damaged, badly soiled, infested, or shipped with non-food grade chemicals, do not accept your portion of the load. Record the defects and reasons for rejection. Inform all parties involved.

Record the temperature of both the carrier and the received products. Be sure that materials meet minimum temperature requirements agreed on with the supplier. Check transporter records to make sure that the container temperature stayed in the acceptable range for the entire trip.

Make sure that staff members are trained in all these points.

What is a 'pallet of mixed product'?

To make good use of space, some suppliers ship products by creating 'a pallet of mixed product.' This means that two or more different products are transported on one pallet (e.g. three different kinds of spice blends, flavouring jugs, bags of starch and boxes of fruit). This increases the chances of cross-contamination between the different products. If the suppliers ship the raw materials this way, make sure there is some form of physical barrier (e.g. plastic wrap, cardboard sheets, etc.) between the different items.

1.3 Incoming Material Inspection

After inspecting both the outside and inside of the carrier, check the incoming materials

See Form B.8 & B.9: Goods Receiving Records.

Develop safety procedures with all suppliers. Make sure that these inspection procedures are then used when receiving product at the facility.

Many facilities use tamper-evident tags or seals on trucks or bulk tanks. This helps to make sure that tampering is noticed right away.

All hatch seals must be examined to make sure they are intact. Record all seal numbers.

Encourage the staff to watch for signs of tampering or unusual appearance. Make sure staff know the procedure for alerting managers or quality assurance staff about issues.

For incoming materials with low risk for food safety hazards, only periodic spot-checks of these materials is necessary. This is also true for products where hazards will be reduced to safe levels during further processing. High risk products, or products that are not controlled later in processing, must be checked carefully.

Follow these key steps during incoming material inspection:

- Make sure that all incoming products, packaging, chemicals and manufacturing aids have clear lot codes on all containers;
- Get the seal number from the supplier before unloading sealed shipments, then verify the number on the receipt;
- Do not accept shipments if seals have been removed or damaged;
- Supervise unloading of incoming materials (including off-hour deliveries) to make sure materials are not damaged in the process;
- Make sure the product and the amount received agrees with the product and amount
    - Ordered;
    - Listed on the invoice; and
    - Listed on shipping documents.
- Record the temperature of all refrigerated and frozen products; and
- Reject questionable food. When in doubt, throw it out. Have the receiving staff hold all suspect food and notify Quality Assurance (QA) immediately.

Stamps are a great way for receiving staff to record the necessary inspection information directly onto the bill of lading.

Some products may need testing for chemical, biological or physical contaminants. Note that allergens, impurities or preservatives are also physical contaminants. Testing may be done in-house or at an approved lab. Remember that your customers may have special requirements when it comes to lab approval.

For more information about product testing, see Chapter 12: Supplier Food Safety Assurance Program.

1.4 Thermometers

Use a calibrated thermometer to take the temperature of temperature-controlled products when received. Remember that an unprotected and unsanitized thermometer is a food safety hazard.

If using a probe thermometer, clean and sanitize it in the following instances:

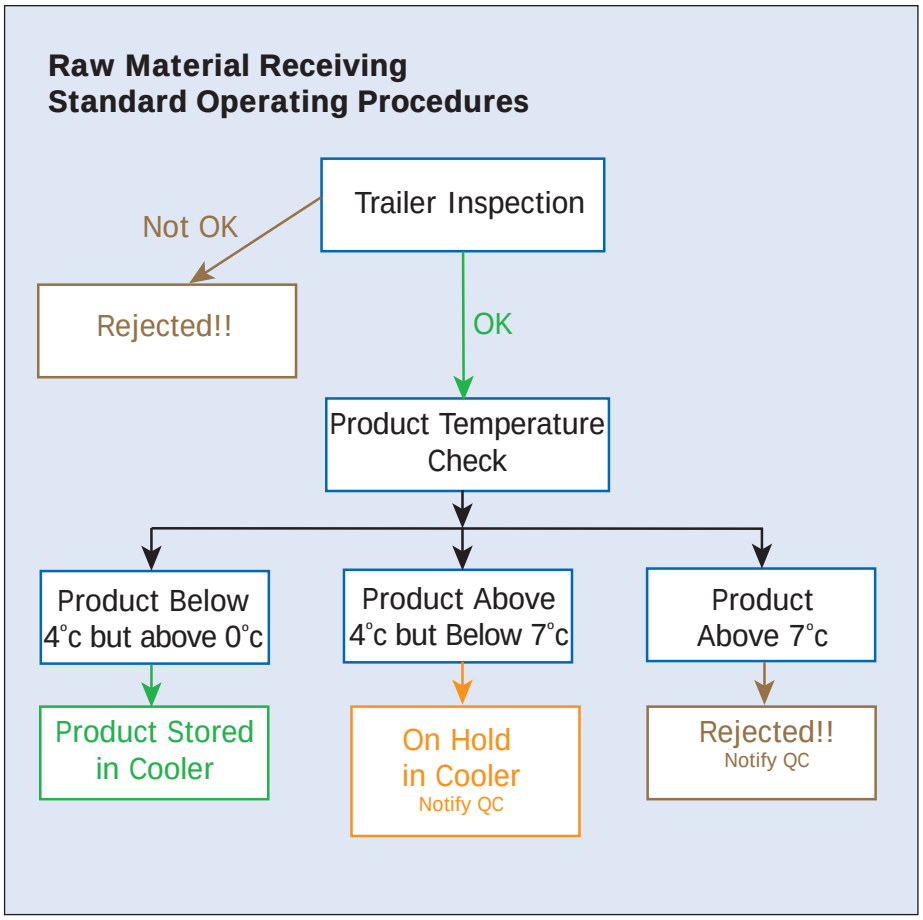
- Before taking any temperatures;
- When changing from raw ingredients to finished products;
- When changing from allergenic to non-allergenic products;
- When changing between different food products (including lot codes, best before dates, etc.); and
- Whenever the thermometer has been handled, set down or otherwise contaminated.

Always have food-contact surface approved detergents and sanitizers within easy reach in the receiving department to make maintenance of the receiving thermometers easier.

1.5 Receiving Flow Charts

Flow charts are a useful way to outline the procedures for receiving incoming materials. Figure 1 is an example for receiving refrigerated, frozen, or temperature-sensitive materials.

Figure 1: Example of a raw material receiving procedure.



Charts should be posted in the receiving area for ongoing, easy reference.

1.6 Defective, Suspect or Returned Product

Developing a Hold/Release Policy is important for a transportation and storage program. Like all other incoming materials, returned, defective or suspect products should display clear lot codes on all containers.

A policy for returned, defective or suspect product should include:

- A process to label all related pallets and products clearly with 'Hold' stickers;
- The date of receipt and the receiver's initials on labels;
- For suspect or defective products, the labels should include the date product was placed on hold, and the initials of the person responsible;
- A way to document the reason for the product being placed on hold;
- A process to decide on how to fix the issue (e.g. rework, reconditioning, animal feed, or destroy and dispose);
- Written unloading procedures that make sure handling of these materials doesn't damage or contaminate other incoming materials;
- Documents for noting and recording the shipping requirements for returned, defective or suspect materials;
- Controls should make sure they are the correct materials, labelled accurately, packaged appropriately, undamaged and free from contamination (unless otherwise noted on any documentation); and
- Controls and documentation must make sure that temperature-sensitive returned, defective or suspect materials are shipped, received and stored at the right temperatures. Temperatures must be monitored.

See Form F.7: Defective, Suspect and Recalled Product Receiving Form

Be sure to identify clearly any returned, defective or suspect products. Set them aside in a designated area for disposal.

Store rejected frozen products in a marked, separate area of the freezer. Similarly, store returned refrigerated products in a marked, separate area of the cooler. Ensure these items are stored under safe conditions to reduce the chances of cross-contaminating other raw materials or finished products. Maintain correct temperatures to ensure that if further testing is necessary, storage conditions will not affect the results. Record the temperature of any returned refrigerated or frozen products.

2.0 STORAGE

A variety of items are stored in a food processing facility including:

- Raw materials (including ingredients and processing aids)
- Cleaning and sanitizing chemicals
- Pesticides
- Maintenance supplies
- Finished product

To prevent cross-contamination among products, provide dedicated areas to store food and non-food items separately.

Areas should be constructed to:

- Protect food from contamination;
- Reduce deterioration of food as much as possible;
- Permit proper maintenance and cleaning; and
- Avoid pest access and places where pests can live.

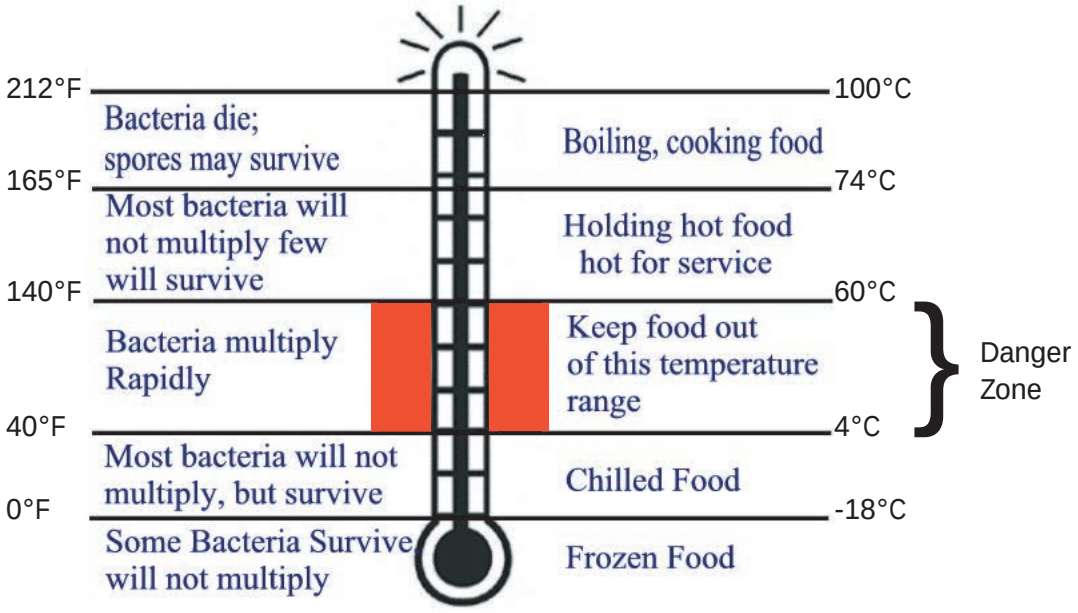
2.1 The Danger Zone

Keep hot foods hot and cold foods cold.

The most important thing to remember when storing temperature-sensitive food products is to keep them out of the 'Danger Zone' (between 4°C and 60°C). The Danger Zone is the temperature range in which bacteria and organisms grow quickly.

Bacteria, yeast and moulds need time, food and moisture to grow. However, they are not able to grow efficiently when the temperature of the food is colder than 4°C or hotter than 60°C. When food is in the Danger Zone, bacteria can grow quickly and can cause illness or injury to consumers.

Figure 2 – The Danger Zone



Courtesy of Marketing Food Safety – Farm Direct Advantage Manual developed in a partnership with Alberta Agriculture and Rural Development and the Alberta Farmers' Market Association.

Protect high-risk foods from extensive exposure to the Danger Zone. These foods include:

- Meat, seafood, fish or poultry and foods that contain those items as ingredients such as casseroles, deli meats, salads and sandwiches;
- Eggs and other protein-rich foods like soybean products and foods that contain these items;
- Dairy products and foods containing dairy products;
- Fresh cut or peeled fruit or vegetables;
- Cooked vegetables, beans, rice and pasta dishes;
- Sauces, gravy, and other low acid food products; and
- Sprouts, such as alfalfa and bean sprouts.

Appearance and touch are not reliable ways to check for safe temperatures. The only way to make sure food is not in the Danger Zone is to take the temperature using a calibrated food thermometer.

2.2 Storing Incoming Materials

Storing Food Products

Always follow the suppliers' storage instructions on incoming materials. Make sure that food is stored:

- In the right place;
- At the right temperature; and
- For the right amount of time.

Storing the raw materials under the safest conditions extends their shelf life. It also reduces the chance that they become a hazard to the product.

Store raw materials promptly after they are received and inspected. Put them in an approved, clean and sanitary area. This will help to protect them from possible contamination.

Key items to remember when developing the food storage policies are:

- Label and date all incoming materials using the 'first in, first out' (FIFO) system for storage and usage policies;
- Set the maximum time allowed for moving product from the receiving area to the appropriate storage areas;
- Store food at least 15 cm (6″) off the floor on approved shelving or racks;
- Ensure dry storage is in a cool, dry area away from direct light; and
- Keep dry storage temperatures below 21°C;

- Place received items that need refrigeration or freezing immediately into coolers or freezers. This prevents the growth of bacteria and/or thawing;
- Maintain freezer temperature at -18°C or less;
- Maintain temperatures of refrigerators or coolers between 4°C and 1°C;
- Do not restrict airflow when loading refrigerators or freezers;
- Store all opened bulk food packages in approved containers. Use tight fitting lids, with a contents and date label. Show the date stored, and other important information such as lot codes, on the label;
- Do not reuse chemical containers or single service containers;
- Cover all ingredients, packaging and finished products to avoid contamination from the above; and
- Keep racking away from walls in storage areas to allow space for cleaning and sanitation.

See Form B.12: Storage Unit Temperature Log

First In, First Out: Effective Food Rotation

Food rotation is a very important part of a food safety system. The First-In, First-Out (FIFO) food rotation method helps to make sure ingredients and materials are safe. FIFO can also decrease waste due to spoiled food.

Ask suppliers to use FIFO procedures. The main steps in the FIFO process are:

1. Label incoming product with the date received or the 'use by' date. Stickers attached to the bottom layer of material will help ensure that pallet remains labeled even when the product is being used. Each label should include date received and, where applicable, the 'best before' date.
2. Store incoming product to ensure older or first stock is used first. Keeping food organized in coolers and freezers may also help save energy by allowing quicker access to the food. The longer the cooler or freezer is open, the more likely the temperature will change to unacceptable limits.

3. Make all production, shipping and receiving staff aware of the in-plant FIFO procedures and their purposes.
4. The last step to FIFO is appropriate use of materials. Make sure that raw materials with the earliest 'use by' date are used first. Generally these dates coincide with the earliest date received. If not, notify management and make sure these products are used in the right order. FIFO is meant to help improve the shelf life and safety of the raw materials.

'Durable Life' is the period that a food product will retain its wholesomeness, good taste and nutritional value in storage. It is not a guarantee of food safety. Durable life begins on the day a product is packaged for retail sale. It is generally expressed in number of days. Food processors are responsible for determining the durable life of food products.

A 'best before' date is a different way of showing the durable life of a product. It states the date until the unopened product will retain its durable life. It must be shown along with correct storage instructions.

A 'packaged on' date states when they are packaged at the retail store, and must be shown with durable life information.

A Durable Life is required on prepackaged foods with a durable life of 90 days or less, with the following exceptions:

- Prepackaged fresh fruits and vegetables;
- Prepackaged individual portions of food served by restaurants, airlines, etc.;
- Prepackaged individual servings of food prepared by a commissary and sold in automatic vending machines or mobile canteens; and
- Prepackaged donuts.

For more information on requirements for Durable Life or Best Before dates, visit the Canadian Food Inspection Agency website at http://www.inspection.gc.ca/food/information-for-consumers/fact-sheets/labelling-food-packaging-and-storage/eng/1331871971167/1331872104067

Freezers

To maintain the best food quality, and to minimize deterioration because of microbe growth, keep the temperature of the freezer at -18°C or colder. Freezing causes bacteria to enter a dormant or non-active stage. However, freezing can't kill or destroy bacteria already in or on the product. Once thawed, these bacteria will become active. They can then multiply to levels that may become harmful.

Follow these rules for storing food in a freezer:

- Keep similar items together. For example, store allergens in one area, frozen flavours in another and frozen vegetables in yet another; and
- Mark all pallets using labels that will not fall off at cold temperatures.

It is important to follow FIFO procedures for all materials, even those stored in freezers. Research has shown evidence of increased chance of illness resulting from frozen food that has been stored for long periods and has freezer burn.

Coolers or Refrigerators

Maintain a target temperature of 4°C or less in refrigerators or coolers. In contrast to freezer storage, certain bacteria are still able to multiply in these cool temperatures but at a slower rate. This means that perishable food will gradually spoil in this environment.

Tips for storing food in a cooler are:

- Keep similar items together. For example, store all meat together in one section, liquids in another and allergens in another;
- Store partially used ingredients in clearly labeled, transparent containers so that food can be identified without opening the containers;
- Organize items to create more storage space and easier access to food; and
- Inspect coolers regularly and remove food that is spoiled or has passed the suggested storage time.

If the refrigerator or cooler is not working properly, the temperature of the food in it may reach the Danger Zone. Before moving the food, check the cooler temperature. If the cooler is above the target temperature (e.g. 4°C) , move the food quickly to another cooler or refrigerator.

Take the temperature of the food. If the temperature of the food items is warmer than than the target temperature , decide what to do and write down the decision and reasons on the Storage Unit Temperature Log (see Form B.12).

Thawing Frozen Product Safely

Frozen food should be thawed in a refrigerator or cooler, not at room temperature or in warm water. Thawing at room temperature or in a warm, wet environment allows harmful bacteria to grow.

Place a drip container under thawing product to catch the juices. This prevents contamination of products or materials that may be stored underneath.

Faster thawing must be done as rapidly as possible. The temperature of the product must be controlled to minimize the time that it is above 4°C. Acceptable active thawing methods include using:

- Forced air; and
- Continuously circulating, temperature controlled water.

Each of these methods must be operated under Good Manufacturing Practices with correct documentation of temperatures and controls.

During thawing, the temperature of the product must be controlled to ensure that it does not go above 4ºC.

To improve air circulation, remove all packaging before thawing the food. This prevents the product from becoming insulated by the packing material. Monitor thawing to know when all parts of the product are no longer frozen (e.g. they have reached a temperature of 0°C or warmer). Once the product is completely thawed, process it immediately or store it at a temperature of 4°C or colder.

Dry Storage

Dry foods, canned goods and high-acid items generally have a low risk of bacteria growth. However, even dried foods have limited storage time.

Never use food from cans or jars that are damaged, bloated or overflowing. These could indicate microbial growth.

Dry storage rooms should be cool, dry, clean, well lit and ventilated. Store food at least 15 cm (6”) off the ground. Keep food in original packages or containers to avoid damage and keep pests away. Place racks far enough from the wall to allow for cleaning and inspection.

Humidity can affect the safety and quality of food products. High humidity levels can allow mould and fungus to develop. Very low humidity levels can dry meat, some fruits and vegetables. It can also lead to loss of flavour and texture. Humidity can be controlled through airflow.

Some processing materials (e.g. nitrite) can become toxic when used improperly. Like other chemicals, store them separately from spice, seasoning or other ingredients.

2.3 Segregation – Chemicals and Allergens

Policies should state: ‘Food shall not be consumed, stored or processed in any room or area where hazardous materials, such as cleaning chemicals or pesticides, are stored or handled.’

Ensure employee and customer safety by protecting against accidental swallowing of chemicals or other hazardous materials. Reduce the possibility of cross-contamination by separating areas where hazardous materials are stored or used, from those where food is kept. Use a separate, ventilated room for storing hazardous substances such as chemical cleaners and pesticides.

See Form B.6: Chemical Spill Incident Report.

Allergens or ingredients containing allergens may require separate storage in a facility. These proteins can easily cross-contaminate non-allergen food items. The easiest way to separate allergens is to set aside specific shelving, racks or storage areas. Colour-coded stickers and equipment will help to identify separate areas.

For more information on allergen control, see Chapter 11: Allergen Control Program.

2.4 Storing Finished Products

Like incoming products, finished products have specific storage requirements. The purpose of this is to:

- Prevent contamination;
- Prevent damage or destruction of the product; and
- Rotate stock so that older products get shipped before newer ones.

To prevent the possibility of cross-contamination between raw materials and finished products, designate separate storage areas for each.

3.0 SHIPPING

To ensure the continued safety of outgoing materials, keep the shipping area well lit. Make sure the area and equipment are clean and dry.

Shipping staff need easy access to materials including labels, tape, permanent markers, thermometers and blank documentation forms. To lower the chances for contamination, the shipping area should be separate from the production floor.

Additional airflow barriers, such as air curtains, may help to separate shipping areas that may be open to the outside environment or production floor.

3.1 Carriers

Shipping is a facility's final control point for finished product. All food must be protected during transportation. The type of carriers to be used depends on the type of food product and transportation requirements.

Choose food carriers that are designed and built so that they:

- Can be thoroughly cleaned and disinfected;
- Permit separation of different foods and from non-food items during transport;
- Protect product from contamination (e.g. dust and fumes);

- Maintain the required temperature, humidity, atmosphere, and other conditions to protect food from harmful or undesirable microbiological growth and other damage; and
- Allow any necessary conditions (e.g. temperature, humidity, etc.) to be checked easily.

See Form B.3: Bulk Loading Report Form, and B.11: Shipping Record.

In certain situations, especially in bulk transport, make sure that the carriers are use only for food. Transport food products that absorb residual flavours or odours in carriers that transport only that particular product.

If the same carrier has been used for transporting different foods or non-food items, ask for the records from the shipping company. Companies that ship food product should maintain records of their most recent cargo. They should also maintain records of the cleaning method used in the carrier they are providing.

3.2 Proper Loading of Food Carriers

There are many ways food can be damaged during transit. Effective loading procedures can minimize damage or cross-contamination of products during shipping.

Follow these guidelines for loading food carriers:

- Avoid overloading refrigerated or frozen carriers to make sure of appropriate airflow;
- Avoid condensation build-up on staged product waiting to be loaded;
- Stack lighter, weaker cases or pallets on top of heavier cases or pallets;
- Load each carrier as quickly as possible; and
- Consider the use of secondary controls (e.g. load locks) to help secure pallets or product, especially when the carrier is not completely full.

When products containing allergens are shipped with products that do not contain allergens, always use some form of physical barrier. Examples include plastic wrap or cardboard dividers used between the products. To further reduce the chance of cross-contamination, never use damaged containers or pallets.

3.3 The Cold Chain

Management of the food supply chain includes consistent and accurate checking of temperature. Maintain safe refrigeration or freezer temperatures during transportation. This is often called the 'cold chain.'

It is important to maintain the cold chain during each step, from placing product on a pallet to unloading carriers. Set up temperature and performance standards for each step. Keep records to make sure that food safety controls are maintained.

4.0 INCOMING CHEMICAL PROGRAM

Any chemical used in a food processing facility can contaminate food ingredients, packaging materials, food contact surfaces and staff.

Before ordering non-food chemicals for the facility, make sure they are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemicals Products, published by the Canadian Food Inspection Agency (CFIA).

online at http://www.inspection.gc.ca/food/safe-food-production-systems/technical-references/reference-listing/eng/1375038742229/1375038784748

Chemicals must be listed formally by CFIA as not posing a health risk to consumers. If a chemical is not on this list, a 'Letter of No Objection' must be obtained from Health Canada to bring the chemical into a facility.

To control the storage and use of poisonous and toxic chemicals (e.g. cleaning and sanitizing agents, pesticides) use the following procedures.

1. Minimize poisonous and toxic chemicals in the facility:

- Keep only those chemicals that are required for the operation and maintenance of the facility; and
- Dispose of all chemicals no longer in use.

2. Control the use and storage of chemicals:

- Store all poisonous and toxic chemicals separately from food handling and storage areas;
- For poisonous and toxic chemical storage areas, limit access and secure area;
- Lock all storage areas, including outside storage, when unattended; and
- Make sure that poisonous and toxic chemicals are stored properly and are labeled clearly.

3. Maintain appropriate labeling:

- Keep chemicals and supplies in their original packaging whenever possible; and
- Remove and dispose unlabeled chemicals (according to bylaws).

4. Regularly inspect and monitor chemical usage:

- Create a list of all poisonous and toxic chemicals on premises;
- Inspect chemical storage, processing and packaging areas daily before production begins;
- Move chemicals stored improperly to the correct storage area;
- Investigate any incidents of missing stock or other unusual situations; and
- Develop corrective actions when appropriate.

Separate chemicals for storage based on their chemical properties (e.g. acid and bases) to prevent chemicals from becoming mixed accidentally. Certain chemical reactions can cause deadly fumes, fire or explosion.

When receiving chemicals into a facility, make sure the products and amounts received agree with the product and amount ordered and the invoice and shipping documents.

Courtesy the Marketing Food Safely - Farm Direct Advantage Manual developed in a partnership with Alberta Agriculture and Food and the Alberta Farmers' Market Association.

See Form B.1: Approved Chemical List, and Form B.5: Chemical Inventory Record.

5.0 DOCUMENTATION

5.1 Incoming Material Records

Incoming material records may include packaging, ingredients (including water or ice), and chemicals. For all incoming materials these documents will include:

- *Cooler and freezer temperature records (See Forms B.12: Storage Unit Temperature Log); and*
- *Receiving records (see B.4: Bulk Receiving Record, and Forms B.8 and B.9: Goods Receiving Records, and).*

Inventory tracking records are also an important part of the documentation. These are covered in Chapter 10: Development of a Recall Plan.

5.2 Shipping Records

The correct exchange of documentation between a facility and the shipping company is important. Documentation may include:

1. Food transportation unit number;
2. Information on previous loads;
3. Time/temperature records; and
4. Cleaning certificates.

See Form B.3: Bulk Loading Record, and Form B.11: Shipping Record.

6.0 TRANSPORTATION, STORAGE AND RECALL

An effective transportation and storage program strengthens the recall program. The manufacturing team's main responsibility is traceability. However, important parts of traceability depend upon the staff responsible for transportation and storage.

- Receiving staff must make sure that traceability information is collected before materials enter production.
- Shipping staff must understand the importance of recording production dates for all materials shipped. These staff members are responsible for creating the link between product information and customers.

Many documents used in the transportation and storage program are also used in the inventory tracking and distribution systems.

For further information regarding traceability in a facility, see Chapter 10: Development of a Recall Plan.

7.0 STAFF TRAINING

Training of shipping and receiving staff should include:

- How to document information;
- How to inspect and ensure that carriers are cleaned thoroughly;
- How to evaluate the received products;
- How temperature can affect the bacterial growth in food products; and
- The importance of controlling pests.

All employees working in shipping and receiving must understand the importance of handling food cargo safely.

For further information regarding personnel training, see Chapter 7: Developing A Personnel Training Program.

8.0 TRANSPORTATION AND STORAGE FORM TEMPLATES

B.1 Approved Chemical List

B.2 Approved Suppliers List

B.3 Bulk Loading Record

B.4 Bulk Receiving Record

B.5 Chemical Inventory Record

B.6 Chemical Spill Incident Report

B.7 Defective, Suspect or Returned Product

B.8 Goods Receiving Record (Option 1)

B.9 Goods Receiving Record (Option 2)

B.10 Incoming or Outgoing Goods Carrier Inspection

B.11 Shipping Record

B.12 Storage Unit Temperature Log

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Chapter 6
DEVELOPING AN EQUIPMENT PROGRAM

1.0 SANITARY FACILITY DESIGN
- 1.1 Pre-owned Equipment
- 1.2 Colour Coding Equipment
- 1.3 Air Quality in a Facility and Air as a Processing Aid

2.0 PREVENTATIVE MAINTENANCE
- 2.1 Value of Preventative Maintenance
- 2.2 Creating a Preventative Maintenance Program
- 2.3 Communication and the Preventative Maintenance Program
- 2.4 Documenting a Preventative Maintenance Program

3.0 EQUIPMENT CALIBRATION
- 3.1 Documentation

4.0 EQUIPMENT FORM TEMPLATES

5.0 SOURCES OF INFORMATION

A good equipment program minimizes the chances of food contamination in a facility. To minimize contamination look at how the equipment is:

- Designed
- Constructed
- Arranged
- Operated
- Maintained

When selecting any equipment, think about what risks it adds or removes from the production process. Because some equipment is purchased before putting a HACCP or food safety system in place, the existing equipment also needs to be evaluated.

A recent European study found that 25% of all food contamination is caused by machinery that is used improperly or designed poorly.

1.0 SANITARY FACILITY DESIGN

Facility design is an important part of controlling potential food safety hazards.

- Chemical hazards can come from lubricants or cleaning chemicals in equipment.
- Physical hazards may come from loose nuts and bolts, or metal-on-metal friction that releases metal fragments.
- Microbial and allergen hazards often come from food or other contaminants that get trapped in the equipment (e.g. blind corners or other areas that are hard to clean).

See Form A.2: Change Control Checklist, and Form A.9: Sanitary Design Checklist.

HACCP is a continuous improvement food safety system. This means that every time there is a change to the production environment or process, the entire process must be re-examined to see if it affects food safety.

When buying new or used equipment, keep the following in mind:

- All food contact surfaces should be made from food-grade material (smooth, non-corrosive, non-toxic and non-absorbent);
- The equipment's design and maintenance program must minimize the risk of food contamination (watch for loose bolts, metal chips or shavings);
- Chemicals, such as lubricants and seals, should be made from food-grade materials and not overused;
- Equipment should be easy to clean and not have cracks, crevices, hollow areas or other 'hang-up' points that collect particles of food, chemicals, allergens, or moisture;
- All areas of the equipment should be easy to reach for cleaning, sanitizing, maintenance and visual checks;
- Failure of any part of the equipment should not cause or risk contamination; and
- The equipment's design and maintenance should reduce the chances of product contamination from dust, condensation or any other sources.

For more information regarding Sanitary Design, see Chapter 4: Developing the Premises Program.

1.1 Pre-owned Equipment

When purchasing pre-owned equipment, it is important to identify:

- How long the machine was used;
- What the equipment was used for, and if these uses have a negative effect on food safety;
- Where the machine was stored when not being used;
- Whether the machine was exposed to any external hazards that might be brought into the new facility;
- How the machine was transported between locations, and whether it needs to be sanitized before bringing it into the facility;

- Why the equipment is being sold (is it reliable or will the reason for sale affect food safety?); and
- Whether the equipment has been evaluated by qualified professionals.

It's important to check the history of any piece of pre-owned equipment. This information is key in understanding how the equipment will affect a food safety system.

Even the smallest change in equipment or process can impact the safety of the finished product.

Ask the supplier for documents that show:

- The types of food products that were previously produced on the equipment;
- How long the equipment was used;
- How the equipment works;
- The servicing records;
- Installation information;
- A record of equipment testing proving it's in good working order; and
- The original operating manual.

The supplier should also be able to offer advice and training on how to use the equipment. This will help to make sure new hazards aren't introduced into the production process.

See Form C.1: Equipment Contact Information.

1.2 Colour Coding Equipment

Instruction sheets and posters about a colour-coding system are useful to employees and visitors.

Colour coding is a useful way of reducing the risk of cross-contamination. It separates equipment used for different products and activities. It also separates equipment used for products that may contain allergens.

Colour coding maintenance and other equipment, as well as clothing and utensils, helps identify raw product operations versus processed product operations. It also helps to identify allergen versus non-allergen operations.

There are no legal guidelines or standards in Alberta or Canada outlining which colour is best for an item or activity.

While colour coding can help reduce cross-contamination, equipment must be cleaned and sanitized between products or different activities. Cleaning and sanitizing is very important between raw meat products. For example, chicken and beef may carry different microbial hazards.

1.3 Air Quality in a Facility and Air as a Processing Aid

It's very important that the air quality in a processing plant is controlled. Air can carry mould, yeast, pathogens, moisture and dust particles. Dust particles can easily carry microbes, allergens, oils or other contaminants

To maintain air quality:

- To maintain air quality:
- Control airflow in the establishment. Make sure that airborne contaminants flow away from ready-to-eat and potentially hazardous foods.
- Direct airflow away from equipment that uses air as a processing aid. For example, negative air pressures in raw product areas and restrooms help prevent air flowing from these places into the processing areas. Positive air pressure can then be maintained in places such as the processing and packaging areas.

- Make sure that filters perform at the manufacturer's standards of performance.
- Filter compressed air, such as oxygen (O2), nitrogen (N2) and carbon dioxide (CO2) used in some packaging, when such air contacts finished products

Air used in processing must be safe. Just as with any other ingredient, make sure that the air is not a source of contaminants. This could include treating or filtering the air

For further information regarding Ventilation Systems, see Chapter 4: Premises.

2.0 PREVENTATIVE MAINTENANCE

An effective preventative maintenance is the best form of an equipment maintenance program in a HACCP system.

Develop procedures that prevent equipment from breaking down or becoming a future source of contamination. Fixing equipment only when it breaks down can be wasteful, costly and can create food safety hazards.

The main goal of preventative maintenance is to avoid equipment failure before it occurs. This is done by inspecting and replacing worn parts before they fail.

Preventative maintenance involves:

1. The care and service that keeps equipment and facilities in good operating condition;
2. Organized inspection, detection and correction of problems before they happen; and
3. Testing, measuring, adjusting and replacing parts to prevent faults or failures.

2.1 Value of Preventative Maintenance

Calculate hourly rates associated with breakdowns (rates = lost production + lost opportunity costs + overtime and other extra input costs).

A good preventative maintenance program reduces downtime. Long-term benefits of a reliable and well-documented preventative maintenance program include:

- Improved system reliability;
- Decreased cost of replacement;
- Fewer production stoppages;
- Fewer large scale repairs;
- Less raw material and product spoilage;
- Increased life expectancy for equipment;
- Less need for standby equipment;
- Identification of equipment with high maintenance costs (leads to checking and correction of misuse, operator abuse or outdated equipment);
- Better spare parts control;
- Greater work safety;
- Lower manufacturing costs; and
- Better control over food quality and food safety.

Long-term cost comparisons show that preventative maintenance leads to lower costs over maintenance done only when equipment fails.

2.2 Creating a Preventative Maintenance Program

There are five accepted steps for setting up a preventative maintenance program.

1. Create a list of all equipment in the facility:

Use the equipments' manuals and previous experience/history to outline all maintenance and repair activities that might affect food safety. Do this for each piece of equipment.

Outline regular maintenance requirements, small part inventories or any other aspects of the equipment that may affect food safety.

2. Adopt a plan:

Detail the who, what, when, and how for each element of equipment maintenance in the facility. Develop ways to perform and document each activity outlined.

Like other prerequisite programs, the preventative maintenance program should be something that can be checked on. It should include steps to prove that activities follow manufacturer's recommendations.

3. Perform the work:

Organize tasks. Do emergency repairs but don't neglect preventative maintenance.

4. Collect data:

Use documents from the preventative maintenance program to adjust the HACCP program. Analyze this data for food safety issues.

5. Inventory the parts required for maintenance:

Keep an inventory of spare parts, especially those needed for common or regular repairs. Keeping spare parts organized or coded for each machine increases efficiency and reduces clutter.

2.3 Communications and the Preventative Maintenance Program

Maintenance activities sometimes create hazards. Any preventative maintenance program should be coordinated with both sanitation and production.

Some preventative maintenance activities are complex and time consuming. This can result in equipment (and sometimes entire areas) being isolated from the processing environment for hours, or even weeks. That's why it is important that sanitation personnel communicate effectively with maintenance personnel. This helps to make sure that:

- All personnel are notified when these items/areas are returned to the processing environment; and
- The equipment and surrounding areas have been cleaned and sanitized.

Maintenance activities also have direct effects on production and scheduling. Consult with production planners, supervisors and management about scheduling preventative maintenance activities. This helps eliminate unnecessary customer or supply issues.

2.4 Documenting a Preventative Maintenance Program

Make sure that all maintenance activities are well documented. Keep records of staff training, regular repairs, purchases, pre-operation inspection findings, etc. Documents should show that the preventative maintenance program supports all other prerequisite programs.

The preventative maintenance program will include:

- A facility's food processing equipment and maintenance requirements;
- Maintenance equipment and what is needed to maintain them; and
- Regular inspection or maintenance activities, procedures and frequencies.

Staff training ensures that employees have the skills they need for effective preventative maintenance.

For more information on documenting personnel training, see Chapter 7: Developing a Personnel Training Program.

Equipment Records

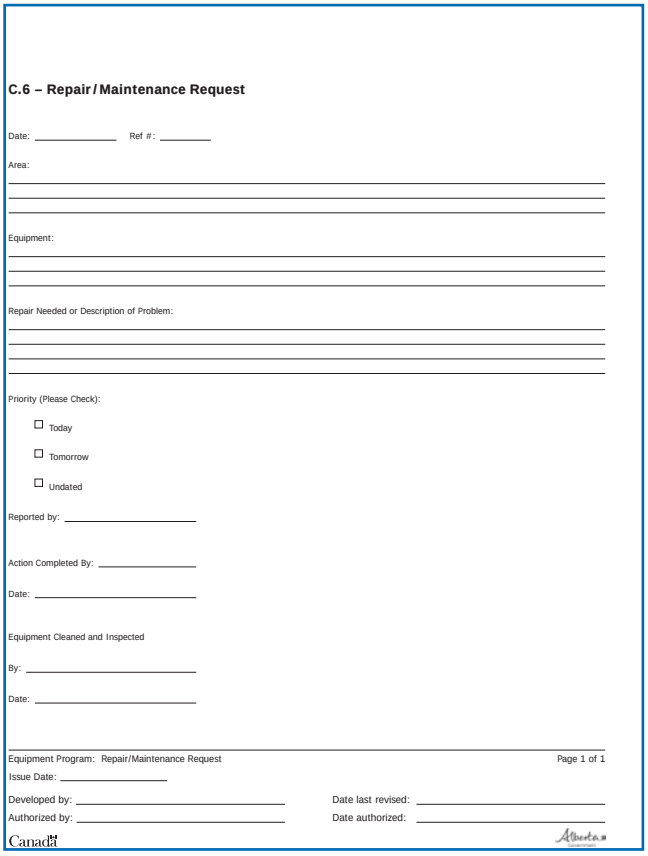
Necessary equipment records include:

- All manufacturers' literature such as manuals, drawings and lists of spare parts;
- Flow diagrams of the entire facility;
- Individual diagrams showing locations of all equipment and production processes; and
- A recording and reporting system of performance inspections and activities for each piece of equipment.

This last point ensures that corrective action is taken immediately after a deviation or unusual event.

Make the system and documentation simple. A Repair/Maintenance Request Card file can be used for the equipment records. See Figure 1.

Figure 1: Repair/Maintenance Request Card



C.6 – Repair / Maintenance Request

Date: _____ Ref #: _____

Area:

Equipment:

Repair Needed or Description of Problem:

Priority (Please Check):

☐ Today

☐ Tomorrow

☐ Undated

Reported by: _____

Action Completed By: _____

Date: _____

Equipment Cleaned and Inspected

By: _____

Date: _____

Equipment Program: Repair/Maintenance Request Page 1 of 1

Issue Date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Canada Alberta

Each card should have space for information about any major changes and repairs. These documents become the health record of the equipment.

Inspection Schedules

All equipment is subject to wear and tear. Over time, efficiency and performance will decrease. Regular inspections are necessary to identify performance issues before a breakdown occurs.

Inspection schedules should include a review of equipment performance. They should also include regularly scheduled servicing and inspection of all other areas of the facility.

When developing the maintenance schedules, also check the instruments used to measure equipment performance. Check or calibrate these testing tools frequently to make sure they are working well.

Inspection and scheduled servicing records can supply important information to the maintenance department. Use this information when drawing up a maintenance schedule.

Lubrication and Other Preventative Maintenance Activity Schedules

Preventative maintenance schedules are an important part of the equipment program. Most machines have parts that require lubrication, tightening or other adjustments.

The following is an example of a six-step process that maintenance staff can follow every day for preventative maintenance.

1. Collect the preventative maintenance schedule cards for the day (or maintenance requests from a department or staff member), or examine the maintenance schedule for required activities.
2. Collect necessary tools and lubricants.
3. Perform necessary activities and then tag machines to show the maintenance activity is complete.
4. Notify the sanitation department or production supervisor that equipment is ready to be cleaned and inspected.
5. Record the job on a card or log, and note any important issues about the maintenance or equipment.
6. Where applicable, return the cards to an appropriate location or employee.

See Form C.5: Preventative Maintenance Schedule, Form C.4: Maintenance Request Tracking, and Form C.2: Equipment Maintenance Log

Spare parts program

A good preventative maintenance program must have a good spare parts inventory system. This helps to make sure that supplies are readily available.

An inventory program also helps to minimize the risk of extra or missing parts that end up in food products. Every maintenance department has various equipment parts ranging from pipes and fittings to nuts, bolts, washers, and electrical components. These can pose a safety risk to consumers.

3.0 EQUIPMENT CALIBRATION

Make sure that all inspection, measuring and test equipment are working. Calibrating or adjusting instruments for accuracy is important.

One way to test an instrument's accuracy is to compare its results to those of an accurate reference instrument. This can be done by shipping the testing or measuring equipment to the manufacturer. It could also be done by hiring someone from outside the company to check the instrument.

You can also test the instrument against controlled conditions. The best example of this is the use of pH standards for pH meter calibrations. In this test, solutions of known pH values are compared to results from the meter.

Whatever method is used, make sure that the calibration standards are traceable. Also make sure that they meet national or international standards. If no such standards are available or practical, use a single reproducible standard or an in-house standard.

Keep in mind that calibration may need to be performed by trained and/or qualified people. For example, scales may need to be checked by licensed technicians, or metal detectors may need to be calibrated by the manufacturer.

The frequency of calibration may depend on the manufacturers' limits or recommendations. It might also depend on the instrument's accuracy in the past. Consider the risk to the product if the instrument is not working correctly. High-risk products (such as ready-to-eat meals), or high-risk activities, need more frequent instrument calibration or accuracy checks.

3.1 Documentation

Calibration documentation should include:

- A list of all equipment requiring calibration;
- Calibration procedures and frequencies. These procedures must include:
    - the frequency of calibration activities,
    - who will perform the calibration, and
    - specific directions and limits for accuracy and precision;
- Description of standards used, where these are applicable, and records of certification; and
- Procedures necessary for maintaining certification of calibration standards or devices.

When calibration limits aren't met, take corrective actions to restore the equipment to its required accuracy. Also check whether there have been any long-term effects on the instrument's quality and operation. Document all related activities.

See Form C.7: Thermometer Calibration Log, or Form C.3: Hand Held Thermometer Calibration Record.

4.0 EQUIPMENT FORM TEMPLATES

C.1 Equipment Contact Information

C.2 Equipment Maintenance Log

C.3 Hand Held Thermometer Calibration Record

C.4 Maintenance Requests Tracking

C.5 Preventative Maintenance Schedule

C.6 Repair / Maintenance Request

C.7 Thermometer Calibration Log

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Chapter 7

DEVELOPING A PERSONNEL TRAINING PROGRAM

1.0 FOOD HYGIENE PRACTICES
- 1.1 Developing a Facility Hygiene Policy
- 1.2 Visitor Information and Hygiene Policy

2.0 TRAINING PERSONNEL
- 2.1 Knowledge vs. Skills
- 2.2 Motivating Adult Learners
- 2.3 Employees with Limited Understanding of English (ESL)
- 2.4 Developing a Training Program
- 2.5 Training Follow-up
- 2.6 Documenting Training

3.0 FOOD SAFETY AND HYGIENE TRAINING
- 3.1 General Hygiene Training Requirements
- 3.2 Food Safety and Food Hygiene Training Resources

4.0 TECHNICAL TRAINING
- 4.1 General Technical Training Requirements
- 4.2 Technical Training and Food Safety

5.0 PERSONNEL FORM TEMPLATES

6.0 SOURCES OF INFORMATION

Training facility staff is very important in making food and food production processes safe. This chapter explains why such a program is important for food safety and the elements of a basic personnel training program.

For more information on documenting the program, see Chapter 3: Documentation and Record Keeping.

1.0 FOOD HYGIENE PRACTICES

1.1 Developing a Facility Hygiene Policy

Personnel health and hygiene policies are important for any successful food safety system. A hygiene policy or statement outlines the company's food safety responsibilities and covers:

Hand washing is always important, even if using gloves while working.

- Hand washing and sanitizing;
- Protective clothing (smocks, footwear, gloves etc.);
- Personal cleanliness;
- Personal behaviour; and
- Illness and injuries.

Post the complete corporate personnel health and hygiene policy in an obvious, visible place (e.g. staff notice board). It must also be endorsed by management and backed by a training program.

For examples on how to oversee putting a policy in place, see Form 2: Employee Hygiene Policy, and Form 1: Daily Hygiene Record.

Hand washing and sanitizing

Hand washing is one of the best ways to increase food safety. Hand washing reduces germs and decreases the chances of contaminating food or food-contact surfaces. Make sure that all food handlers know the importance of washing their hands thoroughly and frequently.

A food handler is anyone who takes part in any activity involving food or food-contact surfaces.

Follow these simple steps to wash hands properly:

- Remove rings and other jewellery (watches, bracelets, etc.);
- Wet hands thoroughly with warm water;
- Lather well using liquid soap or foam soap;
- Scrub hands with soap for a minimum of 20 seconds (long enough to sing the alphabet). Include wrists, forearms, nails, between fingers and around and under any jewellery that cannot be removed;
- Rinse thoroughly;
- Turn off tap with a paper towel; and
- Dry hands with a disposable paper towel.

Everyone has a responsibility to make hand washing a regular activity in a facility. Have staff wash their hands:

Before:

- Preparing food;
- Eating; and
- Starting or returning to work.

Between:

- Handling raw foods (meat, fish, poultry and eggs) and touching any other food or kitchen utensils;
- Changing work areas (e.g. moving from unfinished to finished product); and
- Handling different allergens.

After:

- Preparing food, especially raw foods;
- Being away from the work station;
- Taking medicines;
- Touching body parts (including hair, nose, arms and eyes);
- Using the toilet;
- Changing clothing or gloves;
- Emptying garbage/waste bins; and
- Coughing or sneezing.

Any time:

- Hands may have been contaminated.

Use footbaths and hand-dips to sanitize hands, gloves and footwear. Follow the directions that come with the sanitizing chemicals precisely. If necessary, get help and information about the sanitizing chemicals from the supplier.

Protective Clothing

Food handlers must wear clean, protective clothing that is designed for the operation. Train employees on the importance of wearing protective clothing while working with food.

Change uniforms regularly if they are soiled during a work shift. Uniforms should also be changed before going to different in work areas (e.g. from unfinished product to finished product).

Smocks and Employee Uniforms

Smocks are common in the food industry. They are removed easily when the employee is not on the production floor. Smocks usually cover and contain all street clothing.

Be sure to consider whether uniforms may cause health or safety risks for employees. For example, some smocks may be unsafe in facilities using conveyor belts.

Colour coding is often used to tell the difference between raw and cooked product areas.

Make sure that staff wear the correct uniform appropriate for each production area. Do not let employees wear in-plant uniforms in the following situations:

- Off site or outside the facility;
- While smoking or eating; or
- Inside washrooms, restrooms or in lunchrooms.

Do not let employees take production uniforms home for cleaning.

Remember these points when selecting or using in-plant uniforms:

- Store employee uniforms separately from street clothing;
- Choose uniforms with light colours that show soil easily;
- Colour code uniforms according to the different areas where employees will be working;
- Change uniforms if they are soiled during a shift or if an employee is changing work areas (e.g. moving from unfinished product to finished product areas); and
- Have enough uniforms on site, as dirty uniforms can be a source of contamination.

Shoes

Do not allow street shoes or boots in production areas. Employees should have clean, special purpose footwear for the facility and change footwear when leaving the facility or when entering areas of the facility where contamination may be tracked back into production areas (e.g. animal holding areas, waste disposal areas).

When having visitors to a facility, supply them with special purpose boots or boot covers.

Hair Coverings

A single hair can host up to 50,000 germs, and one person can lose 100 hairs each day.

Provide hairnets and beard-nets to all staff and visitors entering the production areas. Follow the ‘tug test’ to decide if beard nets or hairnets should be used. If someone can grasp enough hair on the head or face to pull, it must be covered.

Personal Cleanliness and Behaviour

The personal cleanliness of food industry employees directly affects the safety of food production. This means employees must learn to follow rules for personal hygiene or cleanliness.

Everyone working in direct contact with food, food-contact surfaces and food packaging materials must follow hygienic behaviour.

Employee hygiene polices should include the following points:

- No eating within facilities except in permitted staff areas;
- No smoking;
- Keep personal items stored in an area away from food storage or preparation areas;
- Tie hair back or cover it;
- Keep nails short and clean;
- Do not use nail polish or false nails;
- Completely cover cuts or wounds with a waterproof bandage and gloves (in case the bandage comes off) to prevent contamination;
- Where possible, prevent people with cuts or wounds from handling food (open cuts and sores may contain germs);
- No horseplay in areas where food is stored or prepared;
- Avoid wearing jewellery in areas where food is stored or prepared;
- No food in employee lockers;
- No gum and candies; and
- Control employee traffic to prevent allergen and pathogen transfer.

Be sure all members of staff understand that anything, or anyone, passing through a facility can be a source of contamination. Such movement must be managed by in-house hygiene policies.

In food processing areas there should be NO:

- *Smoking*
- *Spitting*
- *Gum chewing*
- *Drinking*
- *Eating*

Have a policy clearly stating what jewellery is permitted.

- Do not allow wearing of jewellery, including watches, where food is stored, prepared or packaged.
- If jewellery cannot be removed, adapt the policies to ensure hygienic conditions.

Some facilities allow wearing of wedding bands, medical alert badges and other items if covered by a waterproof cover (e.g. a glove) that stays intact, clean and sanitary.

Illness and Injury Control

An in-house hygiene policy and the related training should prevent the transfer of diseases from known sources of contamination.

Prevent employees who are ill from contaminating food and food production areas. Encourage and train employees to report to their supervisors when they have a cold, open sores, sore throat, fever or diarrhea. Help employees recognize and report signs of illness.

A food hygiene policy should include training employees on what to do when they are ill. They must tell their doctor that they work in a facility that handles food. The doctor may then choose to notify public health if the illness poses any possible risks.

If public health workers believe there is a risk, they will contact the food processing facility. The employee may then be given a leave of absence until they are no longer a possible source of infection. As an alternative, infectious employees may work in an area where they're unlikely to infect co-workers or contaminate food.

The following is a sample illness control policy in a food hygiene program.

Illness Control in a Food Hygiene Policy

Food handlers must complete a Health Declaration Form:

a) Before employment (during pre-work screening); and
b) After returning from holidays outside the country.

Except at pre-employment, once the Health Declaration Form is completed, the employee's manager/supervisor will do the initial assessment. Where necessary, the employee's manager/supervisor may refer the employee to the occupational health physician.

Conditions requiring referral to a occupational health physician are stated in the guidance notes for managers/supervisors on the Food Hygiene Health Declaration Form.

To make sure of food safety – and the health, safety and welfare of all staff and visitors – food handlers are responsible for reporting to their supervisor any incidence of ill health at work or at home.

In accordance with the Sickness Absence Policy, report all absence for periods of one to seven days due to sickness, using the Self-Certification Form. A medical certificate is required for absences of eight or more days. At the discretion of their manager/supervisors or the occupational health physician, a food handler may:

- Be asked to remain on absence due to sickness;
- Stop working until they are cleared for return to work by their own doctor or occupational health physician; and
- Be asked to complete a declaration stating they are fully recovered from his/her illness.

Superficial or surface injuries (e.g. cuts, scratches, boils, sores and skin infections) can be a source of contamination.

Create a policy that includes the use of bright, coloured bandages as well as waterproof coverings (e.g. gloves) over superficial injuries. Specialty suppliers can provide bandages for food facility use.

See Form D.4: Injury Incident Report.

There is always the possibility that employees may be injured while working. For this reason, have in-house policies and training to deal with possible contamination from human blood. Such a policy should involve:

- Developing an exposure plan;
- Preventing a repeat event; and
- Providing personnel training.

Developing a Blood Contamination Policy Based on the "Workplace Safety Toolkit"

1) Develop an Exposure Plan:

- The purpose of the plan is to limit employee and food product exposure to blood. Review and update the plan annually.
- Require employees report all blood-related incidents right away to permit immediate follow-up.
- Determine how the organization will proceed to isolate product that has been exposed to blood.
- Name a person who will be responsible for writing up an exposure incident and reporting it to the appropriate authorities if required.
- Determine if product is affected – if so, determine how to deal with adulterated product.

2) Prevent the Possibility of Occurrence:

- Identify safety hazards that the entity's employees face that may lead to possible injuries.
- Consider what can be done to remove, eliminate or isolate these hazards.
- Purchase appropriate personal protective equipment (PPE) that does not permit blood to pass through to or reach the employee's work clothes, food-contact surfaces, or other food production materials.
- Require that staff members wash hands and other exposed skin with soap and hot water immediately after contact blood spills.
- Provide antiseptic cleaner and paper towels where sinks and soap are not available.

3) Provide Appropriate Training:

- Include all employees whose job responsibilities expose them to injuries that may involve blood.
- Include information about ways staff might be injured, what PPE to wear, how to dispose of the PPE and any bandages, and what to do immediately if they have an injury involving blood.
- Make certain employees receive training before they are placed in a situation where there's any chance they will be exposed to possible sources of blood injuries as part of their job responsibilities.
- Track who was trained and when.

Based on "Workplace Safety Toolkit" Protect Staff From Bloodborne Pathogen Contamination http://www.nonprofitrisk.org/ws-ps/topics/blp/protect-ps.htm.

1.2 Visitor Information and Hygiene Policy

A visitor hygiene policy helps prevent potential contamination at the facility.

Visitors may be potential sources of contamination in a facility. Address this risk through hygiene policies relating to contractors, shippers, auditors, customers and other regular or occasional visitors to the facility. Have ways to inform visitors about the importance of food safety while on site.

The visitor hygiene policy should be very similar to the employee hygiene policy and should include how to control visitor entry to the facility so that they don't contaminate food. The following is a sample visitor hygiene policy.

Example of Visitor Hygiene Policy

A 'visitor' means any person entering the facility other than staff.

Requirements

All visitors must put on the protective clothing provided (e.g. full length white coat and hairnet) before entering food processing areas. This clothing must be worn throughout the visit.

All visits, with the exception of those by environmental health officers (EHOs) and inspection staff, must be authorized by management. Visitors must be accompanied by supervisory staff.

Visits by technical services or outside firms installing, repairing or servicing equipment in the production areas can be authorized by the on-duty supervisor. Before beginning work, visitors must report to the supervisor on duty and wear protective clothing while on site.

Unauthorized persons, including friends and family, are not allowed in production areas.

Some companies require contractors and non-staff maintenance personnel to sign a contract that explains the in-plant hygiene policies. These contracts can also be part of the prerequisite programs.

A visitor contract makes visitors aware, before they enter the facility, what is expected of them. This contract can include information on visitor safety, such as how to leave in an emergency, and may help visitors accept the visitor policy.

See Form D.7: Visitor Hygiene Contract.

Most producers will not require visitors to sign a contract but will make sure all visitors are told about the company's hygiene policies. Identify visitors with a visitor badge so that they are easily identified as non-staff.

See Form D.8: Visitor Log Book.

2.0 TRAINING PERSONNEL

When examining a facility's training needs, consider everyone whose work involves food or food-contact surfaces. Have all food handlers meet training requirements set by the regional health authority. Make sure everyone involved in food production has the knowledge and skills needed to produce safe food.

Training programs should include staff involved in:

- Supervising and managing
- Line and manufacturing activities
- Packaging
- Shipping and receiving
- Maintenance
- New product development
- Sanitation
- Purchasing

Most food safety standards require that those working in food processing facilities have skills, knowledge, and related training in the following areas:

1. **Food-Hygiene Practices** – including personal hygiene practices, food handling skills, and hygienic routines. These ensure that the food, premises, and equipment are clean and well maintained.
2. **Technical Knowledge** – including the skills and knowledge needed for more specific food handling practices. These include receiving ingredients and supplies, monitoring critical control points (CCPs), sanitation of equipment, formulations (measuring of controlled ingredients, development of new products), packaging, machine operation and monitoring procedures.

There are many ways to train employees on the technical and food-hygiene knowledge they need. Employees can gain further knowledge and skills through on-the-job training and through courses. A company may decide that formal training is the best route, especially if employees need specialized or complex knowledge.

2.1 Knowledge vs. Skills

Effective training combines both knowledge and skill. Knowledge alone does not ensure that appropriate steps are taken. But skill without knowledge is equally meaningless – it can result in crucial steps being ignored.

Comparing Skills and Knowledge

Example:

A food handler in a manufacturing facility prepares, stuffs, and cooks beef potpies. The staff member who does this work must have both appropriate food safety and food-hygiene knowledge and skills. These ensure that the end product is produced safely.

The food safety and food-hygiene knowledge needed for this job includes:

- Knowing that raw meat is likely to be contaminated with dangerous bacteria and that eating undercooked product could result in food poisoning;
- Knowing the appropriate cooking time and temperature needed to make sure that the products are cooked thoroughly;
- Knowing the correct storage temperatures for both the raw materials and finished products;
- Knowing that hands, gloves, or the equipment used to handle raw materials can contaminate finished products; and
- Knowing about other possible sources of cross-contamination that might affect the finished product, such as dirty clothes or equipment.

The food safety and food hygiene skills needed for this job include:

- The skill needed to check the product to make sure that it is cooked thoroughly;
- The skills needed to make sure that equipment is set at the right temperatures;
- The skill to wash hands and equipment to reduce the chances of cross-contamination;
- The skills needed to keep the work area clean; and
- The skills needed to take the right corrective actions when necessary.

Based on *Food Safety Standards: Food Handling Skills and Knowledge*. Australia New Zealand Food Authority © May 2001
http://www.foodstandards.gov.au/_srcfiles/39997-TF1a.pdf.

2.2 Motivating Adult Learners

When designing training, keep in mind that people learn in different ways. How they learn best may change as they get older. However, no matter what their age, make sure that all learners are treated with respect and flexibility. When training staff, these tips can help:

- Call the learners by name;
- Clarify goals and expectations before starting;
- Prepare materials (e.g. have photocopy handouts ready, test audiovisual aids and know the material beforehand);
- Learn about adult education techniques;
- Use various learning strategies and adjust them to different situations;
- Give trainees frequent feedback;
- Ask for feedback during training; and
- Respond to requests and feedback from learners.

Always respect an adult student's knowledge and experience. Draw on that experience while training.

Be flexible when giving assignments and let trainees modify projects to fit their learning styles and needs. Adult learners usually prefer training that provides useful knowledge and skills. Adults prefer individualized learning experiences that support their independence.

Also consider the following when developing a training program for employees:

- Adults often like a course or training dealing with a particular issue, topic or subject;
- Do not overload employees with too much information during training sessions;
- Adults need to relate what they are learning to what they already know;

- Training that is too fast, complicated or uses methods that are alien to the adult's experience often reduces what they get from the experience; and
- Make training programs flexible so they can be adjusted for different age levels and for people with different levels of experience.

Many adults prefer self-directed learning but remember that self-direction does not mean learning all alone. Design instruction so that trainees learn not just from experts, but also from each other.

2.3 Employees with Limited Understanding of English

Following food safety and hygiene rules is challenging for everyone, whether English is their language of origin or not. For a new employee, there is a lot to learn and remember about standards, company policies and specific tasks.

Training food processing employees whose English is limited takes time and will likely require the use of non-verbal materials such as posters, drawings, photographs and videos. Colour coding of different products, allergens, or production areas can be useful.

Translating text into other languages may be necessary. Translation of key documents such as manuals and posters is worth the investment. This is especially true if it prevents waste or recall, and protects the reputation of the facility.

Consider partnering with other facilities, or working through an association, to purchase translation services and other materials.

When training non-English speaking employees, an instructor must know what previous training each employee has had. Find out about the employees' education and past experiences. Use the knowledge they already have as a starting point for more training. Failing to assess prior knowledge is a serious mistake in training. It insults the trainee and can stop the learning process.

The following websites provide information on training non-English speaking and ESL employees:

Links for Sites on Food Safety Materials in Various Languages:

- http://www.health.vic.gov.au/foodsafety/language.htm => "In Your Language" – over 10 languages with a variety of different resources, from fact sheets to posters
- http://tulsa-health.org/food-safety/food-service-industry/posters/ => Food safety signs in English, Chinese and Spanish
- http://www.who.int/foodsafety/publications/consumer/5keys/en/ => "Five Keys to Safe Food" by the World Health Organization

2.4 Developing a Training Program

Curriculum design or training development is a professional activity that the facility may choose to hire out. However, many training methods and courses are available and new resources are accessible through the Internet. If a facility is having difficulty, training organizations and industry associations can often suggest new training resources.

Training methods can include:

- In-house training by other staff, with support from management or owners (supports the management-down approach to the food safety policy and shows management commitment to food safety);
- Giving staff food safety and food hygiene information to read;
- Presentations on the responsibilities of production staff and supervisors;
- Sending staff to external food safety courses;
- Hiring a consultant to run an in-house course for staff; and
- Recruiting staff with formal industry-based training.

Regardless of the training option chosen, be sure that staff gain the skills and knowledge needed to do their work.

In developing the training program, ask these questions:

- What are the food handling and safety risks associated with the facility?
- What food handling tasks do the employees perform?
- Have staff been told or shown how to handle food safely within the facility?
- Is someone responsible for making sure set procedures or policies are followed on each shift?
- Do staff have the equipment and space to meet the food safety and hygiene policies?

Remember, training should suit the complexity of the manufacturing process and assigned tasks. Make sure the employee's skill set or background allows them to succeed in training.

Only train staff in the methods that are relevant to their job. Follow up training with regular supervision to check that safe methods are used (see also 2.5 Training Follow-up).

Do not assume that employees have understood the training. Consider everyone's needs. If someone has shortcomings that need to be corrected, provide learning supports that won't threaten or insult that employee.

Creating a Basic Training Program:

What to Do	How?
Identify the appropriate food safety skills necessary in the facility. Develop in-house program to train staff. Ensure that each member of the staff knows the safe methods for all tasks.	Show the member of staff what to do, question them carefully on their knowledge, and then ask them to show you how to do it.
Record training that each member of the staff has received, from management to sanitation staff.	Make a note in the staff training record every time you train a member of the staff.
Evaluate the effectiveness of training.	Observe employees to ensure correct methods are being used. Ask learners to provide feedback on training they receive, even informal casual training. Make sure that their learning preferences are respected and that they find the training enjoyable. Make comments and observations to help staff members improve the way they work. Reward good performance by giving positive feedback each time a member of staff has followed safe food production methods. If a safe method is not being followed appropriately, take the staff member aside and tell them what they are doing incorrectly. Tell them why it is important to follow the safe method. Note corrective actions or observations on the training record for future reference.

Based on *Safer food, better business*. Food Standards Agency, EU © January 2006 http://www.food.gov.uk/multimedia/pdfs/sfbbfullpack.pdf.

2.5 Training Follow-up

Initial training must be supported periodically by follow-up training sessions and evaluations.

Evaluate how well training has worked by observing whether food safety procedures are being used. Also give occasional quizzes at the beginning or end of a shift.

Follow-up sessions do not have to take a lot of time, as a five minute refresher demonstration is often enough. Make training fun by using creative formats and offering prizes for excellence.

2.6 Documenting Training

Besides providing employees with food hygiene and technical training, employers must also keep track of all other kinds of training. Record not only formal sessions but also refresher demonstrations, quizzes and corrective training.

Create a record for each employee so that new managers are aware of individualized training needs. Keep employee evaluations of training techniques. This will help instruction designers to avoid techniques that haven't been successful in the past.

As noted in Chapter 3: Documentation and Record Keeping, the facility is not under control unless it's documenting its operations.

Documents provide records that show training has happened. It provides evidence that training was thorough enough to protect food safety. Training records will show that staff:

- Can locate and follow workplace information for their own food handling operations;
- Can find, correct or report situations or procedures that do not meet workplace practices;
- Know their health and hygiene responsibilities; and
- Know how to complete the daily performance of their tasks.

Training records must be auditable and show the following:

- Who is giving and receiving the training;
- What knowledge and skills are covered and how the training is done (e.g. video, buddy system, hands-on, etc.);
- How often training is conducted; and
- Whether the training is at the appropriate level for the staff. Provide proof through written or verbal examinations, visual supervision or job assessments.

Keep a list of the training required for each position. Use these lists to make sure that all employees, including new hires, have the training they need.

A staff training record is the simplest way of monitoring employee training and a good future reference. This record is an individual summary of the training, testing and evaluation that has been done with each staff member while at a facility. A staff training record normally includes:

- Name of the employee;
- Date of employment;
- Description of training;
- Date of training;
- Comments about unusual situations; and
- Instructor name.

See Form D.3: Employee Training Record, Form D.6: Training Attendance Record and Form D.5: Procedures Training Record.

3.0 FOOD SAFETY AND HYGIENE TRAINING

3.1 General Hygiene Training Requirements

Training must meet the regulatory requirements of the license. Management must ensure that all employees who come into contact with food are trained in safe food handling. They must make sure that training is delivered according to staff needs.

It is very important that food safety and hygiene training delivers clear and consistent information. Remember that employees may be asked by public health inspectors, customer auditors or suppliers about the training employees have received. They may also be asked about their knowledge of what facility policies and expectations are.

What works for one facility may not suit another. The supervision and training needed to produce safe food will depend on the number of employees and the kind of work they do. It will also depend on staff's current training and ability levels. Excellent training programs are especially important if staff turnover is high.

3.2 Food Safety and Food Hygiene Training Resources

As noted in Section 2.4 (Developing a Training Program), there are many possible training resources available. Resources can include outside courses, videos, handouts and professionally developed employee handbooks (see also the websites listed below).

For a complete list of available Food Safety Training Resources visit the Department of Education, Human Resources Development Canada.

Sources of Approved Alberta Health and Wellness Food Safety Training:

1) Attend training at a local Regional Health Authority (RHA), through the First Nations Inuit Health Branch (FNIHB) or through an accredited educational institution (NAIT, SAIT, Red Deer College, and Lethbridge College).

   - These groups teach a food safety course of their choosing.
   - Students write a provincial exam, maintained by Alberta Health and Wellness.
   - Students that achieve 70% or higher are issued a provincial certificate in food sanitation and hygiene and are then entered into Alberta's provincial database of certified workers.

2) Complete an approved independent course.

Four courses have been approved in Alberta as being equivalent to the provincial food safety education program:

- Canadian Food Safety Certification Course - ADVANCED.fst - offered TrainCan (http://www.traincan.com/index-advanced.html).
- ServSafe - offered through the United States National Restaurant Association (http://www.servsafe.com/home).
- National Food Safety Training Program – offers Foodhandler and Trainer Certification developed by the Canadian Restaurant & Foodservices Association (http://www.nfstp.ca/).

Certificates obtained from one of these organizations are considered equivalent to the provincial certificate.

3) Complete a course offered by an approved independent trainer.

- Approved trainers have professional qualifications and appropriate educational background.
- Trainers teach a food safety course of their choosing.
- Students write the provincial exam used by RHAs in Option 1 (above).

If you have any questions or would like more information about any of these options, contact Alberta Agriculture and Rural Development or your local public health inspector.

4.0 TECHNICAL TRAINING

4.1 General Technical Training Requirements

There is no standard that will outline all the requirements for technical training in the food industry. Each facility, product and position is unique and will require specific technical knowledge from staff.

Some positions require more formal training than others. Technical training is not always restricted to 'how to do the job.' In most situations, it is important to combine this training with food safety and other training (e.g. WHMIS).

In a HACCP environment, it is very important that all employees understand food safety principles and what they can do to affect overall product safety. They must also understand the corrective actions to take.

When an employee has met the requirements relating to a technical skill, there should be sign-off or confirmation by management. This will show that the employee has reached a certain competence level.

Each facility should develop a way to test staff's technical training. This would be similar to what is used in food safety and hygiene training (e.g. multiple choice exams, visual supervision during work, buddy review of policies to check on understanding).

4.2 Technical Training and Food Safety

There are various methods for technical training of employees including:

- Using job specific written SOPs (Standard Operating Procedures);
- Videos; and
- Job shadowing (with an experienced individual).

Cross-training Staff

Most facilities ensure that some employees are cross-trained so they are available to fill in on short notice.

Keep these in mind when monitoring critical control points (CCPs):

- *Why the CCP exists*
- *CCP critical limits*
- *Procedures for monitoring the CCP*
- *Abnormal or unusual situations*
- *Correct documentation*

Critical Control Point (CCP) Training

Employees responsible for monitoring critical control points (CCPs) must be trained to understand the importance of the CCP and the critical limits. They must also understand procedures for monitoring the CCP, deviation procedures, and document control procedures.

Staff members responsible for key positions often need training not only for their job, but also in other duties. These include:

- Maintaining documentation;
- Understanding reasons for certain corrective actions; and
- Understanding the importance of the CCP in the plant's HACCP plan.

Calibration/Maintenance Training

Maintenance staff members are often overlooked when it comes to food safety. Most companies hire maintenance personnel with the certification for their specific trade (e.g. plumber's certificate, electrician's certificate, etc.). However, they often overlook the importance of training these employees on how their work will affect food safety.

Employees hired to calibrate or adjust equipment must also understand how their tasks affect food safety.

Maintenance staff must have the skills and knowledge to make sure that equipment is cleaned and sanitized. This must be done before equipment is allowed back into operations.

Create procedures to notify Sanitation/Production/QA Staff when maintenance is complete. Also develop procedures to let maintenance staff and services know when there are changes in process safety or control.

Procedures and training must also stress the importance of controlling and tracking maintenance parts and tools – these can affect food safety.

Sanitation Training

To reduce the chances of accidental food contamination, make sure staff have a basic knowledge of chemical use and sanitation.

Staff members must understand general sanitation training. They must also understand all written sanitation procedures. Pest control and sanitation in a HACCP facility also require a lot of documentation. Train sanitation employees to create and maintain the records they are responsible for.

Often sanitation employees are responsible for both the clean-up and pre-op programs and they must understand how sanitation and pre-op affect each other. Also teach them how to take corrective actions when necessary.

The most important training for sanitation staff is how to correctly handle chemicals. Train sanitation crews in the correct dress and personal protective equipment required for both food safety and personal safety.

Teach sanitation staff how to store and separate chemicals. Make sure they know to store all cleaning, sanitizing and pest control chemicals in areas separate from food processing.

Supervisor Training

Supervisory employees are generally responsible for making sure all food employees on their shift follow company procedures and policies.

Most supervisory staff must be competent and trained to standards in the following areas:

- Relationship between the prevention of foodborne illness and the personal hygiene of an employee;
- The policies and responsibilities of a supervisor for preventing the transmission of foodborne disease from an employee to food or food products;
- The required food temperatures and safe cooking, cooling and storage of any potentially hazardous foods in the facility;
- The relationship between food safety and the management and control of:

    - Cross-contamination;
    - Hand contact with ready-to-eat foods;
    - Hand washing;
    - Maintaining a manufacturing environment in clean condition and good repair;
    - The correct procedures for cleaning and sanitizing utensils;
    - Poisonous or toxic material identification;
- Knowledge of all important processing points in the operation (from purchasing through to packaging); and
- The principles and details of the facility's HACCP plan.

Supervisors must be trained to monitor and correct behaviours and actions respectfully with staff. Supervisors will need to:

- Understand how to reinforce correct actions with praise or rewards;
- Be able to treat all employees with respect (in keeping with other cultural concepts of respect where appropriate);
- Understand the short version of words (acronyms) and the slang used for parts of the facility and its processes;
- Support staff when they ask questions to make sure that all employees understand the information; and
- Encourage line staff to take a personal interest in the facility's food safety.

Specialized Training

Some industries require that production employees take specialized training or courses to do their work (e.g. pasteurization training in the dairy industry). If the facility decides to use off-site training, keep a record on file. Many trainers will provide certificates of completion, attendance or certification. Keep copies of these documents with the in-house staff records to track all training employees receive.

5.0 PERSONNEL FORM TEMPLATES

D.1 Daily Hygiene Record

D.2 Employee Hygiene Policy

D.3 Employee Training Record

D.4 Injury Incident Report

D.5 Procedures Training Record

D.6 Training Attendance Record

D.7 Visitor Hygiene Contract

D.8 Visitor Log Book

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Chapter 8
DEVELOPMENT OF A SANITATION PROGRAM

1.0 THE SANITATION PROCESS
- 1.1 Wet Cleaning
- 1.2 Dry Cleaning
- 1.3 Managing Clean Out-of-Place (COP) Programs
- 1.4 Managing Clean-in-Place (CIP) Programs

2.0 DEVELOPING A SANITATION PROGRAM
- 2.1 Dairies
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- 2.4 Low-Moisture Food Processing
- 2.5 Meat Production Facilities
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3.0 DOCUMENTING A SANITATION PROGRAM
- 3.1 SSOPs (Sanitation Standard Operating Procedures)
- 3.2 Sanitation Matrix
- 3.3 Monitoring the Sanitation Program
- 3.4 Training

4.0 DEVELOPING VERIFICATION AND VALIDATION PROCEDURES
- 4.1 Strategic Sampling
- 4.2 Sampling Methods

5.0 SANITATION FORM TEMPLATES

6.0 SOURCES OF INFORMATION

The sanitation program is an important prerequisite program. Effective prerequisite programs form the foundation of any HACCP system.

An effective sanitation program:

- Prevents pest infestation;
- Reduces the potential for cross-contamination;
- Minimizes the chance for injury; and
- Helps create a more pleasant work environment.

Should office toilets be included in a sanitation program?

It depends. If office area toilets are available to processing personnel, or if processing area toilets are accessible to office personnel, the processor must determine how to control hazards. This might require including toilets in the Sanitation Standard Operating Procedures (SSOP).

1.0 THE SANITATION PROCESS

Cleaning procedures in modern food facilities vary greatly. Such procedures depend on the product, process and equipment used.

Cleaning means to remove physical contaminants such as soil, food and dirt particles.

For example, the type of cleaning needed in a facility producing ready-to-eat meats might differ very much from a flourmill's cleaning requirements. Similarly, the process in a ready-to-eat product facility could differ from a plant whose products are cooked immediately before being eaten.

Sanitation of food-contact surfaces is usually done in the following order:

Sanitizing refers to reducing disease-causing organisms to safe levels.

1. Scrape all loose debris and food particles from surface;
2. Clean surface using some type of cleaning method (wet or dry);
3. Sanitize using an effective and approved sanitizer (wet cleaning only);
4. Rinse (where necessary); and
5. Cover or protect the cleaned equipment.

Once the equipment is washed, sanitized and rinsed (where necessary), keep equipment free from re-contamination.

Let utensils or other equipment air dry after sanitizing, and then cover them. Remember that towel drying can re-contaminate the cleaned and sanitized surface. Also remember that unprotected storage where splashing occurs can also re-contaminate surfaces.

1.1 Wet Cleaning

The main cleaning method used in most food processing facilities is wet cleaning. This involves using a liquid (most often water) and some form of agitation (scrubbing or scraping) to remove soil.

Tools such as brushes, high pressure pumps, air or steam are used in wet cleaning.

Generally, wet cleaning is recommended to get rid of sticky residues containing allergens.

Wet cleaning has several steps:

1. **Flush or rinse excess soil (dirt, debris, or other unwanted material) with water.** The first step is to remove visible soil. Most cleaners aren't designed to work with large amounts of surface contamination.
2. **Use the right cleaner and procedure for each surface.** The chemical supplier can help you choose the cleaning chemicals, procedures and tools needed for each process. Keep in mind that agitation (such as manual scrubbing) might also be needed.
3. **Rinse the cleaner from the equipment with water.**
4. **Sanitize areas that are hard to reach once reassembled.**
5. **Reassemble the equipment.**
6. **Sanitize the assembled equipment parts.**
7. **If necessary, rinse the sanitizer off with clean water.** Some sanitizers, at specific concentrations, can be left on without rinsing.
8. **Dry the equipment.** Equipment is usually air dried.
9. **Cover or protect the equipment from re-contamination.**

Make sure that all cleaning tools:

- are rugged;
- made from non-absorbent material;
- do not retain soil; and
- dry quickly.

Clean and sanitize all tools when finished cleaning. Do not use brooms or brushes in wet cleaning operations because they promote microbial growth.

Occupational Health and Safety and Chemical Hazards

A major issue facing all facilities is the potential for reactions between cleaning products. Some highly reactive chemicals, like bleach, will produce toxic fumes when in contact with other cleaners. This often happens when an acid cleaner is mixed with a base or caustic cleaner.

When using, storing or mixing chemicals, always look at the chemical's *Material Safety Data Sheet*. If you have doubts about how to use chemicals, or need information on possible chemicals reactions, ask the chemical supplier.

> Before using bleach of any concentration, rinse the area. Drain or clean equipment completely of all residual soils, cleaners and chemicals. Never use bleach in a confined space. Always make sure there is adequate ventilation.

1.2 Dry Cleaning

Not all operations can be wet cleaned. In bakeries, flourmills, dry-blending facilities and similar operations, microorganisms are of less concern than moulds, insects, rodents and foreign objects. In these facilities, clean-up crews use brooms, brushes, shovels and vacuum systems to remove waste and spills.

Unlike wet cleaning, dry cleaning does not use a step-by-step procedure. In dry cleaning, the method is to start high and work down.

Use dry cleaning only when there are no sticky, glutinous allergen residues. Remember that allergens can easily become airborne, especially in facilities with a common air supply. Dry cleaning in such facilities could draw allergens into the air supply system and contaminate non-allergenic products. Use a vacuum cleaner to do most of the cleaning.

1.3 Managing Clean Out-of-Place (COP) Programs

Most facilities will have some kind of Clean Out-of-Place (COP) equipment. COP equipment includes items that have to be manually cleaned and sanitized. Examples of COP equipment include removable piping, fittings, gaskets, valves, pumps and product handling utensils.

COP can occur in various ways. Cleaning knives in a sink is one example. Another COP method is chemical agitation cleaning in specialized tanks (e.g. dishwashers).

When developing COP protocols and procedures, pay attention to areas underneath and around pipe gaskets. Also watch for any other small cavities, gaps, niches and harbourage points (places where pests can hide). Residue and bacteria can gather in these areas.

Here are some tips to make COP systems more effective:

- **Try to do all COP tasks in a prescribed order.** Chances of cross-contamination from unsanitized to sanitary surfaces, or overspray, are more likely when sanitation team members perform different activities.
- **Look into using basket, tote or pail washers.** Often facilities will use many small containers in process operations. Washing many containers at once, in a larger washing system, decreases the risk of cross-contamination. This can also reduce the amount of staff needed for the job.
- **Consider having COP operations done on production floors.** Members of the sanitation crew can work directly on the floor or temporary tables. Before putting these in place, it's important to look at the impact such procedures can have on process flow. Also look at how they affect contamination controls.

- **Use racks or COP tanks to hold parts and utensils while they are cleaned.** Place the removed parts either on a rack for cleaning or in a COP circulation tank. Then make sure they are cleaned using hot water, a chemical solution and some form of agitation.
- **Make sure tools and equipment aren't sources of contamination.** Be sure to choose rugged, easy-drying cleaning brushes made from non-absorbent materials.
- **Colour coding or labeling brushes and cleaning utensils as food-contact and allergen surfaces can reduce contamination.** Separating utensils used in different areas of the facility (e.g. barn, kill floor and processing areas) helps reduce cross-contamination.

1.4 Managing Clean-in-Place (CIP) Programs

Clean-in-place (CIP) sanitizing cleans the inside surfaces of pipes and tanks of liquid. It also cleans semi-liquid processing equipment.

CIP usually involves forcing detergent through equipment with a spray or spray balls. These remove soil through agitation. Another CIP method uses water spray to push brushes through pipes to clean and remove debris.

CIP systems can use computerized controls. These can monitor and control the flow, mixing, temperature, time and detergent. CIP might also use manual methods to control pumps, spray systems and the addition of chemicals.

Remember that CIP systems are limited. Before designing a CIP system, assess the production process thoroughly. Determine what will work best for each operation.

Some guidelines for developing a CIP system include:

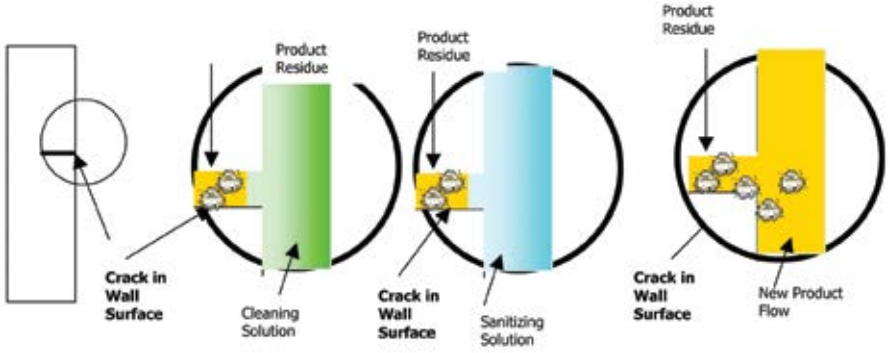
- Lines carrying cleaning chemical should have should have permanent, easy-to-take-apart fittings;
- Pipelines should be rigid, supported and self-draining;
- CIP pipelines and tanks should be designed with access points or viewing windows. This helps during inspection;

- Use an air break to prevent cross-connections between cleaning solutions and product water. Another choice is to use an approved back-flow prevention device;
- Follow the original manufacturer's specifications for flow rate, time and temperature. Follow these guidelines for cleaning and sanitizing solution strengths as well; and
- Build CIP pipes and tanks from 'food grade' material.

Designing tanks and pipe systems are both important to stop the build-up of soil. It also makes cleaning and sanitizing easier.

For more information about sanitary design, see Chapter 4: Developing a Premises Program.

Figure 1: How Joints, Cracks, or Crevices in Tanks and Pipes Reduce or Limit Operation of CIP Systems



When designing the sanitation program for CIP equipment, include the following information:

- Equipment and utensils to be cleaned;
- Accurate circuit diagrams of the CIP system;
- Installation instructions;
- Duties of the person responsible; and
- Methods for checking the concentration and effectiveness of chemicals.

An effective cleaning program should clean equipment, not damage it. Many facilities use traditional 'green scrubbing pads' for cleaning equipment. Remember, green pads are VERY abrasive and can damage equipment. Instead, use 'white pads.' These may cost less and have a less abrasive surface.

2.0 DEVELOPING A SANITATION PROGRAM

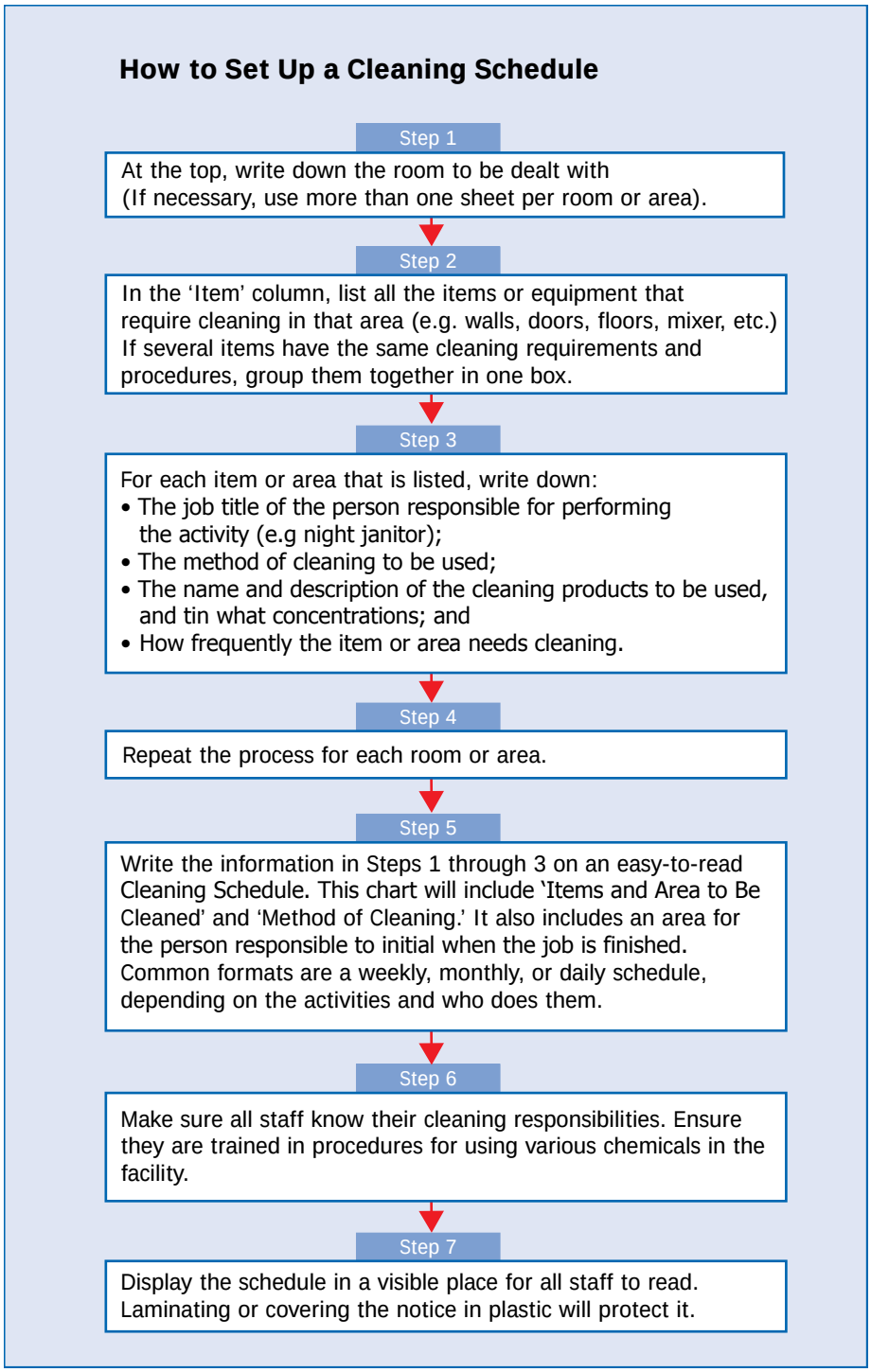
Remember these important tips when developing the sanitation program:

- Make thorough cleaning and rinsing part of the daily cleaning schedule;
- Make sanitizing around floor drains part of the daily cleaning schedule;
- Use sanitizer rings in drains and cooling units;
- Follow the manufacturer's instructions when using cleaning chemicals; and
- Talk to the chemical supplier to learn about the sanitizer and how to use it in the facility.

For examples of Cleaning Schedules, see Forms E.1.1 and E.1.2.

Figure 2 outlines the development of a sanitation program and would be used by production and maintenance staff. Follow this step-by-step guide along with a training and communication program.

Figure 2: How to Set Up a Cleaning Schedule



When developing any form of sanitation program, keep in mind:

- Disease causing microorganisms can be found on almost any surface in a facility including:
    - Floors
    - Drains
    - Overhead beams and pipes
    - Equipment surfaces
- Inspect 'dead spots' on and around equipment. If material can get in, contaminants can get out;
- Clean and inspect more frequently in storage areas with higher humidity and heat. Heat and humidity allow microbes and pests to flourish;
- Check for bits of food left inside empty bins and containers that can attract pests;
- Inspect for condensation, which is a potential source of product contamination;
- Schedule cleaning with routine maintenance activities. Equipment disassembled for maintenance can be cleaned at the same time;
- Display cleaning and sanitation instructions in areas where production or maintenance activities happen;
- Encourage staff to 'Clean As You Go.' This reduces contamination, shortens clean-up time and decreases pest activities;
- DO NOT use untreated, re-circulated water. Make sure that all water used for sanitation is drinkable. Make sure that it meets the requirements of Health Canada's "Guidelines for Drinking Water Quality;"
- Ensure all waste material disposal routes are short and direct; and
- Create a verification system to check on these points. The results may not always distinguish between microorganisms and organics (e.g. in ATP testing). However, results should indicate when surfaces are not clean.

2.1 Dairies

Taste is a key quality indicator for milk. One cause of off-flavour in milk is microbial contamination due to poor sanitation, cooling, and/or rotation. Contamination is effectively controlled by using SOPs (Standard Operating Procedures) and SSOPs (Standard Sanitation Operating Procedures).

When developing a sanitation program for a dairy facility, consider the following:

- Fresh soil (dirt, debris, or other unwanted material) on a cold surface is easier to remove than dried or baked-on contaminants;
- White or greyish materials on the surface of equipment may be milk or waterstone (calcium or lime). This may require different cleaning materials; and
- Reduce the use of hot water to limit baking soil onto equipment.

Many dairy facilities use Clean-in-place (CIP) systems for vats and piping systems. When developing the program with the engineering staff:

- Keep the temperature of the cleaning solution low enough to ensure that the CIP does not bake on soils. This increases cleaning time and the need for cleaning compound;
- Set rinse water temperature to avoid waterstone (calcium or lime) deposits on the equipment; and
- Pay special attention to the type and style of spray devices used. Make sure they meet the requirements of the cleaning program.

2.2 Fruit and Vegetable Processors

Fruits and vegetables are often eaten without cooking or further preparation and because of this they require extra caution.

Many microorganisms can survive and grow on fruits and vegetables. All produce processing facilities (from fresh-cut to packaging) should use the wet cleaning method. This should be the main method of cleaning equipment and facilities.

When developing a sanitation program in a produce facility:

- Separate any unacceptable or returned goods from production, shipping or general storage areas. These goods can be infested and can then lead to contamination of good product;
- Remove as much dirt and mud as practical from fresh produce before it reaches packing facilities or areas;
- Make sure all packaging is undamaged and free of contamination; and
- Protect unused, cleaned, and new packing containers from contamination during storage.

2.3 Beverage Processors

Most bacteria are not a concern for the beverage industry. This is because raw materials, processing techniques and the final product usually don't support bacteria growth. However, yeast, mould and certain types of bacteria that can cause disease, may still be a problem in beverage processing plants.

In a dairy or beverage facility, CIP is the most common cleaning process. When deciding on methods for removing soiling material from conveyor systems, remember that:

- Most soils will be spilled product, grease and filings from containers; and
- Foam cleaning with high pressure rinses work best.

Research has shown that biofilms (slimy layers that develop when bacteria attach to equipment or surfaces) can grow inside cooling towers. They can also grow inside and outside warmers and pasteurizers and inside coolers. The use of cleaners containing quaternary ammonium will help stop the formation of these films.

2.4 Low-Moisture Food Processing

The most common low-moisture food processing facilities include bakeries, nut, seed, pasta, candy and snack food facilities. These products tend to contain little water and therefore don't generally support microbial growth. The biggest concern these operations is the absorption of unnecessary moisture that may lead to mould growth.

Dry cleaning is best in a low moisture food processing environment. Use brushes, brooms and dustpans to remove heavy debris.

When developing the sanitation program for a low moisture facility, ensure that some cleaning is done during operation to help keep the facility tidy.

The two most common methods of dry cleaning are vacuum cleaning and compressed air. Vacuum cleaning is the best equipment cleaning method in many areas, because:

- It's a good way to remove light or moderate debris;
- It reduces dust, which reduces cross-contamination with airborne particles; and
- Vacuums come in many sizes that suit the unique need of a facility.

Be aware that poorly maintained vacuum systems can transport dust over large areas, which will increase the likelihood of contamination from air particles.

Compressed air is also a common method for cleaning equipment in low-moisture environments. It's good for removing debris from equipment and also an easy way to clean hard-to-reach areas.

Follow these tips when developing a compressed air sanitation program:

- Filter compressed air;
- Use low volume and pressure when working with compressed air; and
- Control dust in storage and handling areas.

2.5 Meat Production Facilities

Meat and meat products are more likely to be affected by microbial growth. This is because of their neutral pH and high protein content.

The sanitation program in facilities that handle meat products must pay special attention to the control of bacterial growth. The program must also prevent cross-contamination of the finished product.

It is important to place inedible product in designated tubs or in gut tanks and to physically separate them from edible product.

Inedible waste should be stored in a separate room. Ensure that inedible product is never placed in bins or containers that will at any time hold edible product.

It's important to make sure that the sanitation schedule includes non-processing rooms. It must also include facility areas that aren't cleaned every day. Examples of these areas include:

- Smokehouses
- Coolers
- Cooling units
- Screens
- Water storage facilities
- Spice rooms
- Storage areas
- Delivery vehicles

These areas may not always be checked on pre-ops. Therefore, cleaning staff need to understand the schedule. They must know when to ask a pre-op verifier to inspect certain areas for cleanliness.

2.6 Ready-to-Eat Production Facilities

Ready-to-eat products are not cooked before being eaten, so the sanitation program for these producers must:

- Control physical contamination;
- Control chemical contamination;
- Address bacterial growth, and
- Prevent cross-contamination of the finished product.

Control of Listeria Monocytogenes

Listeria monocytogenes is an example of a pathogen that grows easily under normal storage conditions and can continue to grow when the product is refrigerated.

Listeria monocytogenes can survive with or without oxygen and is found in many food processing plants. It can grow in cool, damp areas (such as those found in any processing area), in coolers or on the slaughter floor.

Sanitation is the key to controlling and eliminating *Listeria monocytogenes*. Pay special attention to:

- Equipment
- Floors
- Walls
- Light fixtures
- Cooling units
- Ceilings and overhead structures
- Floor drains

3.0 DOCUMENTING A SANITATION PROGRAM

Sanitation program documents are important for three reasons:

- They demonstrate due diligence;
- They allow a third party audit the facility on behalf of customers; and
- Documentation of the sanitation program is a regulatory requirement.

The current trade environment demands that manufacturers prove due diligence in all activities. Documentation encourages employees to perform all key activities.

For any food safety program to be auditable, the manufacturer must document what they do. It's important that they prove their activities are following the stated methods. This is shown through documentation.

The *sanitation program* is key to food safety production. Because of this, auditors will likely check the sanitation program in their assessments.

The law requires many food production facilities to have documented prerequisite programs. This is required by:

- The Food Safety Enhancement Program (FSEP), through the Canadian Food Inspection Agency (CFIA);
- The Meat Facility Standards (MFS); and
- Other regulatory standards.

Remember that documentation improves the probability of long term success.

To an auditor, if it's not in writing, it wasn't done.

Everything in the program should be documented. This includes:

- Training
- Dilution rates
- Pre-op inspection findings

The facility should be able to show that the sanitation program supports all other prerequisite programs.

Three formats commonly used to document sanitation program requirements are:

- Sanitation Standard Operating Procedures (SSOPs);
- Matrix or schedules; and
- A combination of matrix and SSOPs.

3.1 SSOPs (Sanitation Standard Operating Procedures)

Sanitation Standard Operating Procedures (SSOPs) are usually written in an essay or report form.

Write out each cleaning procedure so that a new or untrained employee will be able to follow the instructions. They must know exactly what to do. These employees must know what, when, and how to do the job.

A typical SSOP will include a description of the activity to be done. It will also include:

- Information about the chemical(s) to be used – including concentration and procedures for using them, and any personal protective equipment (PPE) needed;
- Detailed step-by-step process instructions – including a list of sanitation equipment to be used, and instructions on taking equipment apart.

Be sure to document:

- Sanitation process to be used (COP or CIP);
- Cleaning and sanitizing instructions;
- Temperature of water;
- Water pressure needed;
- Reassembly instructions;
- Frequency that this activity must be performed;
- Document name of where completion of the activity is recorded;
- Job title of the person(s) responsible for the activity;

- Job title of the supervisor or person who will monitor and supervise the SSOP;
- Job titles of personnel to sign off and date the document after the SSOP is accepted or altered; and
- Pre-op inspection or verification instructions.*

**These instructions should include the title and name of the person who will perform the pre-op inspection or verification of the SSOP. They should also include documents where results are to be recorded. They must state deviation procedures to follow if situations change.*

When a typical SSOP is completed, a person should be able to fill in each space of the following Sanitation Matrix.

	Sanitation Activities	Verification Procedures	Deviation Procedures
Who			
What / How			
Frequency / When			
Records			

For another example of how to document sanitation procedures, see Form E.1.3: Cleaning Procedure Sheet.

3.2 Sanitation Matrix

Like the sanitation program, the sanitation matrix addresses a processing facility's unique needs.

The required information should be completely contained within the matrix. It should also be easy to understand.

There are various ways to develop a sanitation matrix. Some recommended columns to include are:

- Room, area, equipment;
- List of tools and equipment needed;
- Frequency (daily, monthly, yearly or as needed);
- The person responsible (and designated alternate);

- Chemicals used;
- Appropriate chemical instructions (including mixing instructions, concentration, temperature and contact times);
- Cleaning method to be used (manual, automatic, foam, etc.);
- Specific sanitation procedures;
- Disassembly instructions where required; and
- Sign-off record, or associated record.

It's important to make sure that the matrix is completed by relating it to

- Training
- Verification
- Deviation SSOPs

3.3 Monitoring the Sanitation Program

As with any prerequisite program, develop a method to monitor how the sanitation program is working.

These procedures can include:

- Checking the concentrations of the cleaners and sanitizers while in use;
- Checking the temperature of the water during cleaning at a regular frequency; and
- Observing sanitation employees during cleaning to make sure that SSOPs are followed correctly.

See Form E.1.4: Daily Sanitation Report.

3.4 Training

It's important that staff understand chemical usage and sanitation policies. This reduces the possibility of accidental contamination of food products.

Staff should understand written sanitation procedures. Pest control and sanitation in a HACCP facility requires extensive documentation. Train employees to maintain records they are responsible for.

Sanitation staff need to know the following:

- Why sanitation is important to the facility's food safety system;
- Different kinds of dirt and how to remove each type;
- How to use the tools necessary to clean the facility;
- How each cleaning chemical works;
- Skills needed to use each chemical;
- Skills to make sure that all procedures are complete; and
- Documentation.

Remember, the cost of training employees is small compared to the costs that arise from poor sanitation. Such costs include:

- Product line shutdowns;
- Reduced shelf life;
- Product recalls;
- Damage to the brand; and
- Consumer complaints or lawsuits.

4.0 DEVELOPING VERIFICATION AND VALIDATION PROCEDURES

Environmental swabbing (swabbing equipment and surfaces in food production areas) or testing is the most common way to check a sanitation program.

These procedures are not developed to determine if the product should be released. Instead, they are developed to monitor whether current system controls are working.

Generally, these tests are done on both food-contact and non-food contact surfaces. They are part of daily pre-operational activities. These procedures need to be documented within the sanitation program.

4.1 Strategic Sampling

Pre-operational swabbing will help identify trouble spots. These swabs provide baseline information that a facility uses to decide whether its control of microbes is getting better or worse.

Many facilities develop their verification procedures around trouble spots. Locations to sample in the facility will depend on:

- The layout of the facility;
- The kind of product being manufactured; and
- The type of processing line the product is being run on.

On production line equipment take samples from the following two areas:

- Food-contact surfaces – where product comes directly into contact with the surface; and
- Non-food contact surfaces – where contaminants could move from and come into contact with food-contact areas.

Don't just look at equipment and surfaces. All environmental sampling systems should include some form of air sampling. Microorganisms exist in the air as passengers on dust particles. They're also found in condensation droplets and exist as individual organisms.

In-plant sampling sites should include hot spots (check air as well as equipment/surfaces). They should also include unusual locations such as posters or signs. The sampling should change to new locations from time-to-time.

4.2 Sampling Methods

Various methods are available for environmental testing. These include:

- Rapid microbial testing techniques;
- Standard microbiological testing; and
- Allergen residue testing.

ATP Testing Methods

ATP (Adenosine Triphospate) testing is usually done with specific ATP equipment.

In general, ATP takes little time or work to prepare. The testing units require appropriate training to use properly.

ATP tests provide instant feedback on how the cleaning program is working. They are considered to be 'real-time' because the results are available in a minute or two and not days later as with microbial testing.

ATP testing does not require a laboratory at the facility or sending samples to a third party lab.

ATP swabs are often used to assess microbes and allergens. This process is sometimes unable to provide the exact amount or level of organic material or allergens present on a surface. However, it helps fine tune and correct the program.

In addition to ATP testing, it's important to occasionally do a full microbiological analyses or allergen assessment of a facility environments.

Microbiological Testing Methods

There are a variety of rapid microbial testing methods available. These may not be as fast as ATP testing, but they can assess the cleanliness of the facility.

Results of microbial testing can serve as useful guidelines. However, interpreting results based on absolute numbers can be misleading. Sometimes this is even counterproductive. Certain conditions (such as fatty films) can make these bacterial counts inaccurate.

See Form E.1.5: Microbial Swab Record.

Allergen Testing Methods

There are few approved methods to test for the presence of allergen proteins.

Manufacturers may use allergen specific swabbing kits such as ELISA (Enzyme Linked Immunosorbent Assay), which detect allergenic proteins.

A concern with allergen protein test kits is that they don't recognize denatured proteins. These proteins may cause a reaction in sensitive individuals.

DNA Testing Method

Polymerase Chain Reaction (PCR) is one of the newer methods of allergen and microbial testing. PCR tests for the DNA associated with the material of interest.

The main disadvantage of this method is that it doesn't test for proteins. Instead it tests for DNA. This means that a positive allergen PCR test may result in a negative ELISA or ATP result.

Further, a positive microbiological test may end up scanning as negative. This is because of the extreme sensitivity of this testing. The PCR method can find dead and damaged cells as well as living microbes. As a result, most manufacturers have decided not to use PCR testing at this time.

5.0 SANITATION FORM TEMPLATES

E1.1 Cleaning Schedule (Option 1)

E1.2 Cleaning Schedule (Option 2)

E1.3 Cleaning Procedure Sheet

E1.4 Daily Sanitation Report

E1.5 Microbial Swab Record

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Chapter 9
DEVELOPING A PEST MANAGEMENT PROGRAM

1.0 INTEGRATED PEST MANAGEMENT PROGRAM

2.0 ELEMENTS OF A PEST MANAGEMENT PLAN

3.0 CONTROL METHODS

- 3.1 Insect Control
- 3.2 Rodent Control
- 3.3 Bird Control

4.0 DOCUMENTING A PEST MANAGEMENT PROGRAM

5.0 PEST CONTROL FORM TEMPLATES

6.0 SOURCES OF INFORMATION

The presence of a pest in a food product is a physical contaminant.

Pests are insects, rodents, birds and other animals that can contaminate food, spread disease and seriously threaten public health. Pests are known to cause biological, physical and chemical contamination.

Some pests can also be sources (e.g. feathers, hairs) or carriers (e.g. rocks, glass) of physical hazards and disease. Pests can contaminate ingredients, packaging and even finished products with disease.

Also, pesticides or herbicides used to control pests bring chemical hazards into the processing environment. If these chemicals aren't controlled they contaminate food. This happens because of high residue levels (amounts of chemicals) left on the product. It also happens because of spills or other accidental ways chemicals touch ingredients, packaging materials or finished products.

Pest control is one of the easiest ways to increase food safety. Both prevention and treatment steps are needed.

Here are just a few examples of pest activities:

- Orchard bees looking for a nesting place;
- Rabbits eating flowers and shrubs beside a processing facility;
- Pigeons nesting on or near loading docks;
- Empty wasp nests;
- Bug infested pallets or lumber on premises;
- Unusual bugs in production areas; and
- Mice, birds and other animals on or near premises.

1.0 INTEGRATED PEST MANAGEMENT PROGRAM

Integrated Pest Management (IPM) is an excellent way to control pests. Like HACCP, IPM is a decision making process about managing pests. It helps to catch problems that could happen and prevents them from happening in future.

The integrated (or overall, overlapping) process of IPM uses several ways to create lasting solutions. This includes a number of activities such as staff education, waste management, building repair, and maintenance. It also includes biological and mechanical controls. By using all of these, pests can be managed without depending on chemicals that might create chemical hazards. Pesticides should only be used as a last resort.

Steps for Setting Up an IPM

Setting up an integrated pest management program includes five steps.

Step 1: Assess the current situation

Assessing the current situation means to check for what's currently happening at the facility. Look for pest problems that are happening or that could happen. Inspect, monitor and observe for the following:

- Inspect to discover and name the kinds of pests present (check with a pest control company);
- Monitor to understand and study the pest problem and where it is in the facility;
- Double check the results of the inspection and monitoring; and
- List the possible sources of pests (e.g. incoming ingredients such as flour beetles).

To put together a complete pest control plan, research pest problems in other processing facilities that make the same kinds of products. Also research food processors in the surrounding area near the facility. Ask for help from other facility owners or a local pest management company.

Step 2: Develop the plan

Research what ways there are to control pests. Some control methods can include barriers, traps, and removing food debris (bits of food). It can also include changing the environmental conditions (including temperature and humidity).

Think about all parts of the prerequisite programs and how they might affect the pest management program. Identify the key areas that need to be developed or built up to support the pest management plan. Make sure to look at:

- Sanitation (cleaning to remove things that attract pests);
- Transportation and storage (stock rotation);
- Production scheduling ('Just-In-Time' production to minimize stock build-up); and
- Purchasing controls (don't purchase as many ingredients ahead of time to make sure that food products aren't stored too long).

Step 3: Implement the plan

To set up a pest management plan put the following in place:

- Employee education – Each employee should know what pests are and be able to point them out. Tell all employees about the facility's pest management policies. Be sure to include the importance of sanitation and maintenance.
- Communication – Prepare standard written procedures for all parts of the pest management program. Include a way to check these procedures.
- Monitoring activities – Be able to show that pest management activities are working well for the target pest populations. Be able to show that these activities are successful at controlling pests.
- Records – Produce user friendly, written procedures. And as with all prerequisite programs, keep records of management's commitment to the food safety program.

Step 4: Evaluate the plan

Check regularly to see that the pest management plan is working. Review pest control documents. Check or verify whether pests are still being seen around the facility. Check to see whether control methods and corrective actions are working. Make sure these methods are meeting the company's needs.

Step 5: Make adjustments

Adjust the plan for ongoing improvements. Check regularly for new ways to control pests. Also check regularly for ways to reduce the use of herbicides and pesticides. Make sure adjustments also take into consideration that pest behaviours change with the seasons.

2.0 ELEMENTS OF A PEST MANAGEMENT PLAN

Prevention is the key to a workable program. Stopping pests from coming into the facility and keeping the facility clean helps prevent infestation.

There are several key things all pest management programs must have:

1. Building and Equipment Design

The first control in a pest management program is the design of the facility and the way equipment is installed. Make sure that the facility layout discourages pests. Make sure it allows for quick and easy controls.

2. Exclusion Practices

Keeping pests from entering the facility is the next level of control. Do this by:

- Preventing food or ingredients with infestations from getting into the facility;
- Using stock rotation to make sure ingredients and finished products aren't stored too long;
- Developing supplier selection and purchasing requirements; and
- Separating the receiving area from the food production areas.

Maintenance of doors and windows is important to keep pests from coming in. Control pest entry into the processing areas by checking incoming materials in the receiving area.

3. Good Sanitation

Like all living things, pests need food, water and warmth. This means that cleaning and sanitation are among the most important steps to stop pest infestation. Clutter, old equipment and poor storage habits all create safe places for pests to settle in.

Tips to Prevent Pest Problems

Exterior building and property

- Lessen or remove places where pests might live by storing materials off the ground;
- Make sure that garbage handling systems are sealed and don't attract pests;
- Eliminate vegetation and objects that can provide food or shelter for insects and rodents; and
- Inspect the building's exterior regularly for signs of rodents, insects and birds.

Interior facility

- Inspect the building's interior regularly for rodents, insects and birds;
- Seal and keep clean all cracks in floors, walls and ceilings;
- Continually maintain and clean suspended ceilings (where pests will nest);
- Keep floor drains clean and routinely inspect cover plates and catch basins;
- Build doors and windows to repel pests; and
- Develop and enforce door closing and window use policies.

Storage areas

- Store all food products away from walls and off the floor to prevent pest access and to allow for inspection and sanitation;
- Use first-in, first-out procedures; and
- Store all rejected, damaged or infested product that might attract pests, or cause cross-contamination, away from raw materials and finished goods.

4. Building Maintenance

Regular and ongoing preventative maintenance of the building will make sure pests don't find new ways to enter the facility. Reduce dust as much as possible. Prevent and immediately repair leaks in pipes. Fix holes and cracks in floors, walls and ceilings right away to keep pests away and to reduce dust.

5. Inspection and Monitoring

Inspect for pests in all food production facilities. Regular inspections show how well pest control methods are working.

Monitoring usually involves trapping pests. Methods for trapping pests can include pheromone traps, glue boards, mechanical traps and light traps. Follow the manufacturer's instructions. Place traps in a grid pattern throughout the facility. Create and maintain a location map and catch records. These will help to decide how, where and when to set traps and monitor them.

Check all traps regularly. Sudden increases in pests mean there's an infestation. If necessary, ask a pest control company to help identify issues and solutions.

See Form E.2.2: Pest Trap Monitoring Record.

6. Pest Identification

Identifying or knowing what kinds of pests there are, is key when choosing the best way to control them. Talk to a pest control company or another specialist before starting control actions.

3.0 CONTROL METHODS

Insecticides, rodenticides and other control methods that use chemicals to kill pests are not recommended for use in the food industry. These chemicals must never come in contact with or contaminate raw materials, packaging or finished products.

It's very important to understand the difference between the control methods used in non-food areas and those used in food areas.

Non-food areas include:

- Locker rooms
- Machine rooms
- Employee bathrooms
- Maintenance rooms
- Garbage storage rooms
- Boiler rooms

Food areas include any location where food is:

- Stored
- Processed
- Handled

Most food manufacturers treat their entire facility and its premises as food areas. This is a good practice. It lowers the chances of accidental cross-contamination by pest control chemicals.

3.1 Insect Control

In general, there are two kinds of insects that can cause trouble for a food manufacturing facility. The first kind is crawling insects such as ants, cockroaches, warehouse beetles and various flour beetles. The other group is flying insects such as wasps, houseflies and meal moths.

Usually processors need programs to control both types.

Crawling Insects

Most crawling insects are pests that feed on waste products (e.g. feces, animal waste and decomposing food products). They can be found in sewers, warehouses and food storage areas.

Cockroaches

Cockroaches can be found in any area where there is food. Although these insects are generally associated with feces and animal wastes, having cockroaches may not be a sign of unsanitary conditions. Cockroaches can enter a building in a several ways including:

- Used equipment or furniture;
- Infested shipments or carriers; and
- Empty shipping cartons and other food containers.

Cockroaches are more active at night and can easily travel through a facility without being noticed.

The best way of controlling cockroaches is through exclusion (keep them out) and prevention (keep them from getting in again). To do this:

- Clean and sanitize used equipment or furniture before allowing them into the facility; and
- Inspect carriers and shipments carefully for signs of infestation.

Make sure that the facility is maintained by filling in all the cracks and crevices, screening vents, open pipes and drains.

If these methods don't stop an infestation, chemical methods may be needed.

Ants

Ants are one of the most annoying insects for the food industry. They can infest areas where pests seem impossible. Ants sometimes are found nesting in spaces in walls or in moist areas such as water pipes.

Important tips for controlling ants in food facilities include:

- Immediately sponge up ants with soapy water when they're found;
- Plug all possible ant entryways with petroleum jelly or caulking; and
- Use baits to control the ant colony (the wrong bait can make things worse).

Often baiting is the best way to control these determined insects, but don't hesitate to call a professional as chemicals may be necessary.

Stored Product Pests

Moths (meal worms) and beetles feed on and contaminate stored grains. They often come into a facility through an infested food package. These insects can pass through openings that the human eye can't see. As with other crawling insects, the best control is prevention and exclusion.

To exclude or prevent these pests from getting into a facility:

- Rotate raw materials and stock using the first-in, first-out principle, since old stock is most likely to become infested;
- Check all incoming raw materials for packaging infestation. Don't accept any products in broken or damaged packages. Obvious signs of insects are tiny holes in the package and webbing;
- Don't put open packages of foods on shelves. Store all opened packages in sealed containers with tight fitting lids;
- Never mix old and new lots of food products; and
- Remove contaminated product immediately.

Addressing food-infesting insects takes ongoing effort. Some insects can live many weeks without food or water; others can chew through sealed packages. By the time these insects are noticed, they will have spread to other areas or packages. If moths, meal worms, beetles or other pests are found in the facility, identify and get rid of their food source.

Flying Insects

In the food industry, disease spreading and damaging flying insects including houseflies, wasps and certain moths are especially worrisome.

Flies

Flies tend to be the most trouble in warm weather but they can stay around in smaller numbers through the year. Houseflies can contaminate food and must be eliminated. Exclusion and trapping are the most common methods of control. If flies appear to be coming from nearby facilities, ask the neighbours to cooperate by installing controls.

Houseflies breed in dung, fermenting vegetable waste and garbage. Check the premises for what could be attracting them. Look for their breeding environments.

Other Flying Insects

To eliminate other flying insects:

- Avoid placing or pointing lighting at doors or right above entryways;
- Use sodium vapour bulbs (yellow tinged lights) for all outside lighting, including in parking lots (They attract fewer insects than incandescent lighting);
- Don't attach outside lighting directly to the building as it will attract insects into the building;
- Shelter bulbs with covers, canopies or shades;
- Maintain doors and windows in good condition so they close and seal tightly;
- Don't store product near entry doors and windows; and
- Make sure garbage is removed and keep containers clean and covered when not in use.

The key to controlling flying insects is a good monitoring program. Insect light traps (ILTs) are often used to keep track of the number of flying insects in food production facilities.

When using Insect Light Traps (ILTs), keep these points in mind:

- Never place these traps where they can attract pests into the facility (e.g. facing the entrances of loading docks);
- When using light traps don't place other lights nearby;
- In some areas, insect light traps don't work well because of high moisture levels (do not risk electrocution);
- When trying to catch flying insects, place the insect light traps at lower heights. This catches the insects closer to their food source; and
- When monitoring the insects, place the insect lights closer to the ceiling. This will keep these traps from attracting insects close to the processing areas.

Draw a location map for ILTs to help decide how to control flying insects and at what levels.

3.2 Rodent Control

A good rodent management program is needed in any facility that produces food. This is especially true in buildings near large fields, wooded areas or other places that rodents like to live. Rodents include rats, mice, squirrels, gophers and voles.

In order for a rodent control program to work for a long time, pay attention to inspection and sanitation. Exclusion (keeping rodents out) and reduction (reducing rodent numbers) are also very important.

Inspection

As with flying insects, the keys to rodent control are monitoring and inspection. Look for the following when inspecting the facility:

- Droppings
- Tracks
- Gnaw marks
- Burrowing
- Runways
- Grease marks
- Urine stains
- Live or dead rodents
- Rodent sounds and odours

Knowing where to place the bait and traps will depend on how good the inspection and monitoring is.

Sanitation

Like all living things, rodents need food, water and a place to live. Removing or reducing these requirements for life eliminates or reduces pests.

Exclusion

The best way to control rodents is by making it impossible for them to enter the production facility. A building can be rodent-proofed by getting rid of all openings larger than a dime. Open doors and windows can allow rodents to get in. Plumbing and other utility lines can also provide entry. Monitor and control these areas.

Population Reduction

Traps are the most common way to quickly reduce rodent populations. As with insect traps, the use of rodent traps will need monitoring. Since rodents tend to follow walls of buildings, rodent traps should be placed in these locations. Store product, raw ingredients and other materials far enough away from walls, and off the floor, to allow for inspection and sanitation.

3.3 Bird Control

Birds in and around a processing plant, or even near ventilation, can cause serious health problems. Common problems relating to birds include:

- Droppings in-house or on stored materials (bird droppings are known to contain E. coli and other micro-organisms);
- Airborne contamination of food;
- Bringing food or garbage into a facility, attracting other pests;
- Damage to wiring and electrical systems;
- Product destroyed from birds feeding on it; and
- Setting off motion alarm systems.

In most cases, making it hard for birds to find places to stay is a good way to control them. Keep them away from the premises completely. Be sure to use non-chemical methods when handling bird infestation. Keep in mind that some types of birds are protected by law.

The most common control method for birds is nest removal. This means to physically remove the nest and its eggs. It also means to put an end to the return of the young and their parents to the site. They will try to return because of their 'habitual imprinting' instinct. Imprinting means that parents will return to a successful breeding site. The young will also return to their birthplace. Break this cycle permanently.

Often, after a first nest removal, the birds will re-nest. After a second nest removal, the birds will most likely be:

- Physically unable to re-nest (both nest building and laying eggs demands a great deal of their energy);
- Discouraged from breeding in the same place; and
- Highly motivated to move to another location.

4.0 DOCUMENTING A PEST MANAGEMENT PROGRAM

As with all prerequisite programs, set up a thorough documentation system for the pest management program.

Detailed records are necessary when using monitoring and inspecting devices. Whether customizing a monitoring program, or using one from a pest management company, record the following:

- Labels and Material Safety Data Sheets (MSDS) for all products used in the facility;
- In-house policies or service rules;
- Standard Operating Procedures for all activities that deal with pest management;
- Location map of all pest control devices;
- Pest sighting logs;
- Name or job title of person responsible for each activity;
- Detailed description of activities, procedures and corrective actions for pest control; and
- Company name, individual representative name, and services provided by any outside company that may be used.

Also keep treatment records, including:

- Copy of pesticide applicator's license;
- Name of the product and a copy of the label;
- Location where applied;
- Concentration levels; and
- Method and frequency of application.

Like the HACCP plans, pest management programs must deal with changes in production processes, building modifications and variations in pest activity.

See Form E.2.1: Pest Control Service Record, Form E.2.3: Pesticide Record, and Form E.2.4: Pesticide Usage Log.

5.0 PEST CONTROL FORM TEMPLATES

E2.1 Pest Control Service Record

E2.2 Pest Trap Monitoring Record

E2.3 Pesticide Record

E2.4 Pesticide Usage Log

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Chapter 10
DEVELOPMENT OF A RECALL PLAN

1.0 WHAT IS A RECALL?
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1.0 WHAT IS A RECALL?

Recall is the process of quick and efficient removal of questionable food from the supply chain and reaching consumers.

All food recalls have the following aims:

1. Stopping the delivery and sale of the product(s) in question;
2. Informing the appropriate regulatory agencies, such as the Canadian Food Inspection Agency (CFIA); and
3. Timely removal of the product from the marketplace.

The manufacturer has final responsibility for removing products of concern from the marketplace. Manufacturers must remove such products before they cause damage or injury. With a good system for traceability or tracking and a carefully prepared action plan, a recall is likely to be successful. It may also cost the facility less money.

1.1 When is a Recall Necessary?

Any food safety emergency can trigger a recall. Examples include:

- Willful or intentional product contamination;
- Human error (including failure of the prerequisite programs);
- Mislabeling;
- Industrial accidents;
- Pesticide contamination;
- Foodborne illness outbreak;
- Packaging defects; and
- Real or threatened product tampering.

There are a number of sources to use to check these concerns. Sources may vary as to their usefulness at fully understanding the problem.

Sources include:

- Consumer Complaints – Consumer complaints can be sketchy or unclear. They may not provide much detail. Always ask those making the complaint for specific information including the product code, dates, where they bought the product, etc.
- Distributor or Retailer Complaint – Often these complaints are just as unclear as consumer complaints. Distributors or retailers usually tell the facility about a concern when they see repeated complaints about the company or products.
- Suppliers – Suppliers may find something wrong in their own products. A supplier's internal inspections may lead them to recall their own products throughout the supply chain.
- Internal Inspections – Deviations that breach critical control points, or prerequisite programs, can reveal products that don't meet standards. End-product testing may also alert facilities to problems.
- Government Inspectors or Agencies – The Canadian Food Inspection Agency (CFIA) carries out numerous food safety projects and inspections every year. Problems may be found through random testing, inspections or investigation of consumer complaints.
- Health Authority Illness Investigations – Alberta Health documents all outbreaks of foodborne illness. If they are able to track outbreaks to a specific product or lot number, this information can be used to trigger a recall.
- Tampering Threats – No matter what the source of a tampering threat, always track this information completely so the facility can confirm possible affected products.

No matter where the information comes from, take any complaint that involves a health hazard seriously. Check it immediately.

1.2 What is the Facility's Role and Responsibility?

Product recalls are a shared responsibility. Industry, government, and consumers all have roles to play to ensure the rapid, efficient recall of unacceptable product.

Sometimes the media (TV, radio, newsprint) communicates to consumers the need to recall a product.

However, it is the responsibility of the facility to ensure product safety.

If the potential of a food safety hazard exists, it is the facility's duty to work with the CFIA. This is true even if the processor is not a federally registered facility.

Tell the CFIA immediately if the facility believes their products may put consumers at risk. This includes products the facility has made, processed or sold. Telling the CFIA immediately allows for a quick, efficient and thorough recall.

Facilities are generally responsible for:

- Suggesting the scope or size of the recall;
- Preparing and giving out all communications; and
- Deciding what to do with the recalled product.

Be prepared to supply the necessary regulatory agencies (CFIA, Alberta Health Services, or Alberta Agriculture and Rural Development) with the following information:

- A detailed description of the problem;
- The name, brand, size and lot codes affected;
- Details of complaints received and any reported illness;
- Where the product has been distributed or shipped (locally, provincially, nationally, or internationally);
- When the product was distributed;
- Example label(s) of the product(s) in question;
- The total amount produced and distributed;
- The name, phone number or other contact information (email, cell number) of the facility's after hours representative.

The more detailed and specific this information is, the better. The CFIA may need this information to develop a complete risk management plan for a recall.

Role of Government Agencies

The Canadian Food Inspection Agency deals with all product recalls, along with help from Health Canada (providing health risk assessments). This falls under the Canadian Food and Drug Act and Regulations.

The CFIA may take the lead role in investigating and coordinating food safety emergency responses, or it may choose to have the facility keep them fully informed. Regional health authorities or provincial inspectors may also take part in the recall process. This will depend on the situation. All these regulatory agencies are available to help the facility, for investigations and recall activities.

The CFIA has resources available to assist with developing an effective recall program. Please refer to the Food Recall and Emergency Response at: http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/eng/1300375639646/1300376138588

2.0 TRACEABILITY – THE BACKBONE OF RECALL

Traceability is the backbone of any quick and efficient recall. Using recorded information to trace a food item is absolutely necessary. This helps to decide where the product is in the supply chain.

Recorded information to trace includes the food item's:

- History
- Application
- Use
- Location

Being able to track a food item forward or backward through the supply chain can help control costs by reducing the amount of product recalled or destroyed.

Food safety and traceability are both very important issues for governments and industry. Numerous programs to introduce tracking and tracing methods in the food supply chain are underway worldwide.

'Traceability' and 'Product Tracing' are both used to describe such procedures. Since traceability is most common, that is how it will be referred to in this chapter.

It is impossible to give an exact cost for setting up a traceability system. This depends on the technology used. It also depends on the information recorded and what is involved in making the product. Location, customer base and the length of supply chain also affect cost.

2.1 What Traceability is and Does

Generally, traceability systems are record keeping procedures. They show the route a raw material took from the supplier. This includes the supplier's steps to produce the product. It also includes the supply chain from distributors or customers, to consumers.

Any traceability system includes:

- Identification of units / batches of all raw materials;
- Identification of units / batches of all finished products;
- Information about when and where the product(s) were used, transported or sold; and
- A complete system to link this information.

Note that trade items are tracked routinely for availability, inventory management and logistical purposes.

Traceability is a 'reactive' – or after the fact – food safety tool. It lets manufacturers and agencies follow the path of a unit and/or lot of products downstream. It tracks these throughout the supply chain, as they move between different companies or customers.

In order for it to be effective, a traceability system must identify where a particular supply chain unit came from. Check records held by previous owners in the supply chain. Units are usually traced for purposes such as recall and complaints.

See Form F.18: Supplier/Customer Contact List.

A traceability system's goal is to:

- Manage risks related to plant/animal health issues (e.g. BSE, genetically modified materials);
- Promote informed consumer choice by offering label information on product quality and ingredient history;
- Create trust in the marketplace with fair trade practices (e.g. show that organic products really are organic); and
- Improve product quality and processes (e.g. better inventory tracking systems).

Can-Trace identifies industry requirements for a national whole-chain food tracking and tracing standard. Can-Trace's goal is to develop a standard to set up traceability based on international standards. It's a voluntary program developed by Canadian industry. To help the facility develop programs, check out Can-Trace's resources (Traceability Evaluation Tool), standards (Canadian Food Traceability Data Standard) and other materials (Can-Trace News, press clippings, and more) at www.can-trace.org.

2.2 Traceability and the Production Team

The main responsibility for traceability falls on the facility's manufacturing team.

Manufacturing happens when raw materials are blended, formed and processed. Remember, each raw material in a product has a history. Tracking lets the manufacturer understand how this history affects the product.

However, the manufacturing team does not work alone. Traceability requires a collaborative effort by the whole production team. Other key players may include:

Research and Development – These staff members are the facility's 'gatekeepers.' They are responsible for finding out how good suppliers are at tracing their own product. They can help shed light on the suppliers' tracking systems before raw materials enter the facility.

Purchasing and Receiving – These staff members must understand the importance of traceability information to a facility. It's their job to make sure this information is collected upfront, before materials enter production.

IT or Management – The facility's IT or management need documentation systems to internally track ingredients. They will coordinate these systems with suppliers so that the operation's information needs are met. It's important that the facility can easily get hold of this information and understand it.

Operations Staff – These staff members create the link between raw ingredients and finished products. They will record information to trace materials through the production process. They must understand the importance of this information and know where to find it.

Shipping Staff – Shipping staff are responsible for creating the link between product information and the customers. They need to understand the importance of recording production dates for all materials shipped. These staff members make up the last step in the production chain.

Train all key staff on traceability. The right information in the tracking system upfront helps create positive end results.

2.3 Linking Information Throughout the Chain

Traceability requires not only getting information but also using this information.

If a food safety issue is caused by raw materials, traceability back to the supplier increases chances of correcting the problem. It also helps prevent this problem from happening again.

Track ingredients throughout the production process:

- When an ingredient enters production, record its lot number; and
- Link it to a formula or to production information.

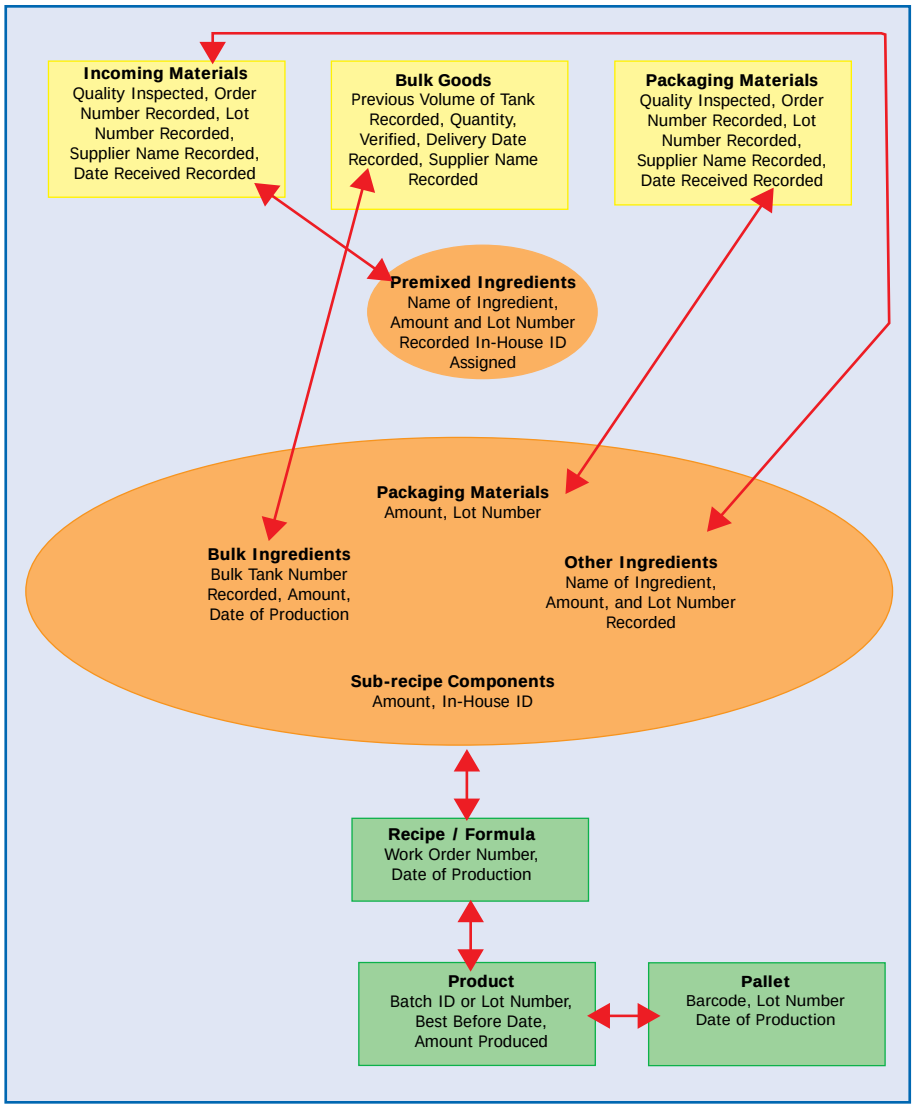
See Form F.13: Raw Material Input.

Give each production run an in-house lot number. This lot number can carry information such as:

- Expiry date;
- ‘Best Before’ date;
- Job or work order number; and
- Other useful or important information.

A good system will track every movement. It will track not only the product’s movement, but also the movement of every part or ingredient in the product.

Figure 1: This diagram shows how information is linked within an in-house traceability system. It shows the flow from raw materials (at the top) to finished product (at the bottom).



2.4 Defining Traceability Policies

Most confusion in developing traceability systems is about defining the right unit size. Unit size includes:

- Batch
- Individual container
- Box of containers
- Volume of product

Often unit size is set according to how a particular process is managed. Each manufacturer must develop its own traceability policies.

Here are some key areas where decisions or policies must be developed:

- Continuous and Batch Processing – Processors must be able to safely separate and identify batches.
- Handling of Bulk Products – These products tend to be mixed with earlier deliveries. So even when they come with clear batch identification, forward traceability may not be possible.
- Rework – Just because rework is traceable does not reduce the chances of contamination. Contaminants can be spread over large amounts of production and over long periods of time. Any rework can seriously influence a product recall.
- Water Used for Processing – Water must be potable and water source traceable.

Each of these key processing areas must be addressed.

The more key information products carry with them, the better the chances of finding and removing them from the marketplace swiftly. Ideally, the facility wants traceability procedures that ensure the greatest safety for the product at the least cost to the operation.

GS1 Canada is a not-for-profit, industry led association. It develops, promotes and maintains global standards. It does so for the identification of goods, services, locations and related e-commerce communication. Check out the GS1 Canada website (www.GS1ca.org) to investigate standards, including the Canadian Food Traceability Data Standard. There are also other materials and services available to help a facility develop traceability programs.

3.0 RECALL PROCESS

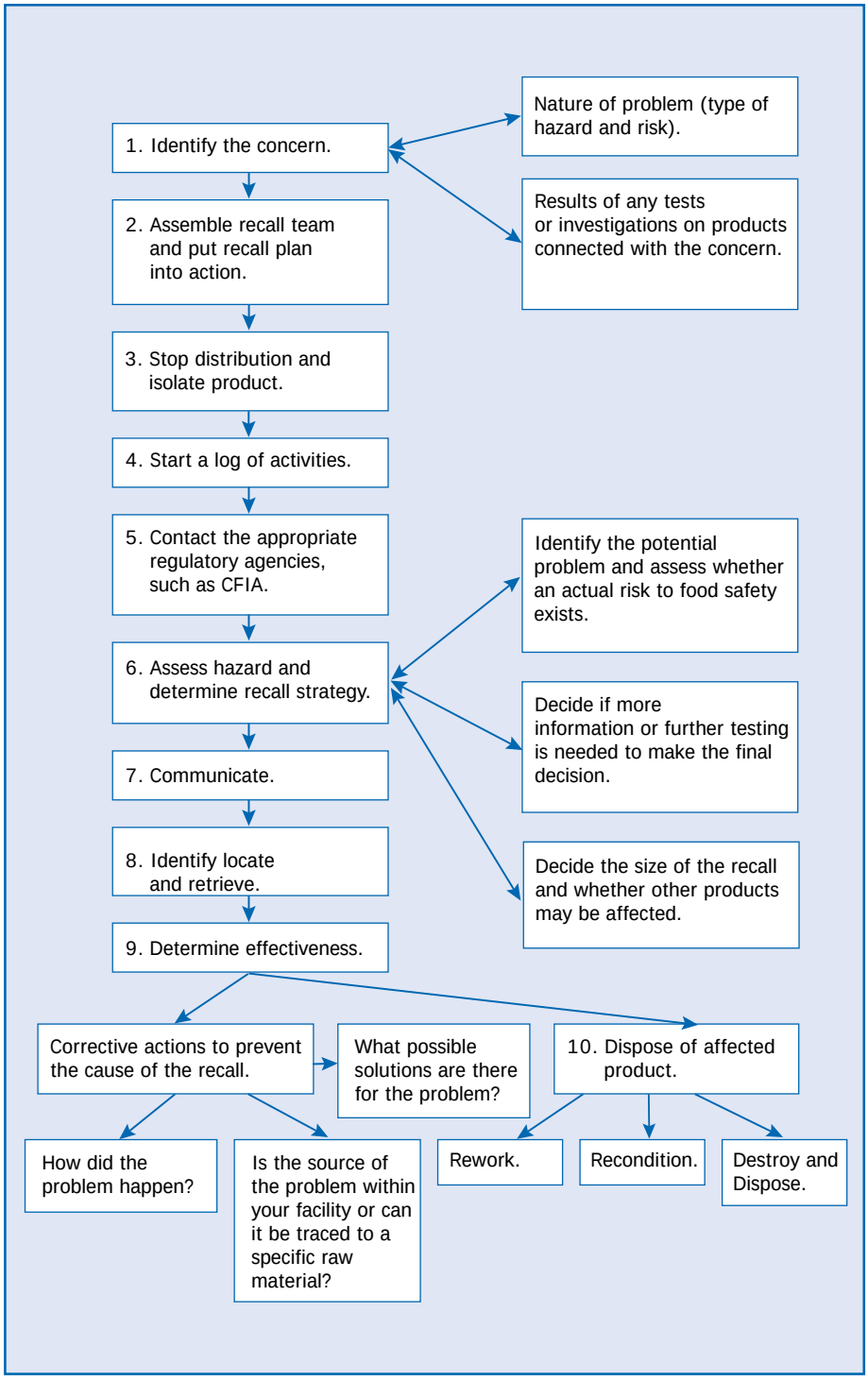
The steps in a recall are usually the same for all products.
For any recall, the facility must:

1. Identify the concern or problem;
2. Assemble the recall team and put into action the recall plan (Steps 3 - 11);
3. Stop distribution and isolate the product(s);
4. Start a log of activities;
5. Contact the appropriate regulatory agencies, such as the Canadian Food Inspection Agency (CFIA);
6. Assess hazards and decide on a recall plan;
7. Communicate;
8. Identify, locate and retrieve the affected product(s);
9. Determine how well the recall is working;
10. Get rid of the recalled product(s); and
11. Fix the cause of the recall.

The CFIA has resources available to assist with developing an effective recall program. Please refer to the Food Recall and Emergency Response at: http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/eng/1300375639646/1300376138588

3.1 Visualizing the Recall Process

Recall Step by Step



Step 1 – Identify the concern or problem.

There are a number of situations that can lead to recalls. Some cause bigger problems than others. However, all such situations can threaten consumers in some way.

The following are possible triggers of a recall:

- Allergens;
- Communicable diseases (e.g. E. coli, Salmonella, Listeria);
- Foreign materials that are not part of the regular food manufacturing process;
- Damaged packaging (e.g. broken seals, faulty seams, etc);
- Notifications from suppliers;
- Tampering or tampering threats; and
- Undeclared or unintended ingredients.

The following information is important to help identify and assess each recall:

- Type of hazard;
- Type of risk; and
- Test results or investigations on products relating to the cause for the concern.

See Form F.16: Recall Hazard Assessment Form.

Step 2 – Assemble the recall team and put the recall plan into action.

Immediately assemble the facility's recall team. Everyone has a role with the process. The sooner the team is assembled the smoother the process can flow.

Put into action the facility's recall plan ensure that all the necessary activities are being performed. Document all activities.

Step 3 – Stop distribution and isolate the product within the facility.

As soon as the facility becomes aware of a problem, immediately stop all further production and/or distribution of the product. This will help to narrow down the problem. Label any suspect product as 'ON HOLD.' Keep this label until it's known whether it's safe or connected with the problem.

The size of a recall will vary from small qualities to large amounts of product. A good product coding system and traceability program makes it easier to narrow down affected product. The easier it is to narrow down the problem, product loss and costs are minimized.

Step 4 – Start a log of the activities.

Record keeping helps the manufacturer prove due diligence. For food recalls, record keeping is particularly important. Record all actions, including decisions and reasons for them. At least one member of the recall team should be named as record keeper. That person should keep an accurate diary of all activities connected with the recall.

See Form F.15: Recall Activities Log.

Step 5 – Contact the appropriate regulatory agency.

Communication is very important and it starts within the plant. Once the required facility staff are aware of the situation and have set aside the recalled product within the facility, broaden communication to include the regulatory agencies.

First, contact the Canadian Food Inspection Agency (CFIA) to ensure that the action or decision is correct. The CFIA staff can help with investigations. They should be notified of all food related health and safety actions taken on a recall, or on a possible recall. Each region in Canada has a CFIA Recall Coordinator who can reach the right CFIA staff.

See Form F.1: Authority Recall Information Form.

Step 6 – Consider the hazard and decide on the recall plan.

Once the CFIA has been contacted, consider the hazard of concern and decide on corrective actions. If the CFIA becomes involved, the Office of Food Safety and Recall (OFSR) will decide the recall classification for the situation. However, the facility, along with the CFIA representative (if one is assigned), is responsible for doing an initial assessment.

This initial assessment will:

- Identify the potential problem and decide whether there is an actual risk to food safety;
- Decide whether more information or further testing is needed to make the final decision; and
- Determine the size of the recall and whether other products are affected.

The OFSR uses the information from this initial assessment and gives the recall a risk classification if necessary. Depending on the classification or level of recall, the CFIA has required actions. The CFIA representative will explain these requirements and communicate the next steps of the recall process.

See Form F.16: Recall Hazard Assessment Form.

Step 7 – Communicate.

The key to any successful recall is communication. Depending on the class of recall, the facility may have to communicate not only with customers, but also with media. From the start, make sure this communication is truthful and accurate. Make it clear and to the point. Different situations require different levels of detail.

The CFIA has resources available to assist with developing an effective recall program. Please refer to the Food Recall and Emergency Response at: http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/eng/1300375639646/1300376138588

See Form F.10: Notice of Recall.

The facility is responsible for notifying all customers or accounts. Notify anyone that may have received the affected product.

Prepare a written notice with all necessary related information. Before handing out this notice, the CFIA may need to approve a draft.

As part of communications, always ask customers to confirm that they received the notice. Ask customers also to confirm they have taken action.

Follow up with customers and make sure they received the notification if the facility does not receive an answer. Keep ongoing records of all these activities.

See Form F.2: Communications Log.

Step 8: Identify, locate and retrieve.

Once all customers have been contacted, develop a plan for recovering and disposing of affected product.

Just as it's important to keep track of amounts manufactured and shipped, it is also very important to keep records of all returned product. This gives the facility a cross-reference that can reveal how well the recall is working.

See Form F.12: Production Numbers Record, and Form F.7: Defective, Suspect and Recalled Product Receiving Form.

Step 9: Determine the effectiveness of the recall.

The first step in assessing a recall's effectiveness is to make sure communication is working. The CFIA will also check up on how well the facility's recall communication is working and will do spot checks with customers. They will find out whether notification was received. They will also check on whether product is still available for sale and, if so, why.

If the CFIA has not become involved, it's a good idea for the recall team to undertake these activities.

See Form F.8: Effectiveness Questionnaire.

The second step in assessing a recall's effectiveness is accounting for all affected product. Require customers to document how many units they had at the time of receiving the recall notice. This will provide the recall team with numbers to compare against production figures.

Depending on how much time passed between product distribution and product recall, some recalled product may have been sold. Therefore, it may not be possible to get all the affected product back.

Examine the seriousness of the situation. Examine how much of the affected product is not accounted for. The facility may have to issue a public warning about the product.

See Form F.11: Product Reconciliation.

Step 10: Dispose of affected product and put in place corrective actions.

When all of the related products have been returned, decide on how to deal with affected product. There are three options available:

- Rework
- Recondition
- Destruction and disposal

The CFIA or another appropriate regulatory agency should first approve any decision regarding recalled product disposal. Use the Activities Log to record the action taken for each product.

See Form F.15: Recall Activities Log.

Step 11 – Fix the cause of the recall.

If it has not already been done, determine the cause of the recall and decide on a solution. To show due diligence, the manufacturer is responsible for ensuring that all reasonable steps have been taken to prevent similar recalls in future.

Depending on the cause of the recall, the CFIA may return to the facility later to check on corrective actions and to see if they are working.

3.2 How to Develop a Recall Plan

Once the recall process is understood set up a plan that prepares the facility in case a product recall is needed. Put this recall plan in writing. The plan must show how a facility will make sure that unsafe product is recalled quickly and effectively.

The recall plan must have procedures and policies to be followed in regard to:

- Raw material tracking throughout the production process;
- Product coding;
- Customer complaint files;
- Situation analysis and ways of informing relevant government agencies;
- Stopping distribution of products within the facility;
- Distribution records and distribution record systems;
- How to inform customers, and public (if necessary) about the recall; and
- Roles of recall team members.

Raw Material Tracking

Recalls can be started in various ways.

Ask the following questions:

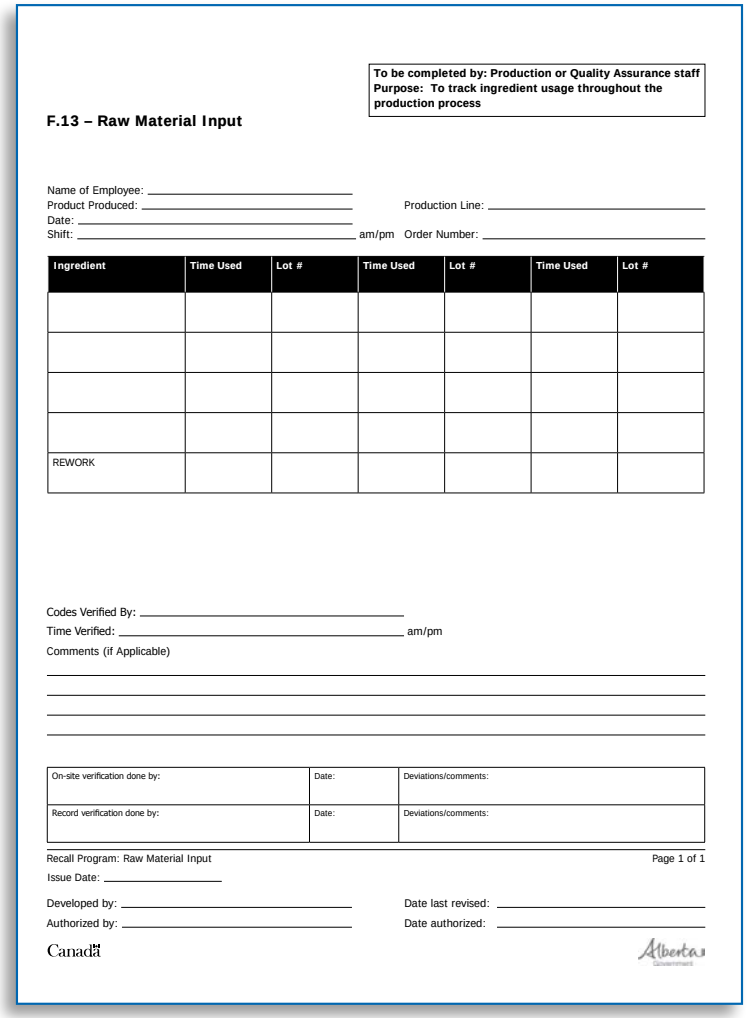
- Is the recall team prepared to act upon a recall by one of the raw material suppliers?
- If an investigation of a complaint finds a problem with one of the raw materials, can the recall team decide which products may be affected?
- Can the recall team follow raw materials throughout the production process to know what products are affected and which are not?

As explained, traceability is the backbone of the recall process. With a good traceability program in place, it will be easy to narrow down what needs to be done during any recall. It also may help reduce related costs.

Every facility has a different way to record the use of raw materials. Some facilities make it part of their current production records. Others have separate documentation forms for raw material use.

At some facilities, production employees record the information, while at others it is the job of quality assurance staff. How the facility tracks raw materials will depend on staff levels, workloads and the amount of information to track.

Figure 2: Raw Material Input Form



To be completed by: Production or Quality Assurance staff
Purpose: To track ingredient usage throughout the production process

F.13 – Raw Material Input

Name of Employee: _____
Product Produced: _____ Production Line: _____
Date: _____
Shift: _____ am/pm Order Number: _____

Ingredient	Time Used	Lot #	Time Used	Lot #	Time Used	Lot #
REWORK						

Codes Verified By: _____
Time Verified: _____ am/pm
Comments (if Applicable)
_____
_____
_____
_____

On-site verification done by:	Date:	Deviations/comments:
Record verification done by:	Date:	Deviations/comments:

Recall Program: Raw Material Input Page 1 of 1
Issue Date: _____

Developed by: _____ Date last revised: _____
Authorized by: _____ Date authorized: _____

Canada Alberta

Product Coding

All products should be coded correctly and easy to understand. The identified recall team member will use this information to tell customers what products are associated with any recall activities. Any recognizable method of coding is acceptable. Letters are often used to single out the month a product was packed (e.g. Jan, Feb, etc.).

Julian dates are three digit codes used to show the manufacture date.

Correct record keeping of these codes lets the recall team trace the cause of consumer complaints. It also helps control distribution and inventory. It ensures product rotation, and if necessary, helps in carrying out a recall.

Record an explanation of the product coding system within the recall plan. For example, define what letters are used to signify the month, and what order the information is being recorded in (e.g. month/ day/ year, day/month/year, etc.).

HOW SHOULD I CODE MY PRODUCT?

Since it should be possible to identify the product by the year and day it was packed, 'Best Before' dates make sense for product coding. They allow for ease in tracing back the product to the exact date of production. If the facility decides to use this type of coding, it is also important to have some form of batch coding. This helps to identify between several batches processed on the same day. If more than one processing facility is involved, each facility must be shown. Be sure to code all cases and individual containers so they can be read easily. And remember that whatever code is used, the facility will need to be able to explain it to both the customers and/ or regulatory agencies.

4.0 STOPPING DISTRIBUTION AND CONTROLLING PRODUCTS WITHIN THE FACILITY

It is in a facility's best interest to immediately hold back all affected recalled products that are still in its control. They should also prevent any further distribution of this product.

This is most easily accomplished by giving one member of the recall team responsibility for conducting an in-house stock assessment. Ensure they isolate any stock that may be related to the problem.

The most efficient way to isolate stock is to identify the product(s) through signs or labeling. These should indicate clearly that the product is 'On Hold.'

When labeling product this way, it is important to maintain control. The sign or label should have the following information:

- 'On Hold' marked clearly;
- Date that the action was taken;
- The initials or name of the person placing the product on hold; and
- Statement that no product is to be disposed of without clearance from the recall team or management.

When the problem and affected lot numbers have been found, develop a plan for recovering this product from distribution. Keep accurate records to help limit the recall and to help produce information accurately and quickly.

The record system should allow for creating a distribution list. This list should give both the specific product codes and lot codes.

See Form F.5: Distribution Status Record – Sales, and Form F.6: Distribution Status Record – Shipping.

The distribution list should include:

- Name of customer and address (including city and province);
- Type of account (e.g. manufacturer, distributor, retailer, restaurant, etc.);
- Product name and lot code;
- Primary contact at the account;
- Telephone number, and other contact information (email, fax, after-hours phone number); and
- Amount of product shipped to the customer.

This information could be gathered from Form B.11 - Shipping Record and Form F.18 - Customer Contact List.

However, the identified recall team member may need to reference other documents to ensure all effected product is accounted for and customers are notified.

For these records to help in a recall, make sure those responsible for the information have enough training. They must understand why the information is important and why it needs to be recorded.

4.1 Communication Plan

The recall communication system can be set up in various ways. Whatever method is used, be sure to control all information released.

Most companies control information by using communication templates or guidelines. This helps to ensure that any written communication is clear and concise. It also shows the company is concerned.

If a recall involves a health risk, include a definition of this health risk in public communications or press releases. Also include some form of medical explanation. Provide some background on the situation. In this way the media are less likely to define the problem. They'll also be less likely to develop the information on their own.

Templates or guidelines for recall communication are available on the CFIA website *http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/eng/1300375639646/1300376138588*

Keep in mind that different levels of information are required for different groups. Different forms of communication should be used when dealing with:

- CFIA
- Retailers and distributors
- Media
- Consumers

The facility is responsible for immediately notifying all accounts (customers or distributors) that may have received recalled product(s).

In some situations companies use communication firms. This helps to remove some of the work associated with recall communication.

5.0 CHECKING THE EFFECTIVENESS OF COMMUNICATIONS

If the CFIA becomes involved it will check how well the facility's recall system is working. It will do so by random surveys of the customers. This helps the CFIA confirm that all affected product(s) are removed from the marketplace.

Where the CFIA decides that the recall efforts are not good enough, the recall may have to be repeated.

If the CFIA has not become involved, it's a good idea for the facility to do an internal or in-house assessment of the communication. This is most easily accomplished by using recall effectiveness checks. These checks involve phoning customers who may have received the affected product(s). Check to find out whether they received notice, removed the product from sale and that they understand the actions requested.

See Form F.8: Recall Effectiveness Check – Questionnaire.

5.1 Mock Recall

The purpose of a mock or trial recall is to test how well the written recall procedures work. Every time there is a mock recall, the facility will learn a little more. A drill lets the facility adjust the plan before there is a real recall. The middle of an actual recall is not the time to test a recall plan. At this time the recall management team will likely be too busy with the actual recall.

A mock recall should be able to answer the following questions:

- Does the facility's system run smoothly?
- How easily can the facility trace and recover the recall products?
- Can the facility look at the lot identification records and find out what ingredients the recalled products have in common?
- Does the plan have the necessary information to work during extreme situations (e.g. if management is not available)?
- Does the plan let the facility recover and account for all affected products with the help of production numbers?
- Is the record keeping good enough to show where affected products have been shipped?

Every time the facility runs a mock recall, it will likely need to 'fine tune' the system. Almost all companies have to adjust their recall system several times.

Scenarios

When testing the recall system, consider using these scenarios:

Test the system forward from the raw ingredient level.

Example: "Our firm received a phone call from Supplier X telling us that ingredient ABC, lot number XXX, has been contaminated. All products related with this ingredient should be pulled from the marketplace immediately."

Test the system backwards from the finished product.

Example: "Our firm recently investigated a complaint. We found that product RQP in the XX-gram-size packages was unsafe. It should be removed from the marketplace immediately."

Test the system internally.

Example: "We recently received notification from our supplier that there may be a problem with ingredient ABC, lot number XXX. The supplier has asked us to put all associated products and ingredients not already distributed on hold until further notice."

If the facility finds shortcomings in the system, adjust the process.

At the end of each mock recall, let the recall committee suggest ways for improvement. Make the results of the mock recall available to all staff.

Record Keeping

As with an actual recall, maintain records during the entire mock recall process. These should include:

- All related recall records;
- A description of the test scenario;
- The date of the test;
- Problems found during the test; and
- Actions needed to correct each problem found (e.g. changes to recall plan, training, etc.).

See Form F.9: Mock Recall Record.

As with the recall plan, the facility should provide a procedure and documentation plan for mock recalls.

6.0 CUSTOMER COMPLAINT FILES

Customer complaint files are the most important part of record keeping relating to recalls. Be absolutely sure to record every customer complaint received. Investigate the basic cause of the complaint.

Accurate files of customer complaints let the facility identify trends or problem products and they help in choosing corrective actions.

The three parts of any customer complaint file are:

1. Recording the original complaint information;
2. Investigating the complaint and recording of findings; and
3. Corrective actions taken based on what the investigation found.

6.1 Recording Complaints

For each complaint, record the following information:

- Source of complaint and contact details;
- Separate quality and food safety issues;
- Description of the problem (e.g. illness, allergy, foreign matter, chemical taste, quality issue);
- Details of injury or illness (where applicable);
- Whether anyone else or an agency has been contacted (e.g. CFIA, Public Health);
- Product details including product name, package size, identifying codes; and
- Retailer information including store where product was bought and when.

See Form F.4: Consumer Complaint Form.

6.2 Investigating Complaints

Check into all complaints right away, no matter how small. Have a trained person in the firm investigate.

The goal of any complaint investigation is to answer the following questions:

- How did the problem happen?
- Is the source of the problem within the facility or can it be traced to a specific raw material?
- Does the problem affect any other products?
- What possible solutions are there for the problem?

See Form F.3: Complaint Investigation Form.

6.3 Corrective Actions

Once all the results of the investigation findings have been written down, decide on corrective actions. If the complaint relates to a product recall, contact the CFIA to ensure that the action plan is suitable.

Record the following:

- Who approved the decision;
- When the decision was approved;
- What corrective action was taken for affected products; and
- Whether the corrective action fixed the problem.

See Form F.3: Complaint Investigation Form.

6.4 Illness or Injury Complaints

If the facility receives a consumer complaint regarding possible illness or injury, take the following steps.

1. Direct the customer to the local public health authority or doctor for medical care. If a connection can be found between the product and the illness, the health region will forward the information to the CFIA. Health Link (1-866-408-5465) is the best resource to help the complainant decide where to report the incident.
2. Contact the appropriate regulatory agencies such as the CFIA. These agencies may send a representative to the plant to help find the source of the problem.

It's important that employees be considerate and helpful to anyone who claims injury or illness. Find out if the person making the claim has had any medical follow-up. Record all details of the complaint including where and when the product was bought, lot code, 'Best Before' date, how it was prepared, when it was consumed, and with what.

Whatever information the facility can get from the person(s) making the complaint will help the investigation.

If the facility can find some of the product in question (if appropriate), keep it refrigerated or frozen in case testing is needed. If the facility has records of test results already on hand, attach a copy to the complaint record.

Be sure to keep copies of all documents related to the particular product and code with the complaint record. If necessary, hand it over to the CFIA or health authorities.

Situation Analysis and Informing Relevant Government Agencies

The recall team is responsible for assessing the situation and for coordinating all parts of the product recall. The original assessment must be done in a timely manner. Find out the following information immediately:

- What is the potential problem and is it a food safety risk?
- Is more information needed (e.g. further testing, expert advice) to make a decision?
- Does the product need to be taken off the market while a complete review is done? Is it an emergency situation?

Notify the CFIA immediately if the facility thinks the products may be a risk to consumers. The Office of Food Safety and Recall (OFSR) determines how serious and what class the recall is.

The CFIA will provide the facility with a link to OFSR to speed up the process. These agencies have their own procedures for making decisions. This means the CFIA staff member working with the facility may not be the person making the final decision.

The facility must be able to supply the CFIA with the following information:

- A detailed description of the problem;
- The name, brand, size, and lot code(s) affected;
- Details of complaints received (especially any reported illnesses);
- The distribution of the product (including customers, dates, and amounts);
- Label(s) of the products that may be affected;
- Total quantity of product manufactured and distributed; and
- The name and number of the facility's after-hours contact.

This information allows the CFIA to develop a complete and correct risk management plan.

If there is missing information, keep a record of all the information that's been asked for. In doing so the facility will be prepared if it's necessary to contact the CFIA again.

7.0 RECALL FORM TEMPLATES

F.1 Authority Recall Information Form

F.2 Communications Log

F.3 Complaint Investigation Form

F.4 Consumer Complaint Form

F.5 Distribution Status Record – Sales

F.6 Distribution Status Record – Shipping

F.7 Defective, Suspect and Recalled Product Receiving Form

F.8 Effectiveness Check Questionnaire

F.9 Mock Recall Record

F.10 Notice of Recall

F.11 Product Reconciliation

F.12 Production Numbers Record

F.13 Raw Material Input

F.14 Sample Raw Material Input

F.15 Recall Activities Log

F.16 Recall Hazard Assessment Form

F.17 Recall Management Team

F.18 Supplier / Customer Contact List

8.0 SOURCES OF INFORMATION

1. Food Science and Human Nutrition Department, University of Florida, Gainesville. The Food Recall Manual. http://edis.ifas.ufl.edu/pdffiles/FS/FS10800.pdf.

2. Kaletunç, Gönül and Özadali, Ferhan. Understanding the Recall Concept in the Food Industry. Ohio State University Extension Fact Sheet. http://ohioline.osu.edu/aex-fact/0251.html.

3. Food Standards Australia New Zealand. Food Industry Recall Protocol 5th Edition (2004). http://www.foodstandards.gov.au/_srcfiles/5th%20FIPR_june04.pdf.

4. Canadian Food Inspection Agency Agriculture and Agri-Food Canada, and Canadian Council of Grocery Distributors. Supply Chain Food Product Recall Manual (2003 CFIA).

5. Canadian Food Inspection Agency Food Recalls: Make A Plan And Action It! Manufacturers' Guide (2001).

6. Electronic Commerce Council of Canada Tracking and Tracing of Food Products in Canada (2003). http://www.can-trace.org/portals/0/docsTrackingAndTracingInitiativeWhitePaper.pdf.

Chapter 11

DEVELOPING AN ALLERGEN CONTROL PROGRAM

1.0 ALLERGEN OVERVIEW
- 1.1 Allergen Control Program
- 1.2 Management Commitment

2.0 ALLERGEN IDENTIFICATION AND MAPPING
- 2.1 Assessing Formulas and Raw Materials
- 2.2 Communicating with Suppliers
- 2.3 Controlling Product Development and Purchasing
- 2.4 Allergen Mapping

3.0 PROCEDURES AND WORK INSTRUCTIONS
- 3.1 Receiving
- 3.2 Segregation
- 3.3 Allergen Clean
- 3.4 Validation and Verification
- 3.5 Rework
- 3.6 Labelling and Packaging

4.0 ALLERGEN TRAINING

5.0 ALLERGEN FORM TEMPLATES

6.0 SOURCES OF INFORMATION

1.0 ALLERGEN OVERVIEW

True food allergies are unfavorable reactions to proteins found in certain foods. Up to six to nine percent of people are sensitive to, or have adverse reactions to, certain foods. Very small amounts of an unfavorable protein can cause reactions.

Although any protein can cause an allergic reaction in sensitive people, the priority allergens identified by Health Canada and the Canadian Food Inspection Agency (CFIA) account for 90% of anaphylactic reactions in Canada. The priority food allergens are:

Eggs	Sesame
Milk	Soy
Mustard	Sulphites
Peanuts	Tree Nuts
Seafood (Fish,Crustaceans and Shellfish)	Wheat

Since sulphites are not proteins, they don't cause a true allergic reaction. Sulphite sensitive people may experience life threatening reactions similar to food allergies and people who have asthma are most at risk to these reactions.

Gluten does not cause an allergic reaction but can cause an adverse reaction for sensitive people therefore its source (such as wheat, rye, barley) must also be declared on the ingredient list and may be controlled through the allergen management program.

Individuals with celiac disease have an intolerance to gluten. Gluten is a type of protein found in wheat, barley, rye and triticale.

The CFIA has excellent information regarding allergens on its website. Please visit:
www.inspection.gc.ca/food/labelling/food-labelling-for-industry/list-of-ingredients-and-allergens/eng/1383612857522/1383612932341

www.inspection.gc.ca/food/information-for-consumers/fact-sheets/food-allergies/eng/1332442914456/1332442980290

If you are a food processor and you wish to explore the growing market for allergy and gluten free foods please visit Alberta Agriculture and Rural Development's Food and Health Unit webpage:
www.agriculture.alberta.ca/foodandhealth

1.1 Allergen Control Program (ACP)

Labels that read 'May Contain [X]' or 'Not suitable for consumption by persons with an allergy to [X]…' are often used to show that products have been produced where cross-contamination is possible. However, overuse of allergen warning labels may limit consumer choice and may reduce the value of the warnings. Also, current best practice for allergen control is to conduct all diligence possible to ensure a safe food product. Therefore, having a strong Allergen Control Program (ACP) is very important.

When setting up an ACP, remember:

- An effective allergen plan needs to be accepted and understood by all food production staff;
- Success depends on management commitment; and
- Unidentified allergens represent a high risk.

The best way to control allergens in the facility is through hazard analysis and hazard management.

The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organization and the World Health Organization. Its purpose is to develop food standards and guidelines. The Codex Alimentarius Commission describes seven steps to control allergens, which are very similar to the hazard analysis required for developing a HACCP plan.

The seven steps to control allergens are:

1. Look at the entire production process from start to finish. Identify any hazards that need to be controlled. Identify any steps in the process where controls can be used. This is referred to as Allergen Mapping.
2. Set limits at critical points for what is acceptable and what is not acceptable.
3. Set monitoring procedures for critical points to check whether allergen hazards are being kept within limits (set in step 2).
4. State what corrective actions (e.g. cleaning up spills) are needed when the process is not operating within the set limits.
5. Regularly check that the methods set up are working.
6. Document, document, document so that there is proof showing that the ACP is working well.
7. Improve as necessary, update when changes happen and make sure the ACP continues to work well.

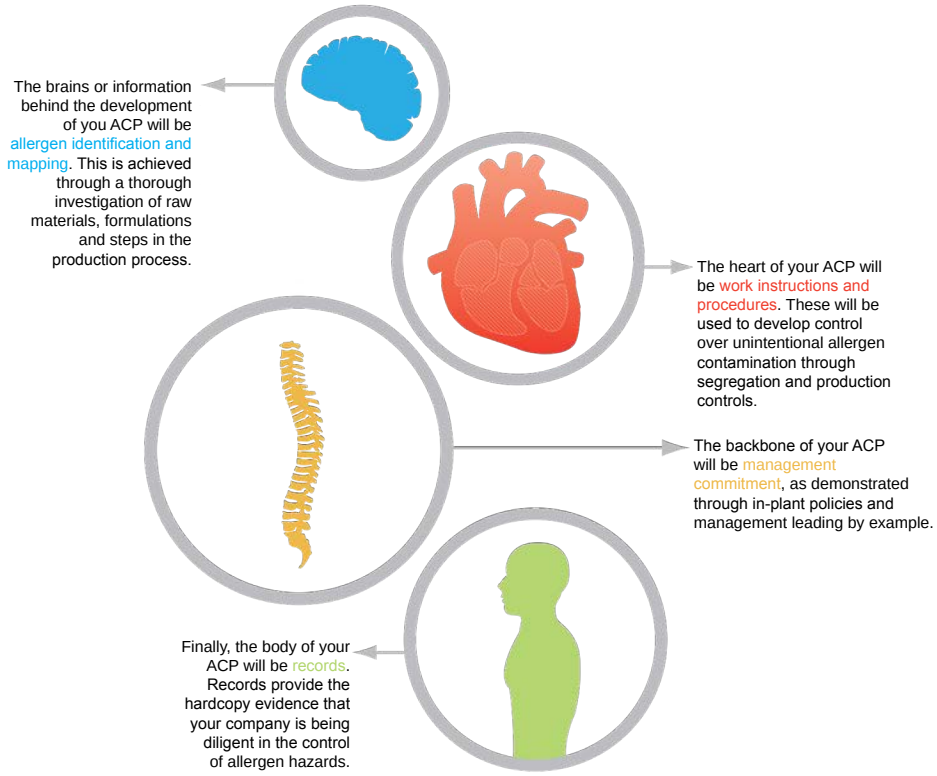
Although these steps may seem to require a lot of work, following this basic procedure will create a very good ACP.

The most common ways for unidentified allergens to enter food products are:

- Cross-contamination of an ingredient with an allergen before or after it is received at the facility;
- Accidentally adding allergens to products that do not usually contain them (mis-formulation); and
- Cross-contamination from a different product containing an unwanted allergen.

Many allergenic food products (e.g. milk powder, sesame seeds, flour, etc.) enter the air supply easily. They can then be deposited onto allergen-free products. This can happen even if the allergenic foods are not produced in the same area or the same production room. Examine whether a common air supply in the facility could cause such problems.

Components of an Allergen Control Program (ACP)



1.2 Management Commitment

Management support is essential. Programs won't thrive without management commitment, however, problems will.

An Allergen Control Program (ACP) needs buy-in or acceptance from all facility employees. The procedures and policies affect all areas of production from maintenance to shipping. However, top management must take a leading and visible role in supporting the ACP.

Strong management commitment will include the following:

- Managers must show that they are acting responsibly and seriously. This impresses on staff that everyone is working under the same standards throughout the facility. It will demonstrate that management sees the ACP as important.
- Make sure communication between personnel and departments are clearly stated and strengthened. This improves the effectiveness of the ACP.
- Develop the program so it takes place with input from production or other departments. For the ACP to be successful, buy-in is needed from all departments. Without needed input and support, the program becomes an ideal rather than a workable means of control.
- Using various resources can strengthen allergen controls. Segregation, labeling and sanitation are examples of areas where better control can be gained by using sufficient resources.
- Make sure employees receive the education, training and experience they need. Employee awareness and training are very important in avoiding allergen contamination of products. Make sure employees understand clearly what allergens might be found in the facility. Make sure they understand what problems an allergen could cause.

2.0 ALLERGEN IDENTIFICATION AND MAPPING

2.1 Assessing Formulas and Raw Materials

The first step to controlling allergens in any environment is allergen identification. To avoid having unintended allergens in products, first identify the sources of allergens in the facility.

- Use a master list of all raw materials used in the facility.
- Identify those raw materials that either contain, or may contain, allergens.
- Consider both primary and secondary ingredients like spices, flavourings and additives.
- Ensure the core components are considered for all ingredients (e.g., bread crumbs must be broken down to its core ingredients).
- Make sure all possible sources are listed.

See Form G.4: Ingredient Allergen Reference.

Depending on the operation, control of all priority allergens may not be required. If certain allergens are present in ALL products they do not require control. For example, a bakery does not control for wheat if it is in all of the products.

2.2 Communicating with Suppliers

It is important to create a complete list of allergens in the facility. To make sure the list is complete, set up a policy and procedure to go over allergens that could come from suppliers.

An excellent tool is the Allergen Check List for Food Suppliers and Manufacturers. This was developed by the Canadian Food Inspection Agency (CFIA) and it lays out a simple way to 'talk' with suppliers.

See Form G.1: Allergen Checklist for Food Suppliers or Manufacturers.

Packaging materials and production aides may also contain allergens and must be assessed. For example, sulphites are used in the production of some food packaging materials such as cellophane. Protective edible coatings and waxes, such as those used by the fresh produce industry, must also be assessed for allergens.

To help manage allergen labeling, keep copies of all raw material specifications and formulations. Also keep copies of finished product labels. All this reference information should be kept so staff can find it easily.

Require all the facility's suppliers of raw materials and packaging to have some form of allergen control program. This reduces the risk of allergens getting into food products unintentionally.

Once a master list of raw materials is created, include this information on the master list of finished products. This complete master list of finished products will then show clearly what allergens are found in each product.

These two lists can then be cross referenced with final products that may share common equipment. The goal is to determine which non-allergen products are processed on equipment also used to process allergen-containing products. Potential points of cross contamination can then be identified and proper control measures shall be designed to avoid unintentional cross-contamination.

See Form G.3: Formula/Product Allergen Reference.

2.3 Controlling Product Development and Purchasing

Controls that are in place at the facility for ingredient substitutions and for product development should also be in place at suppliers' facilities.

Once it is known what allergens are used in the facility, it is important to control allowing any new allergens in. Be especially careful when using new raw materials, recipes or ingredients.

Written allergen policies should include controls for incoming ingredients. They should also include controls for new product development. This will help control the addition of new allergens.

The product development and purchasing staff are very important in controlling incoming allergens. Be sure these staff members know that changes to one production process can risk allergen cross-contamination in other processes and products.

When any ingredient or product changes, a new allergen risk review is needed.

Make sure that product development staff has a master list of current allergens in the facility. This helps staff understand if new products are bringing in new allergenic ingredients.

Also give the master list to ordering staff. This will help when it is necessary to order substitute ingredients. Staff can make sure that replacement materials do not bring new allergens into the product or facility.

Inform those responsible for maintaining the Allergen Control Plan (Quality Assurance, management, etc.) of any changes to raw materials. Also inform them of any changes to product formulation. If new products containing allergens are tested in the facility ensure a validated allergen cleaning procedure is in place as part of the product development process.

2.4 Allergen Mapping

After it is decided what products have allergens, do a walk-through of the facility. This will help the staff determine if there is any shared equipment. It can also help point out and control possible allergen issues. Look for issues related to scheduling, ingredient substitution, cross-contamination, rework and labeling. Ask the following:

- What type of clean-up is used in the plant? Is it thorough enough to remove allergens? Has it been validated to remove the allergen of concern every time?
- Do any conveyors or pipe systems cross over each other, or over exposed product?
- What kind of inventory control is in place?
- What is reworked (if anything)?
- Is there a system for maintaining labels?
- Are allergen issues being dealt with through production scheduling?

Create both a process flow diagram and a plant schematic. These will reveal key areas in the process or facility that might be sources of cross-contamination. A spreadsheet can be used to identify which allergen containing products are produced on equipment that also produces non-allergen containing products. This is a great way to determining where cross-contamination may occur.

See Form G.5: Production Process Allergen Assessment.

3.0 PROCEDURES AND WORK INSTRUCTIONS

3.1 Receiving

Receiving is a facility's entry point for raw materials and non-food items. By placing controls over what is allowed in, the facility can better control incoming allergens.

Incoming material inspection should involve:

- Making sure that all incoming products have clear lot codes on all containers;
- Supervising unloading, including allergen-containing materials;
- Supervising off-hour deliveries to ensure materials are not damaged (which may result in cross-contamination); and
- Rejecting suspicious incoming food, ingredients and other raw materials that are questionable. When in doubt, throw it out.
- Cross reference each incoming ingredient with a list of approved (i.e. reviewed for allergen content) ingredients

If it looks like raw materials that are normally allergen-free have been contaminated, write down observations and do not accept the shipment.

See Forms B8 or B9: Goods Receiving Record Option 1 or 2 found in Chapter 5 Transportation and Storage.

Have the receiver clearly label that these incoming products contain allergens. A predetermined colour coding system should be put in place. A reference guide / key should be posted for employee reference. These can reduce the possibility of allergens getting into products.

3.2 Segregation

Once the source of allergens in the facility is pointed out, identify and segregate or set aside these allergens. Store allergenic materials in areas that are identified and marked clearly.

One method is to set up allergen zones. Do this by painting areas on the floor or racking, or by using colour coded signage Create allergen zones for both finished products and raw materials. This will reduce the possibility of cross-contamination.

Segregation strategies are ways of keeping material apart and controlling the flow of allergens in the facility. Strategies include:

- Having the receiving department identify or mark packages of incoming ingredients that contain allergens. Be sure this is done when ingredients are received.
- Always store allergenic materials on bottom racks so that if spillage occurs there is less opportunity for cross-contaminating allergen-free materials.
- Identify and record all ingredients with unusual or different lot numbers. Be sure this is done when these ingredients are received.
- Track lot numbers throughout production. Link ingredient lot numbers to finished product batches.
- Only allow rework containing allergens to go into products that contain the same allergens (i.e., like into like).

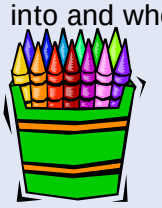
If an allergen is contained within all the facility's products, it is not necessary to identify and segregate the allergen.

Colour coding Equipment and Uniforms

The easiest way to separate allergens in production areas is by setting aside equipment, scoops, utensils and storage areas for dedicated or special purpose use. Colour-coded stickers and equipment will make this segregation clear.

Similar colour coding can be used on maintenance equipment that is dedicated to allergen processing lines.

Another place to use colour coding is on rework material. Colour-coded tags will show when the reworked product was produced. They will show where it is stored, what product it is reworked back into and when it was added and what allergens it contained.



Make sure all employees are trained fully in colour coding. Make sure they're aware of its importance and the meaning of colour codes. Post signs showing what colour can be used with each product. This ensures consistency and reduces training time.

Dedicated Equipment

Cross-contamination with an allergen is the main cause of undeclared or unintentional presence of allergens in food products.

Unplanned entry of allergens into a product from equipment or employees during production is one of the most common causes leading to a product recall.

The best way to avoid this problem is to have production facilities set aside for making or processing specific allergenic products. However, this is not possible in all manufacturing facilities. It is therefore important to have written procedures to dedicate processing equipment and areas. Also create written policies to segregate these products during scheduling and cleaning procedures.

Strategies that can be used during production include:

- Scheduling production of allergenic products just before the end of shifts, then following these up with major clean-ups (validated allergen clean procedures);
- Placing physical barriers (shield covers, catch pans, etc.) to prevent spillage or cross-contact;
- Reducing use of equipment with multiple crossovers and conveyors to decrease potential contamination;
- Using production systems that decrease the equipment exposed to allergens;
- Limiting production of allergenic products to certain areas of the facility; and
- Using care when doing rework.

When doing factory trials of new allergen-containing products, these trials risk cross-contamination with existing products. These new products are just as likely to cause cross-contamination as products already identified and controlled.

Product Scheduling

Most facilities can't set aside equipment and areas only for allergen products. Therefore, it is very important to develop strict segregation of allergenic products. Do this through production scheduling.

Determine if it's possible to manufacture allergen-free products first, and then do allergenic products at the end of the run. Another strategy is to schedule production so that longer runs of allergenic product can be produced at one time. This reduces changeovers and the need for major sanitation shutdowns.

Allergen scheduling tries to ensure that a complete allergen clean is done on all equipment. It should also be done on shared areas that are used for allergenic and non-allergenic products alternately.

3.3 Allergen Clean

Cleaning the production lines in between allergen and non-allergen product runs reduces the risk of allergen cross-contamination. This method is often called an 'Allergen Clean.'

Documented cleaning procedures are necessary to avoid unintentional allergen contamination. As noted, very small amounts of allergens can cause unfavourable reactions in sensitive individuals. Therefore, clean up any spills immediately. Do this for spills that happen during production, storage or transportation of allergen products. This will help to reduce cross-contamination.

During an Allergen Clean, pay special attention to processing aids and the final product lines. For example, oil used for cooking allergenic products cannot be used later for cooking non-allergenic products. As part of an Allergen Clean program, get rid of this oil and clean the vats before producing the next product.

In an allergen clean program consider the following:

- When switching from allergenic to non-allergenic products, change or clean dust socks inside collectors and other absorbent materials.
- Use equipment that is designed for easy cleaning and that provides access to all dead spots, rough surfaces, void areas, etc.
- Use air as little as possible when cleaning allergen areas. Be careful around allergens that can easily become airborne, especially in facilities with a common air supply. Using compressed air for cleaning in these facilities may let allergens into the air supply. This can contaminate non-allergenic products.

- Create check sheets to mark off each cleaning.
- Validate or confirm the cleaning procedures with allergen testing to ensure procedures are working.
- When validating the cleaning program, use tests which are specific to the allergen of concern and sensitive enough to meet the critical limits for the allergen.

Allergens are proteins, not micro-organisms. Therefore, sanitizing will not get rid of allergen risk even if it reduces the levels of cells present. Bacteria-free allergen proteins will still cause a reaction in sensitive people.

When planning an Allergen Clean program, include all splash zones, indirect product contact surfaces and utensils. Ensure that the cleaning of one line or area does not lead to the contamination of another. Generally, use wet cleaning for allergen cleaning. This eliminates any sticky allergen-containing residues.

Current industry best practice for validating the allergen clean program is to use and document some form of allergen residue testing program for product contact equipment.

Depending on risk, finished product testing can be used to enhance the validation and verification of cleaning procedures. However, finished product testing alone is not adequate and should be combined with specific allergen testing on shared equipment.

3.4 Validation and Verification

Validating an Allergen Clean Program

An allergen verification program should be built upon an initial validation study that demonstrates the cleaning procedures being used are effective for the targeted allergens. The validation study will provide proof that the allergen is removed, or reduced to an acceptable limit, by the “allergen clean” procedures.

Testing used for the validation study should be specific to the allergen being removed. For example, ELISA (Enzyme Linked Immuno Assay) test kits are available for most of the common allergens and are commonly used in the food industry. They are available from several manufacturers and are relatively inexpensive and easy to use. These tests are also sensitive and the results are obtained quickly. ELISA tests can have limitations, it is important to research your options carefully.

PCR (Polymerase Chain Reaction) is another method of allergen testing and can also be used to validate your cleaning procedures. PCR tests for the DNA related to specific allergenic materials. These tests are sometimes used on high-risk products. However, PCR is expensive, requires highly trained laboratory staff and specific equipment, and can require up to six hours for results to be ready. For these reasons, most manufacturers do not use this technology.

When there is a mixture of different allergens in the products it is generally accepted to test for the highest risk allergens. Consider concentration of allergens and which are most difficult to remove.

Finished product testing can also be used to validate cleaning procedures and is very important where “allergen free” claims are made. It is recommended to refine and validate the allergen cleaning procedures before conducting finished product testing. When conducting finished product testing put the product on hold in case the allergen is found.

See Form G.2: Allergen Validation Record.

Verifying Allergen Clean Procedures

After the cleaning procedures have been validated, and shown to remove the allergenic materials of concern, verification procedures must be put in place to show that the validated clean procedure is effectively carried out each time.

The first step for verifying your Allergen Clean procedures is by visual examination. Formally inspect the equipment and production areas and document the results. Wait until the equipment and surfaces have dried. Some residues cannot be seen on a wet surface. There should be no visible product on any surface after a complete Allergen Clean.

In addition to the visual examination, direct observation of the validated cleaning procedures during the sanitation process can be used.

Another commonly used practice is to test product contact surfaces with protein swabs. These swabs are highly sensitive and verify that the equipment has been thoroughly cleaned. These swabs test for total protein, not for specific allergens, therefore they are not acceptable for validating the removal of specific allergens.

Another widely used method to verify the Allergen Clean procedures is to test with ATP swabs. ATP (adenosine triphosphate) is a chemical that is associated with living cells. This form of testing is generally used in the food industry to decide the cleanliness of equipment. It helps find 'dirt' quickly.

The major drawback with ATP testing is that it is a non-specific indicator of contamination. In other words, it may be positive when allergens are not present. Also, ATP testing will not tell the amount or the level of allergens present. However, by revealing the cleanliness of the equipment being examined it can serve to verify your cleaning procedures.

When utilizing total protein swabs or the ATP swabs to verify the cleaning procedures, these methods must be calibrated with the validated cleaning procedure. In other words, when conducting your validation by testing with allergen specific ELISA test kits, also test (immediately after the ELISA test) with the total protein swabs or the ATP swabs, and record both results.

3.5 Rework

Inadequate segregation due to poor scheduling and labeling causes loss of control in an Allergen Control Program. Next to this, unregulated rework is the most common reason for manufacturers losing control over their ACP.

Rework is manufactured product that has failed a usability test. It requires additional work, processing or ingredients to avoid being thrown out.

Most often, rework is added in small percentages to newly produced product. Rework that contains allergens should only be used in products containing the same allergens. To ensure this policy is followed, be sure to label and track all rework product throughout the production process.

3.6 Labeling and Packaging

The last step of the ACP is product labeling and packaging. In Canada, new food allergen labelling regulations came into force on August 4, 2012. Some of the highlights include:

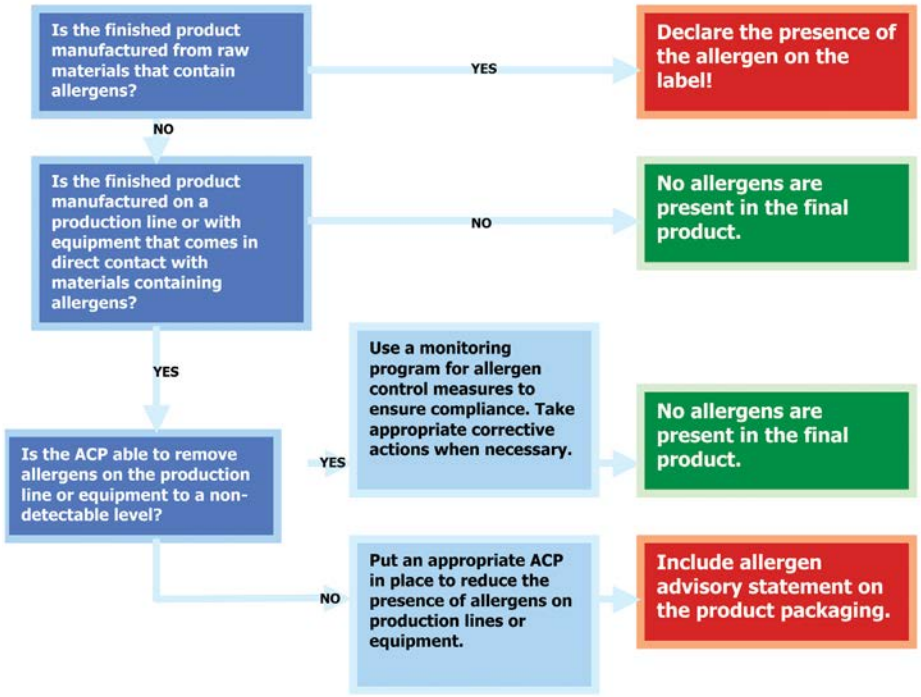
- Food allergens, gluten sources, and sulphites need to be labelled in the list of ingredients or in a statement that begins with “Contains:..”.
- The food allergen or gluten source must be written in commonly used words such as (“milk” or “wheat”).
- Mustard seed has been added to the regulatory definition of food allergen.
- Common name for the plant sources of hydrolyzed protein must be declared. For example, the label may indicate soy, or hydrolyzed vegetable protein (soy), rather than just hydrolyzed vegetable protein.
- For the allergen source: spelt and kamut will be declared as wheat.
- Sulphites above 10 ppm must be treated the same as other allergens. Use of a separate “Contains” statement is optional.
- If a food allergen is present in wine and spirits as a result of the use of fining agents from eggs, fish or milk, the allergen source must be shown on the label of the prepackaged product.
- The source of any allergen or gluten present in the wax coating or their compounds will be required to be shown on the label of prepackaged fruits and vegetables.

It is recommended to refer directly to the Health Canada and Canadian Food Inspection Agency websites, and consult with knowledgeable professionals, when determining the proper labeling of food products. Please visit: www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/index-eng.php

For general information about food labeling visit the CFIA Food Labelling and Advertising webpage at: www.inspection.gc.ca/food/labellingeng/1299879892810/1299879939872

Also, for Guidance on labelling oils derived from food allergens sources: www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/oil-refined-huile-raffinees-eng.php

Allergen Risk Assessment and Labelling



Make sure all products are labeled to identify all allergens. Then use procedures to ensure all labels remain current and correct.

Ways to ensure the accuracy of labels include:

- Install systems, checklists or policies that make sure product is packed in the right secondary packaging.
- When reformulating products, get rid of all packaging material or labels that do not state ingredients correctly.
- Similar products that contain different formulations (e.g. flavours) should have packaging with a different colour or other special identification. This prevents confusion.
- Use verification sheets to prove that labeling is being checked when the product is received, and where it is being used.

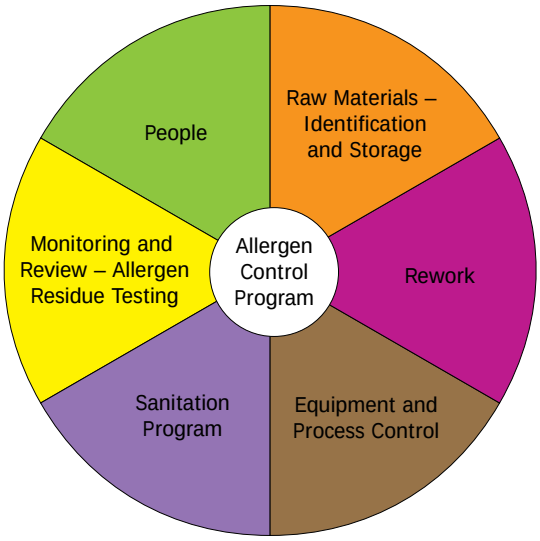
Any new labeling policies should be created with the purchasing and product development teams. Indicate on the label any recipe changes. Also be sure to include the addition of allergenic ingredients. This will help ensure that consumers do not mistakenly consume familiar products that have been redeveloped to contain allergens.

Schedule regular verification or reviews. Make sure that all ingredients are declared correctly on each approved label. Do the same whenever ingredients change or substitutions are made.

4.0 ALLERGEN TRAINING

For all these procedures and policies to work in controlling the facility's allergens, employees must be trained and aware. As the figure below shows, people are a critical part of the ACP.

Functional Allergen Control Program



It only takes one untrained employee for an undeclared ingredient to turn up in products.

All staff who handle and order ingredients, equipment, packaging and finished products must be aware of food allergens. This includes temporary workers, contractors, and management. They must all be aware of the dangers posed for people with allergies.

Train everyone working at the facility on:

- Which allergens are of concern;
- How to avoid cross-contamination;
- How to notify management of allergen concerns during production;
- Policies related to allergen control;
- Handwashing;
- Clothing requirements;
- Waste control;
- Rework control;
- Cleaning procedures;
- Dedicated equipment;
- Storage procedures;
- Labeling procedures;
- Production scheduling;
- Recipes and formulation; and
- Results from sensitive individuals eating allergens.

Most recalls are triggered by products containing allergens. These allergens are not declared clearly on labels.

Communication is very important to allergen control procedures and policies. Make sure that:

- Detailed procedures on allergen controls are readily available;
- Information on prevention of allergen contamination is readily available;
- All information is visible in manufacturing areas;
- All employees know about this information and where to find it; and
- All employees are told about any changes to policies, procedures or formulations (ingredient requirements).

5.0 ALLERGEN FORM TEMPLATES

G.1 Allergen Checklist for Food Suppliers or Manufacturers

G.2 Allergen Validation Record

G.3 Formula/Product Allergen Reference

G.4 Ingredient Allergen Reference

G.5 Production Process Allergen Assessment

6.0 SOURCES OF INFORMATION

1. Anderson, Allen E. *Designing an Allergen Control Plan*. Food Quality Magazine (July/August 2003).

2. Goodwin, Philip R. *Food Allergen Testing*. Food Quality Magazine (April/May 2004).

3. American Bakers Association. *ABA Allergen Usage Guidelines* (2000).

4. AIB International. *Allergen Information Manual and Auditor Guidelines* (2002).

5. Food Standards Agency *Guidance on Allergen Control and Consumer Information* DRAFT (2005).

6. Australian Food and Grocery Council. *Food Industry Guide to Allergen Management and Labelling* (October 2002).

7. Peach, Robert W. et al. *The Memory Jogger 9000/2000 – A pocket guide to implementing ISO 9001* (2000).

Chapter 12

SUPPLIER FOOD SAFETY ASSURANCE

1.0 PARTS OF A SUPPLIER FOOD SAFETY ASSURANCE PROGRAM

2.0 CHOOSING SUPPLIERS
- 2.1 Supplier Approval
- 2.2 Approved Supplier List

3.0 PRODUCT SPECIFICATIONS AND CONTROLS
- 3.1 Product Specifications
- 3.2 Certificate of Analysis
- 3.3 Letter of Continuing Guarantee

4.0 EVALUATING SUPPLIERS
- 4.1 Incoming Product Control
- 4.2 Supplier Audit

5.0 CORRECTIVE ACTIONS

6.0 SUPPLIER FOOD SAFETY ASSURANCE FORM TEMPLATES

7.0 SOURCES OF INFORMATION

A chain is only as strong as its weakest link. Food from unsafe sources is one of the most common causes of foodborne illness and product recalls. Making sure that a facility is hazard free is good food safety practice. However, it's also very important to make sure that sources of incoming materials are hazard free.

Ensuring that incoming materials are free from hazards is the best way to keep dangers away from the food and the facility.

A safe finished product depends on using safe materials in production. A good Supplier Food Safety Assurance (SFSA) program helps ensure that happens.

An SFSA is a formal agreement between a facility and its suppliers. It ensures that those who provide materials will meet stated standards in the products they deliver.

SFSA agreements help create confidence when developing a food safety system. For example, a facility may reduce how often it monitors for a potential hazard because its suppliers have met SFSA requirements in procedures, controls and records.

1.0 PARTS OF A SUPPLIER FOOD SAFETY ASSURANCE PROGRAM

Having many suppliers can reduce control over food safety. The reduced control of sourcing raw materials from many suppliers can outweigh its economic benefits. An important part of a good HACCP system depends on knowing that suppliers understand and assist in controlling hazards in a facility's products.

A strong SFSA program includes:

- A supplier approval program for ingredients, packaging and other services or supplies that may affect food safety;
- An Approved Supplier List;
- Requesting and maintaining (where possible) on file a Letter of Continuing Guarantee from each supplier;
- Supplier performance evaluations;
- Plans for buying from 'non-approved' sources in emergencies;
- Incoming material specifications (if necessary, ask suppliers for input on the facility's incoming product specifications);

- A written specification change procedure to organize and record all changes; and
- Incoming product and release protocol (e.g. based on Certificate of Analysis or internal testing) for the facility's receiving department. This ensures that incoming materials meet required or agreed upon specifications.

By having an agreement with a supplier, the supplier shares responsibility for a safe final product. Share as much information as possible with suppliers when developing and running the facility's food safety system. Good communication helps ensure that the facility's food safety information is up-to-date and correct.

Determine if any materials that arrive could affect food safety. This includes not only raw ingredients and packaging, but also those materials that are added indirectly to the product, such as processing aids. For example, in a smoked product, wood chips (or wood byproducts such as sawdust) are used to produce a natural wood smoke ingredient. In this case, sawdust should be controlled in the SFSA.

Controls involve setting the specifications, or conditions, that arriving materials must meet. It also means that the facility must check those products to confirm their standards. How much each product is controlled depends on what the risks are, and how further processing could affect the risks.

2.0 CHOOSING SUPPLIERS

The first level of control in the SFSA is the Supplier Program. This involves picking the right suppliers.

Ensure that the raw materials, services and other materials received from suppliers are safe. Using approved suppliers is a big first step toward this.

Choosing a supplier that can deliver a safe product should be the goal. Consider the following guidelines when selecting and keeping suppliers:

- Ask suppliers what type of food safety systems they have in place. Facilities with HACCP systems in place or certified against one of the Glabal Food Safety Initiative standards may require less investigation than those without.

- Find out whether suppliers are manufacturers or wholesale warehouses. Find out whether they receive raw materials, products and services from licensed and dependable sources.
- Before signing an agreement, inspect the supplier's warehouse or facility. This is especially important if they supply high-risk products or if there are questions about their food safety systems.
- Once an agreement is in place, check on the supplier from time to time. Check that the supplier's facility remains clean and well run. Base the frequency of these assessments on the risk level of the supplies provided.
- Find out what kind of food safety training the supplier provides to its employees.
- Examine the condition of the supplier's delivery trucks and equipment. These regular "mini" assessments will help shed light on their food safety practices.
- Monitor the supplier's products. Make sure your suppliers provide consistently quality and safe products. The type and level of monitoring will depend on the risk associated with the incoming materials.

Be sure that suppliers are committed to food safety. This commitment can have several benefits. Besides helping product safety, it may also improve the facility's profitability. It can do so by increasing the shelf life of ingredients and finished products.

2.1 Supplier Approval

Get started on supplier approval by sending a simple questionnaire to potential suppliers. How the questions are answered will help to determine if a supplier can meet the facility's food safety requirements.

Here are some questions to consider asking suppliers:

- Does the supplier have a product that meets the contracting facility's specified requirements?

- Is the supplier licensed or permitted by the appropriate regulatory body?
- What types of food safety programs do they now have?
- What is the age and condition of the facility?
- What types of third party or outside audits are done?
- Do they have an SFSA?

After the initial assessment, it is useful to do formal, written and/or visual evaluations. These evaluations can be obtained a variety of ways:

- Checking the supplier's knowledge of manufacturing processes. Look at their process flow diagrams, identification of critical control points, monitoring programs and corrective action or verification procedures.
- Checking the supplier's knowledge of the wholesale process. Look at their product handling procedures, stock turnover programs and corrective action or verification procedures.
- Look for information showing the suppliers can continue to meet product specifications (e.g. able to pass in-house or contracted analytical testing).
- Check their random supplier performance evaluations. These assessments may include internal audits or inspections, third party audits and/or questionnaires.
- Make sure that documents are provided by the supplier to confirm product safety. Examples include Certificates of Analysis and Letters of Continuing Guarantee.
- Decide what actions will be taken if a supplier does not meet requirements (e.g. requests for corrective action).

On-site Visits

To confirm the food safety programs of potential suppliers, it's good practice to visit their facility. Prepare a simple checklist covering important product safety concerns. Use this list to assess the facility during the tour.

Develop separate checklists to assess manufacturing and warehousing facilities. This allows for focusing on the food safety issues important in each type of facility environment.

See Form H.7: Supplier Audit Checklist, Form H.6: Supplier Approval Questionnaire and Form H.5: Supplier Approval Letter.

Consider what is observed on a tour. Use the information to decide if the supplier can meet safety needs. This is a more direct means of supplier evaluation than supplier questionnaires and can be more suitable for products with a high potential for food hazards.

2.2 Approved Supplier List

Once suppliers are decided on, set up an Approved Supplier List. This list will change as suppliers are added or removed and depending on the supplier's performance.

The Approved Supplier List should include:

- What product(s) the supplier is approved for;
- Whether the product is supplied from a wholesaler. If so, include the name of the manufacturer, address, and contact information;
- Details of the supplier name and individual contact information. Get an emergency contact in case of recall;
- Date of approval, and date the supplier started working with the contracting facility; and
- Date and signature of person(s) in the contracting facility responsible for this list.

Some facilities add to their list:

- The facility's name or code for the product being purchased;
- Shipping method or how the item is delivered (e.g. truck, mail, etc.);
- Whether it is bought from a local wholesale market and picked up by staff members; and
- Supplier code number and an explanation of the lot code of the incoming materials.

Enter all this information as soon as the supplier is approved. Update it each time a supplier is added or dropped. Review this list at least once a year. Make sure that all information is up-to-date.

Keep the updated list available to all staff involved in purchasing and receiving. This helps ensure that only the right materials are brought in.

Make sure that old versions of this list are kept and are easy to find. That way, if there's a problem or recall related to any raw materials it's possible to find out who supplied them. The supplier can then be contacted.

See Form B.2: Approved Suppliers List.

3.0 PRODUCT SPECIFICATIONS AND CONTROLS

The second level of control in SFSA is the Product Program. These programs ensure that material from the supplier meets stated specifications.

When raw materials arrive at the facility, be aware of important food safety characteristics. These characteristics or special features can be:

- Chemical (e.g. antibiotic residues, amount of preservation agents);
- Physical (e.g. free from metal contaminants);
- Microbiological (e.g. presence or amount of pathogens or spoilage organisms);
- Sensory (e.g. flavour, texture or odour that may indicate spoilage);
- Allergenic (e.g. residues that may cause reaction in sensitive individuals); and
- Visual (e.g. condition of packaging materials or carrier vehicle).

A facility must decide on what specifications and characteristics are acceptable.

Besides conditions that are important to the safety of the food product (e.g. water content, microbiological levels), there are other things to keep in mind. Examples include the amount of extra materials allowed, temperature of the received products and food particle size. These other requirements may be set by industry, consumers or facility needs.

3.1 Product Specifications

Product specifications are requirements that a product must meet. Specifications may include acceptance criteria or expectations, a list of tests, and analytical procedures. They may also include required or allowed (numerical) limits or ranges for the test results.

Acceptance criteria refer to the specified limits for the amount or presence of contaminants, impurities or foreign material. A lot, batch or shipment must be within these limits to be accepted into the facility.

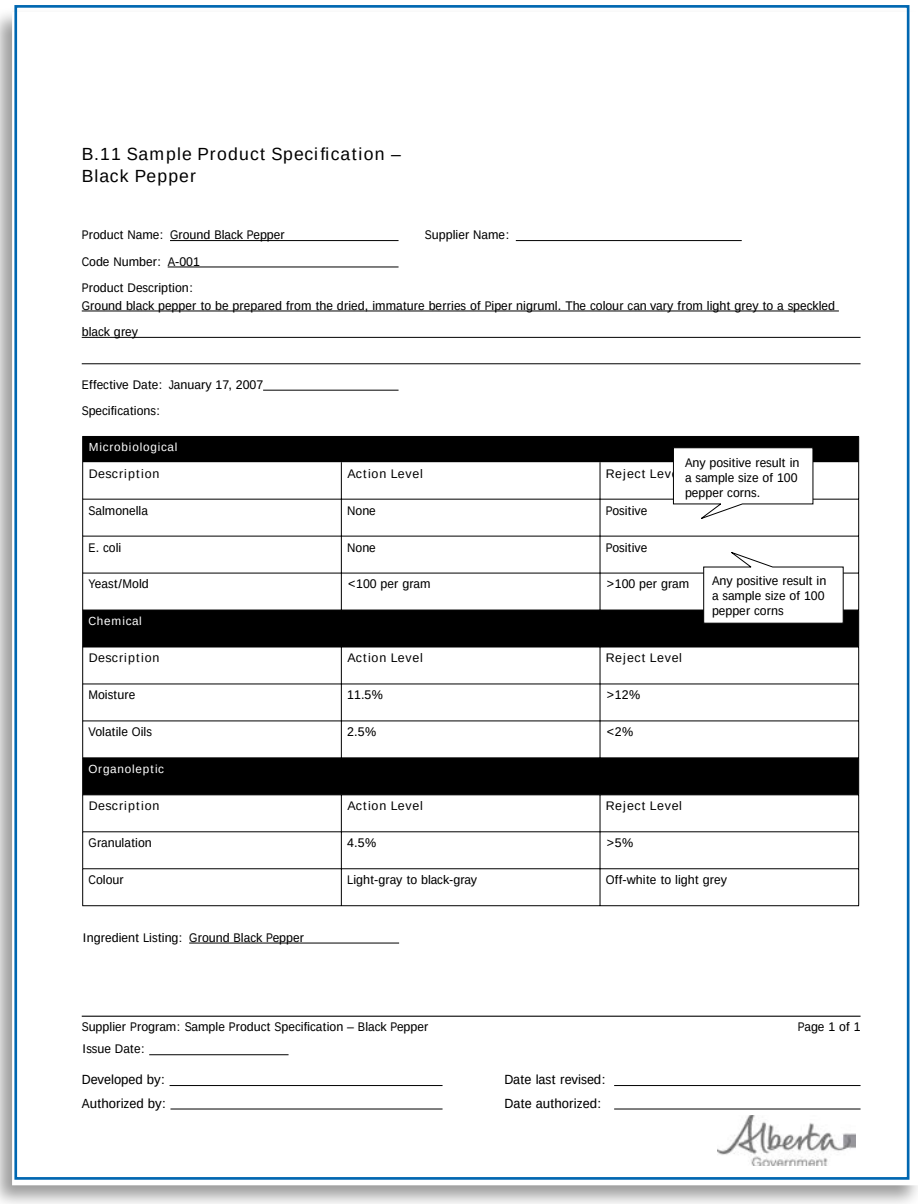
Document the product specifications to make sure they're in line with the facility's food safety needs. Product specification documents should include:

- Name of ingredient, packaging material, or chemical;
- Internal code number;
- Effective date;
- Description of product;
- Specifications or acceptance criteria;
- Accept or reject levels;
- List of ingredients;
- Allergen information;
- Signature of reviewer (e.g. receiver, Quality Assurance personnel); and
- Date of the most recent review.

The product specification document will become an important control tool for the facility. Make the information under each heading simple but useful.

Suppliers are the best starting point for developing product specifications. Try to discuss and agree upon acceptable criteria with each supplier directly.

B11: Product Specification – Pepper



B.11 Sample Product Specification – Black Pepper

Product Name: Ground Black Pepper Supplier Name: _____

Code Number: A-001

Product Description:
Ground black pepper to be prepared from the dried, immature berries of Piper nigruml. The colour can vary from light grey to a speckled black grey

Effective Date: January 17, 2007

Specifications:

Microbiological		
Description	Action Level	Reject Lev
Salmonella	None	Positive
E. coli	None	Positive
Yeast/Mold	<100 per gram	>100 per gram
Chemical		
Description	Action Level	Reject Level
Moisture	11.5%	>12%
Volatile Oils	2.5%	<2%
Organoleptic		
Description	Action Level	Reject Level
Granulation	4.5%	>5%
Colour	Light-gray to black-gray	Off-white to light grey

Any positive result in a sample size of 100 pepper corns.

Any positive result in a sample size of 100 pepper corns

Ingredient Listing: Ground Black Pepper

Supplier Program: Sample Product Specification – Black Pepper Page 1 of 1

Issue Date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Alberta Government

Have a process to record changes to specifications. Specifications may change for various reasons, ranging from changes in suppliers to recipe changes. Therefore, each specification should be reviewed and updated at pre-determined intervals. This protects food safety in the finished product. Make sure employees work from the most recent specifications.

3.2 Certificate of Analysis

A Certificate of Analysis (COA) is a document from a supplier that states the identity, purity or microbiological state of a product. It shows that the supplier completed the required testing and that the results meet the product specifications. If this information does not meet the facility's needs completely, get the required information from the supplier.

Some important components of a COA are:

- Date of the COA;
- Name and address of the supplier;
- Name and contact information of the product's processor, if not the same as the distributor;
- Name/UPC (Universal Product Code) number of the product;
- Product lot number;
- Description of tests conducted;
- Test specifications and results; and
- Name, title and qualifications, or training, of person certifying the analysis.

Sample Certificate of Analysis.

- This form should be customized to suit individual facility requirements.

Certificate of Analysis

Supplier Details Company Name: _____
Address: _____

_____

Company Quality Assurance Contact Name: _____

Product Details
Product Name and UPC Code: _____

Date of Manufacture: _____

Process Lot Number: _____

PROCESS TESTING

Attribute	Range of Acceptability	Results	Corrective Action

Microbiological Testing and Food Safety Characteristics

Analysis	Specification	Results	Corrective Action
TPC			
Coliform			
E. coli			
Visible Foreign Material			
Metal Contamination			
Other			

Packaging Integrity

Analysis	Specification	Result	Corrective Action
Seal Integrity			
Weight Control			

Signature/Accreditation of Responsible Personnel: _____

Date of Analysis: _____

Supplier Program: Certificate of Analysis Page 1 of 1

Issue Date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Alberta Government

When the facility receives the COA, review it and compare it to the product specification document. Follow up on any deviations or results that differ unacceptably from acceptance criteria. Investigate and reject those lots that do not meet requirements.

If the COAs received for one product continues to stay outside acceptance criteria, it may be necessary to check into the values for acceptance. This may show that the requirements need to be changed.

Keep all COAs on file longer than the shelf life of the products analyzed. Industry consensus is to keep them for one year after the product's shelf life expires.

3.3 Letter of Continuing Guarantee

Ask for Letters of Continuing Guarantee (LOCG) from all suppliers. Do this for each product supplied. This letter should state that:

- The supplier guarantees their product is not in any way adulterated, or contaminated, and meets food regulations;
- All allergens are listed; and
- The contracting company will be informed of any changes to the formulation (ingredients or way the product is made).

Every year, check and update all LOCGs. Have them signed and dated by a senior manager from the supplying company. These letters do not replace the Certificates of Analysis supplied with each lot or shipment of supplied product.

Letter of Continuing Guarantee.

Sample Letter of Continuing Guarantee

(to be sent from an approved supplier)

(Supplier Company Letterhead)

The Undersigned, _____ (seller)
With offices located at: _____ (address)
_____
_____
_____

Hereby certifies that:

The articles comprising each shipment or other delivery made hereafter is guaranteed as of the date of such shipment, to be on such date; 1. Not adulterated or misbranded within the meaning of Federal or Provincial Food and Drug acts, 2. Not an article which may not be introduced into commerce by the same acts, and 3. Not in violation of the regulations of any other governmental authority.

The seller further guarantees that if any article contains a colour additive or allergen, said additive or allergen has been, is and will be identified as present in the ingredient listing.

The Seller does agree to indemnify and save the Buyer from and against any and all charges, actions, and proceeding brought by any governmental authority against the article or the Buyer for, or on account of, any alleged violation for which the Seller is responsible, by reason of the guarantees a, and b in the paragraphs above, including the loss and reasonable expenses if any, incurred by the Buyer as a result thereof.

The guarantees given herein are continuing and shall be in full force and effect until revoked in writing.

Signature of Officer: _____

Name: _____
Title/Detail of Qualifications: _____

Date: _____

Supplier Program: Sample Letter of Continuing Guarantee Page 1 of 1

Issue Date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Alberta Government

4.0 EVALUATING SUPPLIERS

Just as with a facility's other programs, the SFSAs must have procedures to check how well supplier controls are working. The SFSAs should be verified or checked by knowledgeable staff. Verification points include:

- Inspection of incoming materials;
- On-site audits of suppliers;
- Input material testing; and/or
- A combination of all three.

If specific controls are defined in the facility's supplier food safety agreements, it is best to do some form of on-site verification.

4.1 Incoming Product Control

One place to verify supplier controls is at receiving when supplies reach the facility. Do this by documenting and recording receiving procedures. Documents must confirm that incoming materials meet the facility's product specifications.

Receiving procedures may include:

- Getting a Certificate of Analysis from the supplier;
- Visual inspection at receipt; and
- Analytical laboratory testing.

The receiving procedures chosen will depend on the risk involved with each product.

In some situations the facility's program may require only random spot checks of incoming materials. This is true for incoming materials with a low risk of food safety hazards. It's also true for products where hazards will be reduced to safe levels during further processing.

For higher risk product(s) that have no controls later in processing, it's a good idea to check each individual shipment and make sure they meet specifications.

Analytical Laboratory Testing

Testing may be done to determine the presence or amounts of chemical, biological or physical contaminants. This would include testing for allergens, preservatives or any contaminants. Depending on the facility's resources, tests can be done in-house or contracted out.

All tests should be done by qualified personnel. They must be able to prove they have the knowledge, skills and abilities to produce accurate results.

The test equipment should be reliable and regularly calibrated, or adjusted. Keep a record of the test equipment checks. Compare the results to nationally recognized reference standards and information. If resources are available, check test equipment in-house. Otherwise, send the testing equipment to a certified outside laboratory.

Keep records of all tests for a period of one year or longer than the shelf life of the equipment tested.

4.2 Supplier Audit

Some facilities use supplier audits to confirm the effectiveness of supplier food safety systems.

In a supplier audit, someone from the contracting facility visits the supplier's facility. For products with higher food safety risks, supplier audits help maintain safety controls over incoming materials.

The supplier audit should confirm:

- **Management Commitment** – Make sure that the supplier's plant manager(s) and corporate management encourage and support attention to food safety.
- **Fundamentals** – Check that the supplier's facility and equipment are well maintained. Make sure they allow for sanitary operations and have a well-documented plant and equipment sanitation program. Look to see that actions and records show all programs and SOPs are followed. Confirm that all of the following lead to safe, quality production:
  - Pest control;
  - Chemical control;
  - Personnel training;
  - Material handling and storage;
  - Recall; and
  - Maintenance programs.

- **Food Safety Systems** – Verify that there is a well-developed, written food safety system. Make sure this system includes procedures and records. A preventative program, such as HACCP, should be in place.
  Find out about the use of end product control, microbiological testing and/or foreign material and allergen control. Ask if the suppliers are audited by a third party and if they are willing to reveal the results of their audits.
- **Manufacturing Quality Program** – Where applicable, confirm that the supplier has a program to inspect or test the quality of finished products.
- **Regulatory Requirements** – Check that all required regulations are followed. Also ensure that there's a way to review the corrective actions taken when these regulations haven't been followed.

See Form H.7: Supplier Audit Checklist.

5.0 CORRECTIVE ACTIONS

Another part of the SFSA may be a Supplier Corrective Action Request (SCAR). This is used when evaluations have been done, but the supplier still isn't meeting requirements. This non-conformance information is sent back to the supplier and they are then required to investigate and find the cause of the deviation or problem.

See Form H.9: Sample Supplier Corrective Action Request.

Try to get the supplier to provide documents showing that the problem was found and corrected. These documents should prove that steps were taken to prevent the problem from happening again. Documents may include inspection checklists, operator training records or a change to the process.

The SCAR ensures that there is a way to provide feedback when supplier performance is below standards.

Every time a supplier is given a SCAR, record it in the facility's Supplier Corrective Action Log. A Supplier Corrective Action Log confirms that the facility follows up on issues about supplied products. It also allows the facility to track any continuing problems in follow-up with the supplier in question.

See Form H.8 Supplier Corrective Action Request Log.

6.0 SUPPLIER FOOD SAFETY ASSURANCE FORM TEMPLATES

H.1 Certificate of Analysis

H.2 Corrective Action Request

H.3 Sample Letter of Continuing Guarantee

H.4 Product Specification – Pepper

H.5 Supplier Approval Letter

H.6 Supplier Approval Questionnaire

H.7. Supplier Audit Checklist

H.8. Supplier Corrective Action Request Log

7.0 SOURCES OF INFORMATION

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4. U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition. *Draft Report of the Food Advisory Committee Dietary Supplement Working Group on Ingredient Identity Testing, Records and Retention* (1999).

5. Hernandez, Jorge. Supplier Relationships Are Key to Safe Food Receiving. Food Management (March 2006). www.food-managment.com/article/11629/.

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Chapter 13

PRODUCT PROTECTION PROGRAM

1.0 PREREQUISITE PROGRAMS

2.0 IDENTIFICATION AND CONTROL OF CRITICAL FACTORS

3.0 CRITICAL PROCESSING STEPS AND CRITICAL FACTORS

4.0 MONITORING CRITICAL FACTORS

5.0 DEVIATIONS AND CORRECTIVE ACTIONS

6.0 DOCUMENTATION OF CRITICAL FACTORS

7.0 VERIFICATION OF CRITICAL FACTORS

8.0 TRAINING STAFF IN PRODUCT PROTECTION PROCEDURES

9.0 SAMPLE PRODUCT PROTECTION PROGRAM

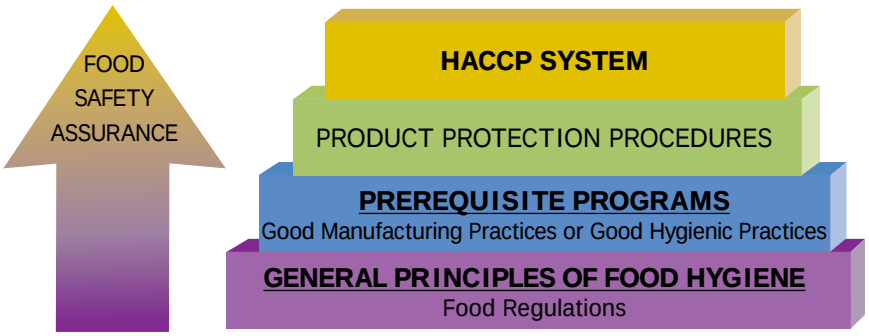
10.0 SOURCES OF INFORMATION

Food processors that **do not** have HACCP plans in place should follow the steps in this chapter to control food safety. This chapter may be less important for those processors who already **do** have HACCP plans in operation.

A *Product Protection Program* allows processors to increase food safety and helps to meet the basic requirements of HACCP – without setting up a full HACCP plan.

A product protection program helps make sure that a company is noticing, monitoring and recording information about food safety procedures. All food processing companies should already be meeting food regulation guidelines. Therefore, a product protection program may not be very different from the food safety procedures a company already has.

Figure 1



If the facility is just starting to put together a food safety system, the product protection program should be worked out first. Developing and putting in place a program can take several months. During this time it's very important to have a product protection program to control food safety issues.

Create the product protection program at the start of food safety system development. During this period, it's very important to have a product protection program to control food safety issues.

Prerequisite programs provide the basic operating conditions to produce safe foods. A product protection program controls the most important steps in the process. It also sets up important records that prove safety controls are in place.

Product protection programs may be used in the short term while developing and putting in place a HACCP plan or it can become another food safety tool. It can be used by processors who already monitor critical points, but who don't have a formal documentation process set up yet.

1.0 PREREQUISITE PROGRAMS

There are common hazards in food operations that are found in many facilities. These hazards include foreign objects, pests or germs that contaminate food during production and handling. Prerequisite programs can generally control these hazards.

A prerequisite program allows a company to operate in conditions that produce safe food. Prerequisite programs set up the procedures that are part of the HACCP system including Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP).

Good prerequisite programs improve food safety. They also help reduce the number of things the food processor has to keep an eye on.

The main prerequisite programs that help in creating a product protection program are:

- Employee practices;
- Equipment;
- Sanitation practices; and
- Specific and general facility maintenance.

Make sure the company has procedures in place so that none of these activities will lead to product contamination.

See Chapters 4 to 12 for more information on prerequisite programs.

2.0 IDENTIFICATION AND CONTROL OF CRITICAL FACTORS

It's important to develop a product protection program and to control critical factors. These can be done by following these food safety principles:

- Conduct a hazard analysis;
- Determine the critical factors;
- Set critical limits;
- Decide on actions to take when a critical factor or something important is not under control;

- Put in place a system to monitor or control the critical factors; and
- Set up verification – checking procedures – to confirm that the product protection program is working.

These are also the basic principles behind the development of a HACCP plan.

No program is under control without a managing system that documents and records operations. Make sure the company has adequate and correct documentation. This helps create a cost-effective operation. In other words, it helps save money. It also guarantees that all food safety information is documented in official files, where all staff members who need it can find it.

See Chapter 14: Developing and Implementing a HACCP Plan for more information on hazard analysis, as well as understanding and controlling critical factors.

See Appendix D: Food Safety and Risk Analysis for information on how serious or how likely various hazards are, and for help in choosing the right control measures.

3.0 CRITICAL PROCESSING STEPS AND CRITICAL FACTORS

In the food production process there must be steps to get rid of and prevent foodborne hazards. There must also be steps to reduce some hazards to safe levels. The facility's product protection plans should point out these steps and should show ways to control them. It should also put this important information in writing.

Each critical processing step has certain key factors, or requirements, which make that step work well. If any of these requirements aren't fully met, it can affect the safety of the finished product.

There may be more than one critical factor for each processing step. For example, one important processing step may be cooking a product. This will reduce germs to safe levels in raw materials.

How well this step works depends on several key requirements and some examples include how long and at what temperature the product is cooked. If these set limits aren't met, this step might not destroy enough germs to make food products safe.

Some examples of critical process steps and their contributing critical factors are:

Critical Process Steps	Critical Factors
Cooking	Time, temperature
Cooling	Time, temperature
Formulation	pH, concentration (e.g. parts per million – ppm and nitrite levels)
Dehydration	Water activity
Chemical treatment	Ozonation (ozone levels)
Metal detection	Sensitivity (test sphere)
Freezing (fish, pork, wild game) for parasite control	Time, temperature
Skinning	Microbiological factors
Sifting	Mesh size
Chlorination	Concentration, volume
Filtration	Filter size

Critical limits are the lowest and/or highest allowable levels for critical factors. These relate to each key processing step. Reaching or staying within these limits means the difference between a product being safe or unsafe, or a product being acceptable or unacceptable.

Critical limits should be based on government regulations, industry standards, scientific findings, and/or risk levels related to the product (see Appendix D: Food Safety Risk Analysis).

Each critical limit should be set or defined clearly and should be measurable whenever possible. When monitoring a sample, if a result is outside the defined limit there is a deviation – a situation that isn't normal. It's important to correct these abnormal or unusual situations right away.

4.0 MONITORING CRITICAL FACTORS

It isn't enough to simply have controls. To provide the greatest food safety, the controls must be tracked – or monitored – to make sure they're inside critical limits. Monitoring includes regular measuring and recording of values (results) at certain fixed times.

Use monitoring to constantly check all critical factors. Activities could include:

- pH and temperature tests;
- Visual observations; and
- Checking documents.

While monitoring critical factors, it's also important to check on employee practices. Also check on equipment, sanitation practices, and both specific and general facility maintenance. Again, have procedures to prevent these factors from causing product contamination.

Decide ahead of time all procedures for monitoring and put them in writing. This document should show who will do the monitoring, how often, and what the critical limits are. It should also show what corrective actions to take when there is a deviation or something goes wrong.

Monitoring should allow for corrective actions immediately, before the situation gets out of control. The frequency of monitoring will depend on the risk related to the product. It also depends on how hard it is to monitor within the operation.

Examples of records that could be used as part of a production protection program include:

- Calibration record;
- Action taken record;
- Recording charts;
- Quality control pasteurization verfication records;
- Quality control audit records;
- Product deviation records;
- Records of discussions; and
- HTST equipment and controls test records.

5.0 DEVIATIONS AND CORRECTIVE ACTIONS

When a critical limit is not met, a deviation has occurred. This may be because of a failure in standard operating procedures (SOPs) or in a prerequisite program.

For each possible deviation, decide on a corrective action. Write down procedures for each corrective action and make sure all employees know them and follow them.

Training employees on corrective actions ahead of time gives them clear direction on what to do if a deviation occurs. If workers are trained in using this knowledge, they often will realize when something goes wrong.

However, because staff may lack the necessary skills, they might be unwilling or unable to correct the deviation. In additional, they might not be able to correct the deviation quickly enough. Documenting and training staff in corrective actions helps to make sure that consistent action is taken. It also provides records that can point out unusual patterns.

Corrective actions should:

- Make sure that the critical factor is brought back under control;
- Prevent unacceptable product from reaching consumers;
- Prevent a deviation from happening again; and
- Allow for changes to the process or to the monitoring to make them work better.

Corrective action documents should state:

- Date and time the deviation is noticed;
- What the deviation is;
- Corrective actions to be taken;
- Name of the employee responsible for taking the corrective action; and
- Date, time and signature of employee responsible for confirming that the corrective activity was done as required.

Corrective actions can be recorded directly onto related records. It might be useful to develop separate corrective action request forms as stand-alone records. Again, these may be useful in spotting problem trends.

6.0 DOCUMENTATION OF CRITICAL FACTORS

The documents required in a product protection program include:

- Written procedures for how critical factors will be controlled in the facility; and
- Records to show that these procedures are followed, and that the critical limits are met.

These documents should prove that monitoring and verification happen often enough to protect food safety and that critical limits for food safety are met.

The company should also be able to show that:

- Monitoring and verification are recorded at a reasonable frequency; and
- Deviations and corrective actions are recorded when critical limits aren't being met.

All documentation created provides a historical record of the company's process and monitoring. It also shows any deviations and the related corrective actions taken. If there is a problem, exact records help to trace back or troubleshoot.

See Chapter 3: Documentation and Record Keeping for more information on documentation.

7.0 VERIFICATION OF CRITICAL FACTORS

Someone other than the operator and monitor should verify that:

- Monitoring is being done as written in the product protection program; and
- Accurate and complete records are kept.

Verification procedures used to check the safety of the product also show how strong food safety controls are. Verification activities might include:

- Product sampling;
- Audits (detailed checks) of monitoring records;
- In-house inspections or audits; and
- Environmental sampling.

Verification procedures should involve a review of records, corrective actions, and onsite activities. This makes sure the monitor is checking activities correctly.

8.0 TRAINING STAFF IN PRODUCT PROTECTION PROCEDURES

Employees who are responsible for monitoring critical processing points should be trained to understand the importance of the critical limits. Staff must also be trained to understand procedures for monitoring these limits. They should also understand deviation procedures and how document control works.

Staff members who monitor critical processing points need training in the following:

- Their job functions;
- Filling out forms;
- Understanding reasons for certain corrective actions; and
- Understanding the importance of the processing step in the facility's product protection program.

When training staff members on how to monitor critical processing steps, teach them to keep these points in mind:

- Why the processing step exists;
- What the critical limits are;
- Procedures for monitoring the critical factors;
- Abnormal or unusual situations; and
- Effective documentation.

Comparing Skills and Knowledge

A food handler in a manufacturing facility prepares, stuffs, and cooks beef potpies.

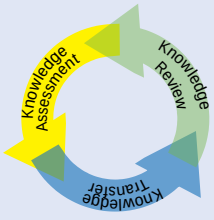
The staff member who does this work must have both food safety and food hygiene knowledge. They must have the skills to make sure that the end product is made safely.

The food safety and food hygiene knowledge needed for this job includes:

- **Knowing** that raw meat is likely to be contaminated with dangerous bacteria and that eating undercooked product could result in food poisoning;
- **Knowing** the right cooking time and temperature needed to make sure that products are cooked thoroughly;
- **Knowing** the correct storage temperatures for both the raw materials and finished products;
- **Knowing** that hands, gloves, or the equipment used to handle raw materials may contaminate finished products; and
- **Knowing** about other possible sources of cross-contamination that can affect the finished product, such as dirty clothes or equipment.

The food safety and food hygiene skills needed for this job include:

- **The skill** needed to check the product to make sure that it is cooked thoroughly;
- **The skills** needed to make sure that equipment is set at the right temperatures;
- **The skill** to wash hands and equipment in ways that reduce the possibility of cross-contamination; and
- **The skills** needed to keep the work area clean.



Based Upon - Food Safety Standards: Food Handling Skills and Knowledge. Australia New Zealand Food Authority © May 2001
http://www.foodstandards.gov.au/_srcfiles/39997-TF1a.pdf.

9.0 SAMPLE PRODUCT PROTECTION PROGRAM

Pasteurization in the Production of Unsalted butter

Raw milk, used in the production of unsalted butter, could contain pathogens. These are harmful substances that cause foodborne illness.

In production, a pasteurization step is needed to destroy these harmful pathogens. This must be done without affecting the quality of the finished product.

Assuming that the facility in this example has prerequisite programs providing a food safe environment, the following shows how a 'critical factor monitoring program' might look.

Hazard Description:

- Pathogen survives because of inadequate time and/or temperature of pasteurization.

Critical Limits:

- Pasteurization temperature not less than 75ºC (166ºF) for a holding time of not less than sixteen (16) seconds.

Monitoring Procedures:

- Operator monitors cut-in/cut-out temperature at start-up for each batch.
- Operator checks that the indicating thermometer reading is 75ºC (166ºF) and is recorded on the pasteurizer chart. (do we need to say how often they check?
- Operator checks that the recording thermometer is reporting the same temperature as the indicating thermometer.
- Operator records this temperature check information on the pasteurizer chart.
- Operator checks every day that the seal is intact on the flow control device.

Corrective Actions:

- Activate manual divert. Hold all the product processed since last satisfactory check.
- Inform quality control supervisor, who will decide on disposition (disposing of, or removing product).
- Investigate, identify and correct the cause of problem. (what does do quality control mean?).

Verification Procedures:

- Quality Control calibrates and checks (including thermometric response) the indicating and recording thermometers every three months.
- Quality Control reviews and verifies recording charts of every production batch for completeness.
- Quality Control double checks operator's monitoring procedures at least once a month.
- Quality Control verifies re-direction of affected batch.
- Quality Control verifies hold time, either when the system changes, or at least once per year.
- Quality Control verifies HTST equipment and control test results twice per year.

10.0 SOURCES OF INFORMATION

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Chapter 14

DEVELOPING AND IMPLEMENTING A HACCP PLAN

1.0 HACCP PRINCIPLES

2.0 HOW MANY HACCP PLANS ARE NEEDED?

3.0 STEPS IN THE DEVELOPMENT OF HACCP PLANS

- 3.1 Assembling the HACCP Team
- 3.2 Describing the Product
- 3.3 Identifying the Intended Use
- 3.4 Constructing a Process Flow Diagram and Plant Schematic
- 3.5 On-site Verification of Process Flow Diagram and Plant Schematic
- 3.6 Listing Hazards Associated with Each Step and Incoming Materials
- 3.7 Determining Critical Control Points
- 3.8 Establishing Critical Limits
- 3.9 Establishing Monitoring Procedures
- 3.10 Establishing Deviation Procedures or Corrective Actions
- 3.11 Establishing Verification Procedures
- 3.12 Establishing Record Keeping and Documentation Procedures

4.0 HOW TO FILL IN HACCP FORMS

5.0 COMMUNICATION

- 5.1 Communication Guidelines for HACCP

6.0 SOURCES OF INFORMATION

HACCP stands for *Hazard Analysis Critical Control Points*. It was first developed in 1959 and is based on the Codex Alimentarius. The Codex Alimentarius Commission is a committee of the United Nations Food and Agriculture Organization and the World Health Organization. This commission develops standards, guidelines and related texts on food safety.

The Codex Alimentarius Commission has worked to set up a standard method for HACCP program development including seven principles. These principles are now used worldwide to develop HACCP plans. They're also used by governments for standardized HACCP programs.

1.0 HACCP PRINCIPLES

HACCP plans are developed using the seven principles standardized by the Codex Alimentarius Commission. These seven principles are reflected in the HACCP plan steps. They cover repetition of food safety analysis and recording tasks to ensure product safety.

The HACCP plan must include:

- Preventative measures;
- Control limits;
- Monitoring procedures;
- Corrective actions;
- Record keeping; and
- Ways to verify that control procedures are followed and are adequate.

Principle 1: Conduct a Hazard Analysis

A hazard analysis is the process of identifying and evaluating hazards. This means looking at agents that might affect a particular food product, or raw ingredient. It looks at how this happens in specific processing operations.

A hazard analysis also includes collecting and evaluating information on each hazard. It examines the conditions that lead to hazards being present in food products and looks at how hazards increase.

A food safety risk assessment is then used to decide which hazards could affect food safety. It points out what should be dealt with in the HACCP plan.

For more information regarding food safety risk analysis, see Appendix D.

Principle 2: Determine the Critical Control Points

A critical control point (CCP) is a point, step or procedure outside of the prerequisite programs. It is a control measure used to prevent, eliminate, or reduce a hazard to an acceptable level. A CCP should be used at any point in a food safety system where loss of control could result in a health risk.

Correct determination of CCPs is very important for product safety. Decisions about CCPs involve (look at) places in the processing operation to prevent, reduce or eliminate the hazards noted.

A HACCP plan should determine CCPs based on each unique food product. This ensures that resources are focused in food safety risk areas.

Principle 3: Establish Critical Limits

Critical limits are hazard levels or standards that must be set for each CCP. Critical limits must be clearly defined and measurable whenever possible. For example a critical limit for a cooler might be that the temperature is 4ºC or lower. Above or below these points, a product or process is unsafe.

Principle 4: Establish Monitoring Procedures

Monitoring means checking to ensure a CCP is under control. It is done by testing, observing, or other means. Methods to monitor each CCP should be put in place. Show that the critical limit(s) are being met. Monitoring procedures should be conducted on-line and should provide immediate results. This enables the facility to take corrective actions immediately if necessary.

Principle 5: Establish Corrective Actions

Corrective actions are taken when CCP monitoring shows that a deviation or loss of control has occurred at a CCP or when results are outside of critical limits. They should be planned out in advance to ensure that problems can be taken care of immediately.

Corrective action must not only be taken when monitoring shows that loss of control has already occurred, but also when production could cause unsafe food in the future. For each CCP, there must be planned, written corrective actions.

The purpose of corrective actions is to:

- Regain control of the hazard;
- Decide how to deal with the affected product; and
- Prevent the problem from occurring again.

Principle 6: Establish Verification Procedures

Verification means to check on whether the HACCP system is set up correctly and is being followed. It involves tests, procedures and other means.

Principle 7: Establish Record Keeping and Documentation Procedures

Document all HACCP plans, including the prerequisite programs. Make sure monitoring and verification records are complete. Check them for accuracy.

Activities related to food processing should be documented to prove they are under control. Ensuring adequate and correct documentation will lead to efficient and economical operations. It means that food safety information is on file where staff can find it.

It's important to encourage good record keeping by all employees. Records should be legible and completed at the times of checks.

2.0 HOW MANY HACCP PLANS ARE NEEDED?

Each food safety system is designed specifically for the facility where it is used. The same is true for HACCP plans. The number of HACCP plans a facility needs depends on:

- Number of products produced;
- Variations between products (e.g. different ingredients or equipment); and
- Differences between production processes.

Sometimes it's necessary to group the facility's products into categories. Identify the differences between the categories.

It may be necessary to have a different HACCP plan for each category. Similar products, with similar production processes and hazards, can use the same HACCP plan. However, if the facility produces similar products, with differing hazards (e.g. allergens), these products must be separated out. The facility will need to develop a distinct HACCP plan to deal with each different product.

3.0 STEPS IN THE DEVELOPMENT OF HACCP PLANS

The development of a HACCP plan takes a lot of work and is more than just filling in forms. The development process should be based on the seven principles outlined earlier in this chapter.

HACCP plans should also follow the twelve steps listed below. These steps are recommended by the HACCP Working Group of Codex Alimentarius.

3.1 Assembling the HACCP Team (Step 1)

Look to the people who know the operation of the facility's business when picking the facility's HACCP team. At least one member of the HACCP team should be someone who is very familiar with the facility and its products.

See Chapter 2 for a detailed explanation of how to select the HACCP team.

3.2 Describing the Product (Step 2)

Describe each product and point out possible hazards in raw materials or in packaging materials.

Refer to the end of this chapter for information on How to Fill in HACCP Forms. There are a number of forms that will be noted throughout the remainder of this chapter that can be found in Appendix E.

To complete steps 2 and 3, fill in Form 1 and Form 2. Be sure to attach any necessary records.

A product description is entered on Form 1 and should include:

- The name(s) of products associated with this HACCP plan;
- The formulation (recipe) for the product(s) – generally attached to the primary form; and
- Important product characteristics (e.g. amount of free water in the food, acidity, preservatives used).

Form 2 further breaks down the formulation of the product(s) into basic parts. It starts with ingredients and continues through to packaging.

In certain products, hazards are prevented by:

- Acid levels in the final product;
- Available free water in the final product; or
- Microbial growth inhibitors (e.g. nitrite, sulphites).

The product composition or make-up can be important to product safety. Also consider whether the composition needs to meet regulatory requirements. If so, formulation may once again be a CCP, since the facility's food safety system must meet regulations.

3.3 Identifying the Intended Use (Step 3)

The intended use of a product should be based on how end users or consumers normally use it. Steps to identify the intended use include:

- Description of how the product is intended to be used (e.g. ready-to-eat, refrigerated, to be cooked or further processed, heated prior to consumption, frozen, etc.);
- Description of the intended customer, including those with special needs or requirements (e.g. infants, food sensitive people, seniors, etc.);
- Shelf life of the product;
- Type of packaging used, including material and packaging conditions (e.g. modified atmosphere); and
- Labeling and special distribution instructions.

3.4 Constructing a Process Flow Diagram and Plant Schematic (Step 4)

To complete steps 4 and 5 fill in HACCP Forms 3 and 4.

A process flow diagram and plant schematic give the HACCP team an overall view of the manufacturing process.

The process flow diagram (Form 3) will identify the important process steps in the production of the product(s). The plant schematic (Form 4) will show product flow, employee traffic, equipment layout and hand-wash facilities. It will help to show possible cross-contamination points.

3.5 On-site Verification of Process Flow Diagram and Plant Schematic (Step 5)

Compare the draft versions of the process flow diagram and plant schematic to actual on-site activities and facility layout. Remember, the process flow diagram and plant schematic must show the *actual* conditions in the facility and not the ideal conditions.

3.6 Listing Hazards Associated with Each Step and Incoming Materials (Step 6 and HACCP Principle #1)

This step is associated with Codex Principle 1. The information is entered directly on Form 2, Form 3, and Form 4. All hazards need to be identified so that controls can be put in place. Be sure to enter a B, C, P, or A beside all incoming materials that have biological, chemical, physical, or allergenic hazards associated with them.

Background Research

Before starting the hazard listing, it may be necessary to do some background research. The team will need an up-to-date understanding of all hazards related to the facility's production process and products. They will need current information on all raw materials and the ingredients that go into them.

There are several sources that can be used in background research including:

- **Canadian Food Inspection Agency's (CFIA) Hazard Identification Database** – The CFIA has developed a hazard identification database that is available to industry and inspection staff. To access this database, visit the CFIA website at www.inspection.gc.ca.
- **Appendix B of This Publication** – Appendix B has a list of questions about hazard identification that a facility's team should ask. Although it doesn't cover all areas, it points out controls that may be necessary.
- **Reference Texts** – Depending on the experience and knowledge of the facility's HACCP team members, a simple review of current texts on HACCP, food microbiology, processing and plant sanitation might be useful.
- **Food Safety Consultants** – Food safety consultants can help a facility. Alberta Agriculture and Rural Development (ARD) has a list of Alberta-based food safety consultants listed on their website at: www.agric. gov.ab.ca/app68/agriprocessors?cat1=Food +Consultants#15391

Alberta Agriculture and Rural Development (ARD) has developed a fact sheet: How to Select a Food Safety Consultant. Find it online at www.agriculture.alberta.ca/foodsafety

- **Food Processor Organizations** – There are many food processor associations or organizations that can help in the development of HACCP plans. Contact an ARD Food Safety Specialist to find out what resources are available.
- **Complaint Files** – A facility's complaint file may provide a great deal of information on issues the facility is facing.

Reviewing Incoming Materials

Use HACCP Form 1 and 2 to complete this task. Review Form 1 and get a complete understanding of the facility's product(s), and how these may affect findings.

On HACCP Form 2, for each incoming material, write a letter A, B, C, or P directly beside the related material. These indicate if there is an allergen, biological, chemical or physical hazard. Every time a hazard is identified on HACCP Form 2, transfer it into HACCP Form 5 (Hazard Identification and CCP Determination) by filling in the first two columns.

Evaluate the Facility's Operations

This identifies all the hazards associated with each processing step.

Use HACCP Form 3 (Process Flow Diagram) and HACCP Form 4 (Plant Schematic) as references. Give a number to each processing step on the process flow diagram. Then for each process step, write a letter A, B, C, or P directly beside each step number on Form 3. This shows if a hazard exists from an allergenic (A), biological (B), chemical (C), or physical (P) source. Each time a hazard is identified on HACCP Form 3, transfer it into HACCP Form 5 (Hazard Identification and CCP Determination) by filling in the first two columns.

Observe Actual Operating Practices and/or Take Measurements

It's important that a HACCP plan shows what is actually going on in the facility. That's why it's important for the HACCP team to take a first-hand look at the operation, the employees and the steps involved. This helps the team understand how everything relates and what will affect the possibility of product hazards and contamination.

During this process, it may be necessary to take measurements to confirm actual operating conditions. Remember to enter FACT, NOT OPINION. It may be necessary to measure:

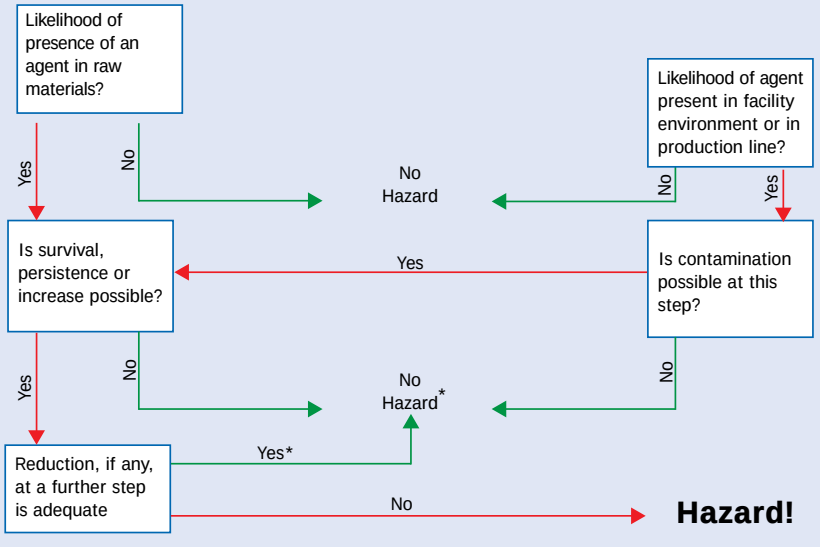
- Product temperatures;
- Product cooking times;
- pH at beginning, during, or end of process steps;
- Water activity (amount of free water in the food); and/or
- Sample collections.

Once these measurements are collected, have a qualified person analyze the numbers to interpret the data accurately.

Hazard Determination

Potential hazards can exist in raw materials. Hazards may also enter through the environment, from employees or the production process. Evaluate each hazard that the HACCP team identifies. Also check for hazards by using the following decision tree.

The Decision Tree Questions to be asked for each potential hazard:



*Not a hazard to be controlled at this step
**Reduction step may become a CCP

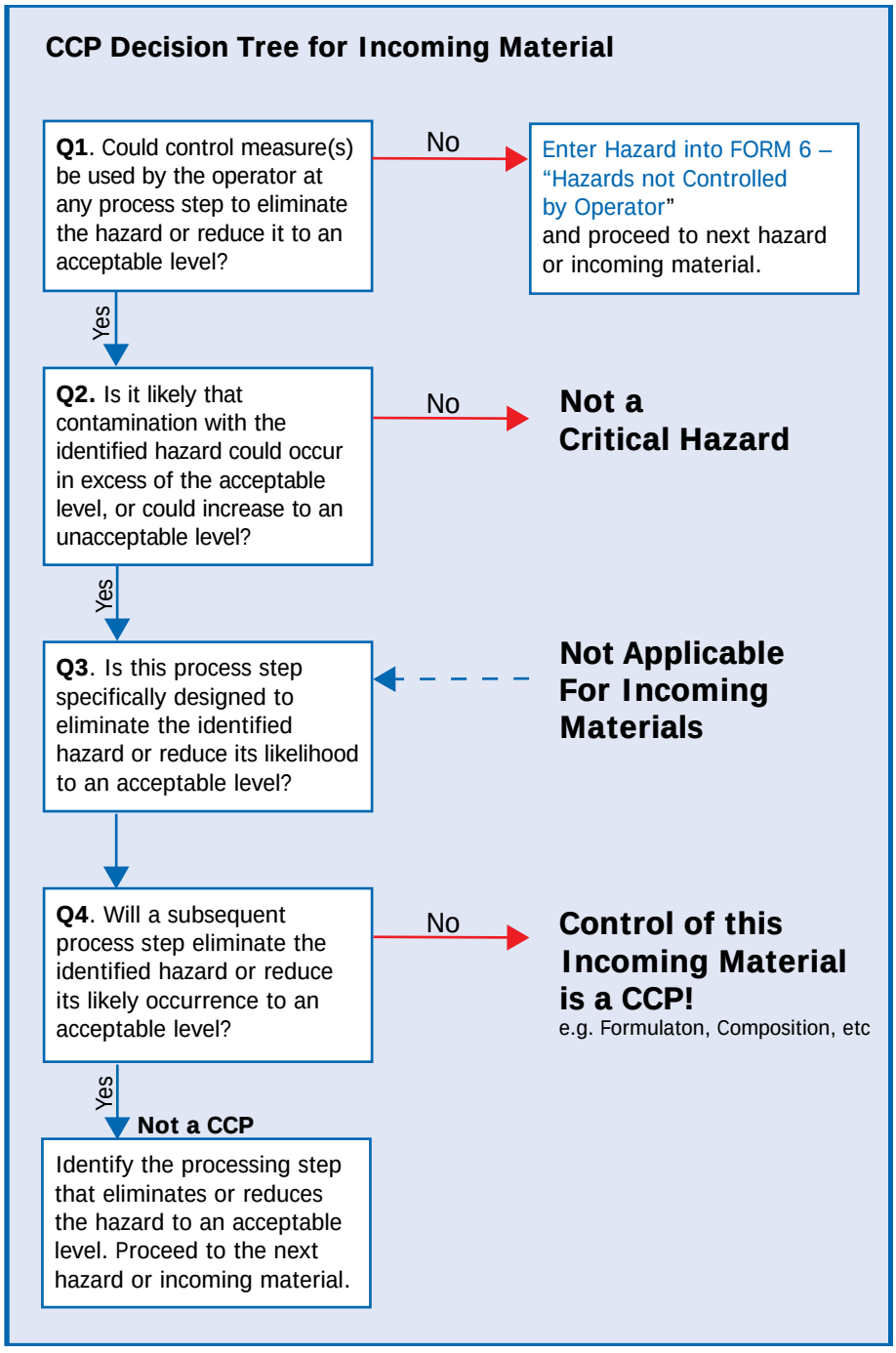
The assessment of hazards is not based only on the presence of an agent, or cause. It's also based on the severity and likelihood of that agent reaching unacceptable levels. For example:

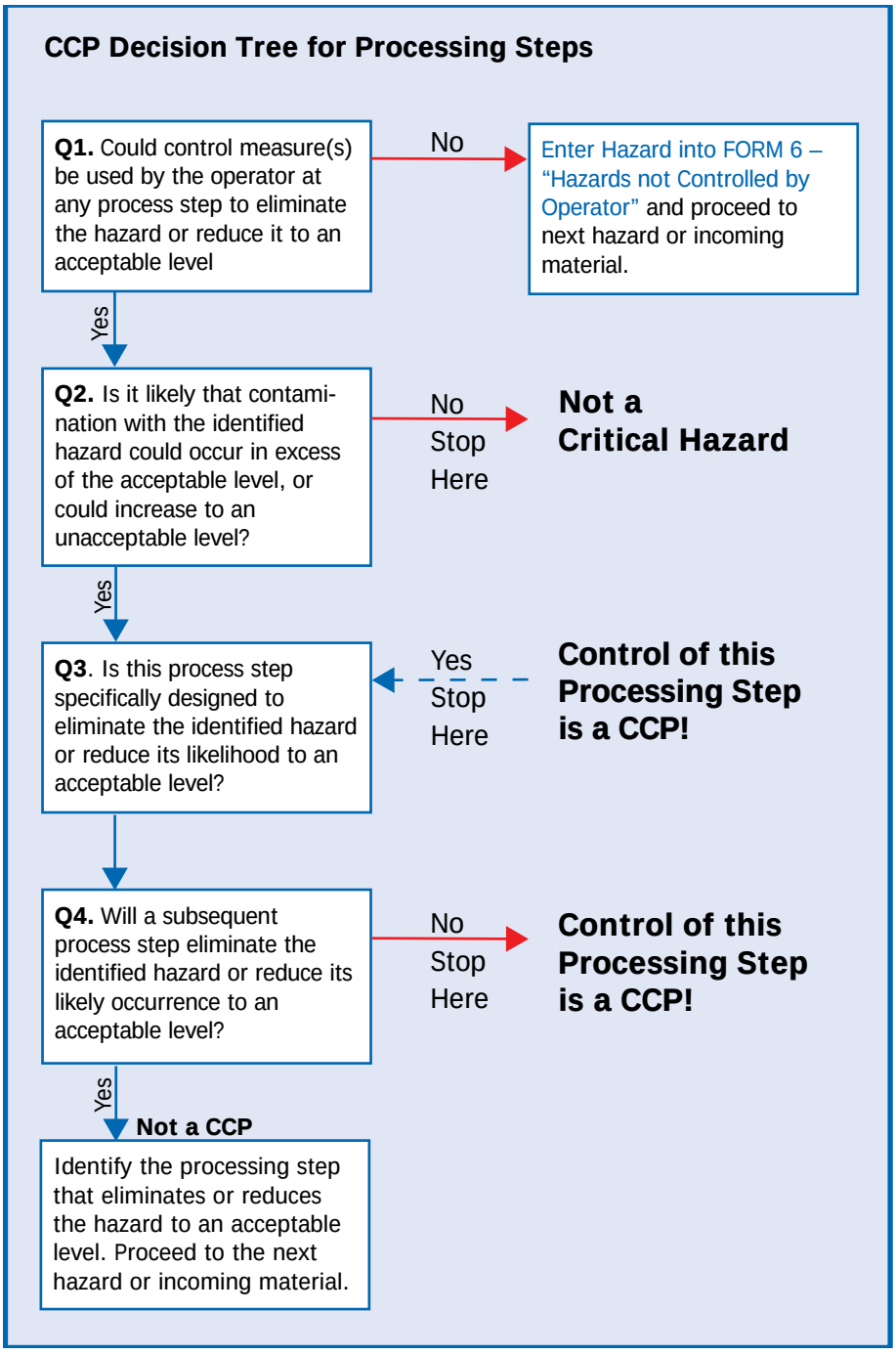
- If an agent is not present in the raw materials, production lines or environment, it may be safe to assume it is not a hazard.
- If an agent is present in the facility environment, but there's no way it can contaminate the product, it may be safe to assume it's not a hazard.
- If the agent can contaminate the product, survive, persist or increase, it may become a hazard.

3.7 Determining Critical Control Points (Step 7 and HACCP Principle #2)

Once all the stages are completed, a list of hazards has been identified and the team has an understanding of conditions leading to the hazards, the team is ready to decide on Critical Control Points (CCPs). Use the HACCP decision tree to do this.

HACCP Form 5 (Hazard Idenification and CCP Determination)
For incoming materials, walk through the decision tree steps.
For every hazard found, answer each question in order.
For each question, fill in 'yes' or 'no', and include a brief explanation where necessary. If it is decided that the hazard is controlled at a particular point during the process, this point is a CCP. Identify, order and number the CCPs.


CCP Decision Tree for Incoming Material
Q1. Could control measure(s) be used by the operator at any process step to eliminate the hazard or reduce it to an acceptable level?
No
Enter Hazard into FORM 6 – "Hazards not Controlled by Operator" and proceed to next hazard or incoming material.
Yes
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?
No
Not a Critical Hazard
Yes
Q3. Is this process step specifically designed to eliminate the identified hazard or reduce its likelihood to an acceptable level?
Not Applicable For Incoming Materials
Q4. Will a subsequent process step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?
No
Control of this Incoming Material is a CCP!
e.g. Formulaton, Composition, etc
Yes
Not a CCP
Identify the processing step that eliminates or reduces the hazard to an acceptable level. Proceed to the next hazard or incoming material.


CCP Decision Tree for Processing Steps
Q1. Could control measure(s) be used by the operator at any process step to eliminate the hazard or reduce it to an acceptable level
No
Enter Hazard into FORM 6 – "Hazards not Controlled by Operator" and proceed to next hazard or incoming material.
Yes
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?
No
Stop Here
Not a Critical Hazard
Yes
Q3. Is this process step specifically designed to eliminate the identified hazard or reduce its likelihood to an acceptable level?
Yes
Stop Here
Control of this Processing Step is a CCP!
Q4. Will a subsequent process step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?
No
Stop Here
Control of this Processing Step is a CCP!
Yes
Not a CCP
Identify the processing step that eliminates or reduces the hazard to an acceptable level. Proceed to the next hazard or incoming material.

If there are no control measures, the hazard is entered into HACCP Form 6 (Hazards not Controlled by Operator). As each hazard is listed, show how the hazard will be managed either before or after the production process. If the hazard is managed by consumers, enter in consumer instructions that will be included on the packaging label. If no control measure exists for the hazard identified, it may be necessary to reconsider the production process. Include a step that will reduce, prevent or eliminate this hazard.

Once the critical control points related with the production process are identified, copy the information into HACCP Form 7 (The HACCP Plan). At this point, use HACCP principles 3 to 7 to develop the complete HACCP plan. Use HACCP Form 7 to record critical limits, deviation procedures, verification procedures and record keeping requirements.

3.8 Establishing Critical Limits (Step 8 and HACCP Principle #3)

By using Good Manufacturing Practices (GMPs), existing production lines will normally produce safe products. However, watch for deviations or changes. Be ready to prevent and control them.

Ask the question: "How much of a deviation from normal can be allowed before products are considered unsafe?"

A critical limit separates those risks that are acceptable for consumers from those that are not acceptable.

To answer this, first define or decide on the normal procedure in the facility. Then define what could happen if circumstances move beyond what is normal. If a hazard is found, the point where it becomes unacceptable becomes the deviation point.

The CFIA provides excellent examples of critical limits in their Food Safety Enhancement Program manual. Here are some of their examples:

- An acidified beverage that is hot-filled may have acid addition, or temperature of fill, as potential CCPs. If insufficient acid is added, or if the temperature of the hot-fill is insufficient, the product will be under-processed. There is potential for microbial growth to unacceptable levels. The critical limits in this case are pH and fill temperature.

- Beef patties are cooked in a continuous oven. There are many critical limits necessary to control the hazard of heat resistant pathogens. These include minimum internal temperature of each patty, oven temperature, time in the oven and patty thickness.
- In a ready-to-eat production facility, the manufacturer has identified final packaging as a CCP. The hazard to control is contamination of the product because of employee handling (cross-contamination from workers). The critical limit in this case is that workers must follow documented procedures (e.g. utensils, gloves, hand washing and sanitizing at required times). This ensures that workers don't contaminate the packaging or the ready-to-eat food product(s).

These three examples show that a critical control point may have several critical limits needed to control hazards.

3.9 Establishing Monitoring Procedures (Step 9 and HACCP Principle #4)

Monitoring means regular measuring and recording of values at specific times.

The next question to ask is: "How can the deviation be identified or monitored?" One example is to check the internal temperature of a meat product by measuring with a thermometer. Another is to check whether employees follow the correct practices and procedures. Be sure to make records of monitoring activities. Monitoring is a key part of controlling hazards.

Ideally, measuring and monitoring should be done constantly. This may not be practical under most conditions, so it must be decided what monitoring intervals will ensure the safest products. To make these decisions, it's necessary to have an in-depth understanding of the technologies and methods used to control hazards.

Questions for each CCP and hazard:

- How can this CCP or hazard be monitored or identified?
- How often should it be checked?
- How should the results be recorded?

For each CCP, state the monitoring requirements. Also, state the means to ensure the facility will stay in these critical limits.

Monitoring procedures are generally quick tests or checks done during processing. Examples include:

- Visual observations
- Monitoring of documentation
- pH measurements
- Temperature
- Water activity

The monitoring system must state clearly how often testing is done. It must state the person (or job title of the person) responsible, and the procedures to be used. Failing to describe in writing the control of any CCP generally means the HACCP plan is not being followed.

3.10 Establishing Deviation Procedures or Corrective Actions (Step 10 and HACCP Principle #5)

A deviation is a failure to meet critical limits. When a deviation occurs, corrective actions must be taken. When considering deviation procedures, ask: “What is the appropriate reaction to this failure?”

Corrective actions should be taken immediately. They should happen before deviations cause the hazards to reach unacceptable results. The main goals of corrective actions are:

- Preventing unacceptable product from reaching consumers; and
- Preventing a repetition of the deviation.

Corrective actions need to be set out in a formal way. By doing this, the employees responsible for each CCP can understand and deal with each deviation quickly and effectively.

Set up and record procedures for all corrective actions. These activities can be recorded easily. See example table below.

WHAT	HOW	WHO	RECORD
Action to be taken	Step-by-step instructions	Person responsible	Generally this is recorded directly on Monitoring Records.
Increase temp	raise to 75ºC	TF	

Once this information is recorded, the associated corrective action matrix document can be noted in the deviation procedures column on Form 7.

3.11 Establishing Verification Procedures (Step 11 and HACCP Principle #6)

Often the terms 'Validation' and 'Verification' are used incorrectly.

- **Verification** means to use methods, tests, procedures, monitoring, and other evaluations to determine CONFORMITY with the HACCP plan. In other words, to see if the HACCP plan is being followed.
- **Validation** is defined as obtaining EVIDENCE to show that each element of the HACCP plan is EFFECTIVE.

The following may be helpful in understanding verification and validation:

- Verification - Activities are being performed according to standard procedures (e.g. a supervisor observes an employee washing their hands correctly, as documented in the hand washing procedure).
- Validation - The right results are being obtained (e.g. the facility's in-house microbial swabbing is sent to an outside lab to validate the facility's own in-house test results).
- Validation - The monitoring procedures are updated if there is process change (e.g. a formulation change might require increased cooking times. Validation is required to determine this).

Verification

Verification refers to activities done to check conformity – whether the HACCP plan is being followed. These verification activities need to be planned ahead, and are generally done by supervisors or quality assurance staff.

Verification is an ongoing activity. As a result of trends discovered through monitoring results, changes may be needed. These changes need to be verified.

Verification activities differ from monitoring activities. Although the activities may be similar, results from verification activities aren't intended for making decisions on product safety. Instead, the verification results are used to check the adequacy of food safety controls or how well controls are working. Verification activities may involve:

- Product sampling
- Audits of monitoring records
- Observations of employee practises
- In-house inspection audits
- Environmental sampling
- Any other appropriate activities

Create and keep records of all verification activities. Verification activities can be recorded easily by using the following table.

WHAT	WHY	WHEN	HOW	WHO	RECORD
Product test for coliforms	Assess product cook-kill step	End of each batch	Lab – Instructions	Lab tech	Finished product testing
Monitoring trends	Institute improve-ments and catch devations	End of each month	Review of documents – Graphs	QA manager	Document trend review

The table lists two verification procedures on how to record this information.

Verification activities can vary greatly and have different purposes. Remember, the goal of verification procedures is to get evidence showing that the system works well..

Validation

The manufacturer (food processor) is responsible for validation. Validation helps ensure that the operator can maintain control and that the measures in place can control hazards. Validation may require highly professional skills or specialized training (e.g. a food safety consultant). It may take time and be costly.

Validation is performed for the following HACCP plan development steps:

- Hazard determination
- CCPs
- Critical limits
- Monitoring activities
- Corrective actions

With each change to the system, perform a new hazard analysis. It is necessary to check the results of this analysis and to validate how well the control measures (existing and new) work. For this reason, validation becomes a part of the HACCP maintenance system.

For more information on how to maintain the HACCP system, see Chapter 15: HACCP System Management and Maintenance.

3.12 Establishing Record Keeping and Documentation Procedures (Step 12 and HACCP Principle #7)

HACCP records are the documents required at each critical control point (CCP). These ensure that the HACCP plan is followed. These records differ slightly from those kept to check that prerequisite program standards are met.

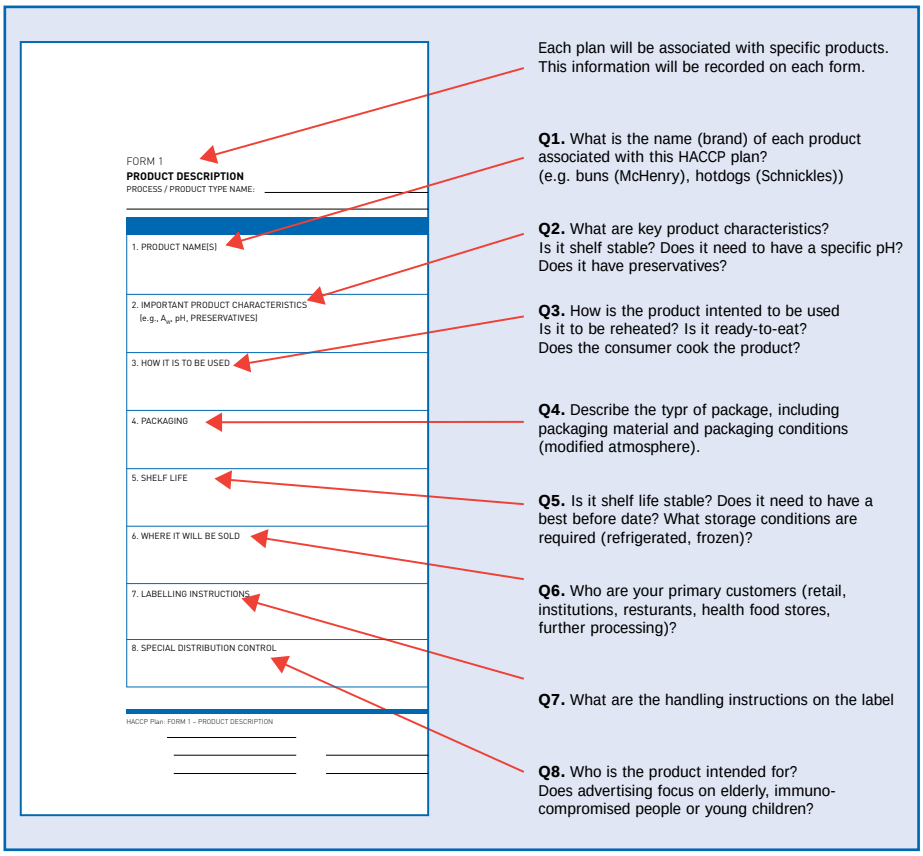
There are various types of HACCP records (e.g. processing charts, checklists, written records, computerized records). They give a historical record of the process, monitoring procedures, deviations and any necessary corrective actions undertaken. Accurate HACCP records help in tracing product and with troubleshooting if there's a problem. The facility must keep up-to-date and accurate records.

All HACCP documentation should include a record of who documented, reviewed and signed off on the information.

Most of the record keeping will be done on Form 7. This form has space for recording monitoring procedures. Monitoring results are most often recorded with deviations, as well as with corrective actions that may have been taken.

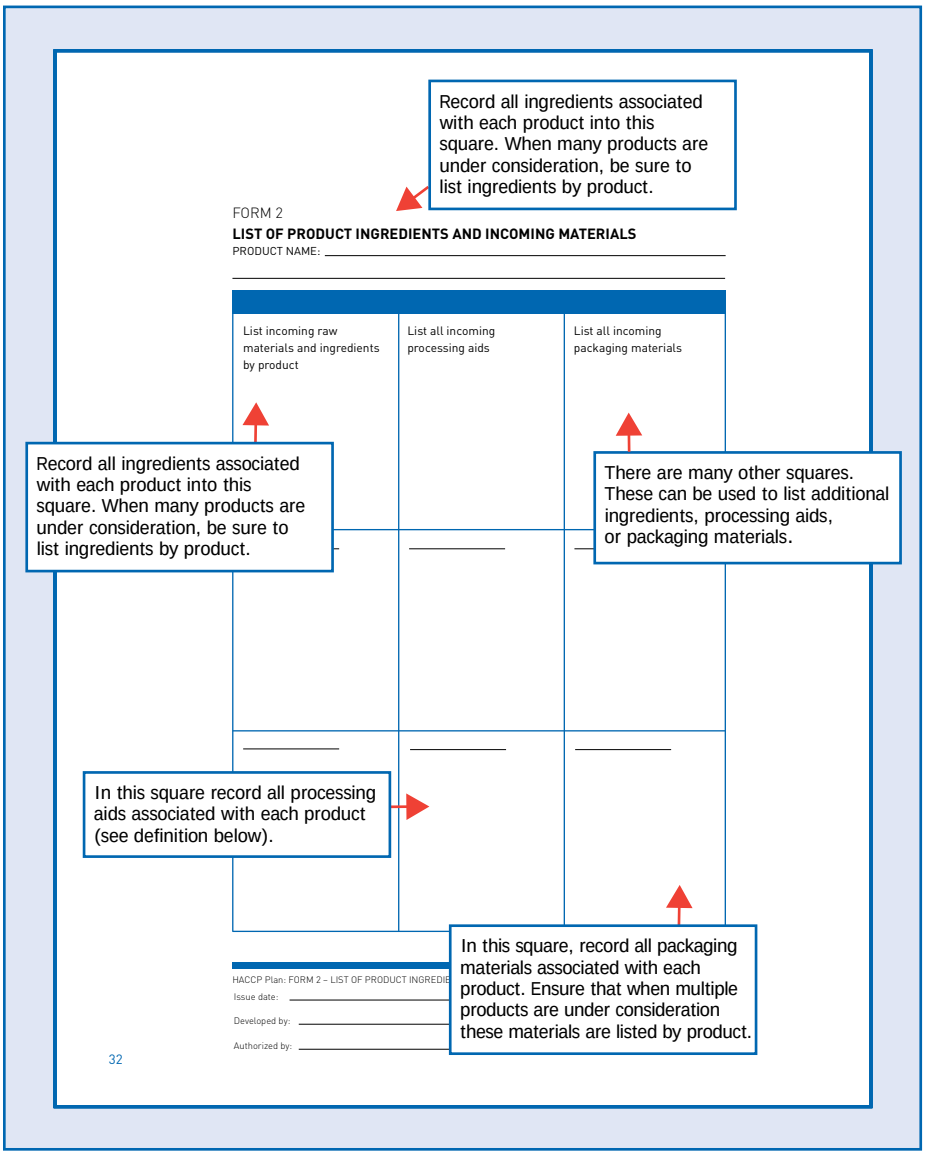
4.0 HOW TO FILL IN HACCP FORMS

Form 1: Product Description



This form is used for steps two and three of HACCP plan development. It is useful to attach the formulation (recipe) for each product listed to this form when completed. The more detail provided for each question, the more information the HACCP team will get from the form.

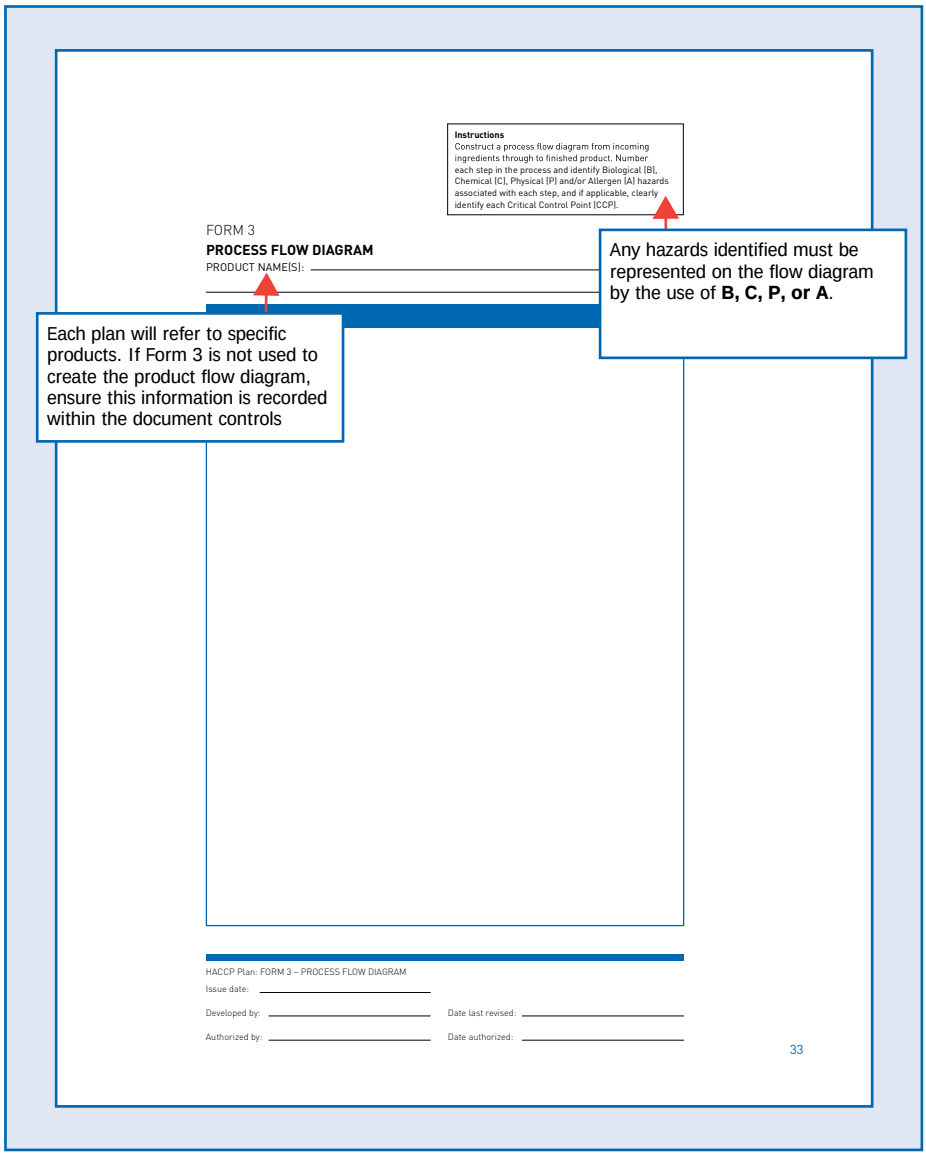
Form 2: List of Incoming Materials



Using the formulations attached to Form 1, copy the ingredients and incoming materials onto this form. As the hazard assessment progresses, use this form to identify the hazards connected with each item listed.

Processing aid – (a) substance that is added to a food during the processing but is removed in some way from the food before it is packaged in its finished form; (b) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and (c) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.[9]

Form 3: Process Flow Diagram



Form 3 is a blank form to construct a flow diagram. For most facilities, there is not enough space on this form to draw a flow diagram. If that is the case, use a separate page. If a separate sheet of paper is used, make sure to record the necessary information to associate the document with the rest of the HACCP plan.

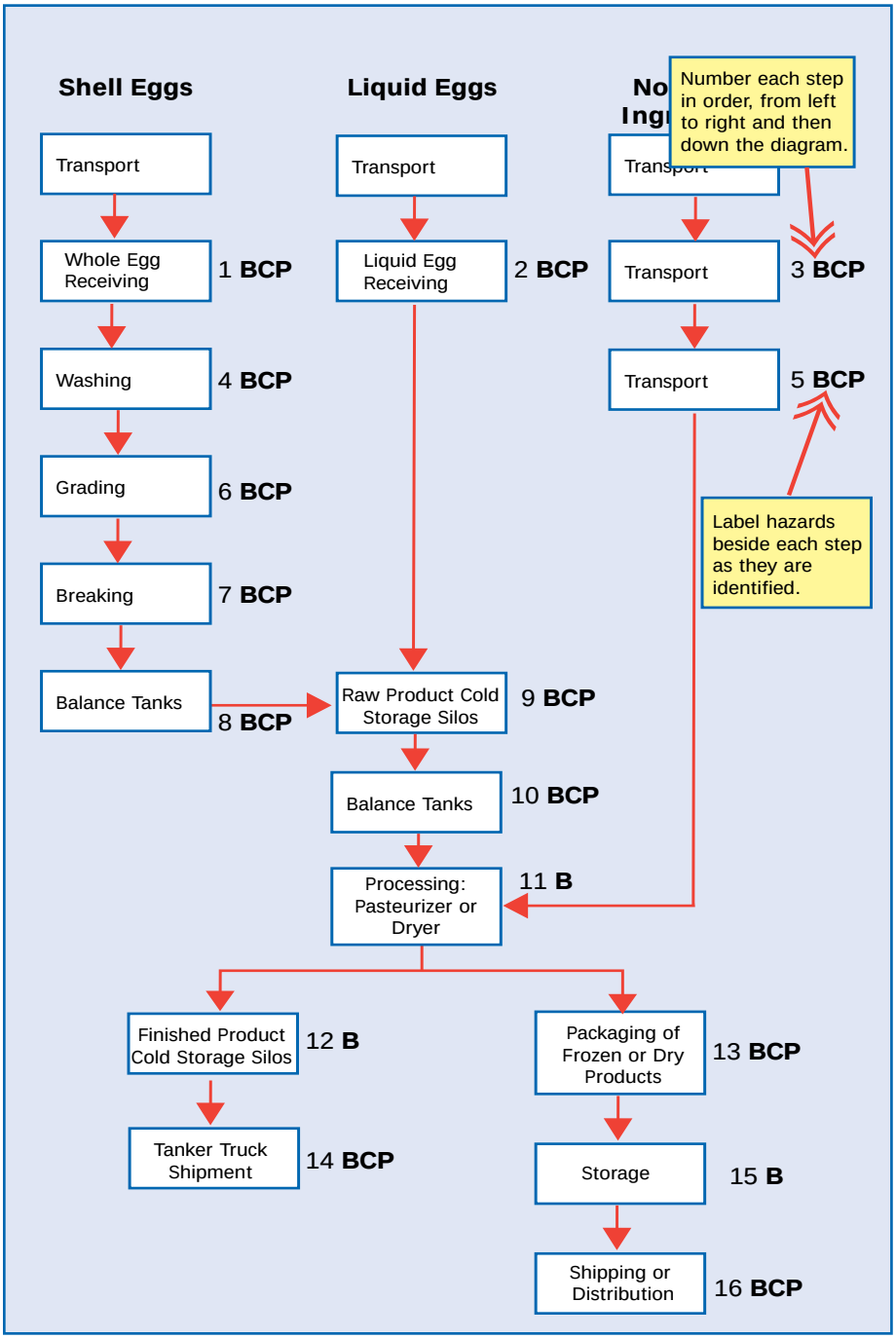
When drafting a flow diagram, use arrows to show the process flow between steps. Once the diagram is drawn for each step, ask:

1. Is there a potential biological hazard (e.g. bacterial contamination, opportunity for bacterial growth) associated with this step?
2. Is there a potential chemical hazard (e.g. too much preservative use, pesticide contamination and sanitation residues) related with this step?
3. Is there a possible physical hazard (e.g. wood chips, metal shavings, plastic) connected with this step?
4. Is there a potential allergen hazard (e.g. cross contamination between allergen and non-allergen products, allergen residues) associated with this step?

The following are examples of possible flow diagrams.

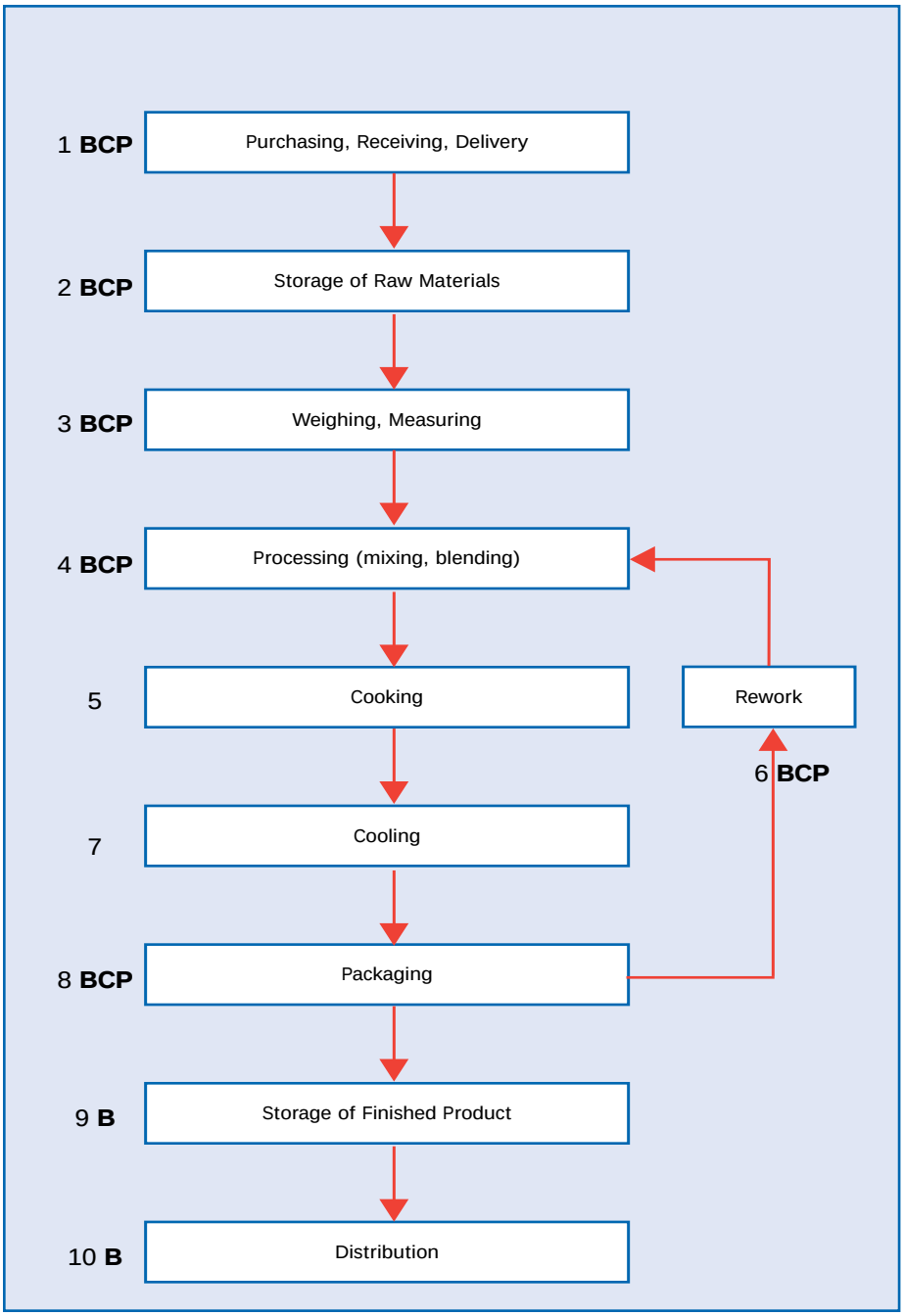
Flow Diagram – Example #1

Process Flow Diagram Form #3
Product Name(s): Example #1 – Generic Egg Processing

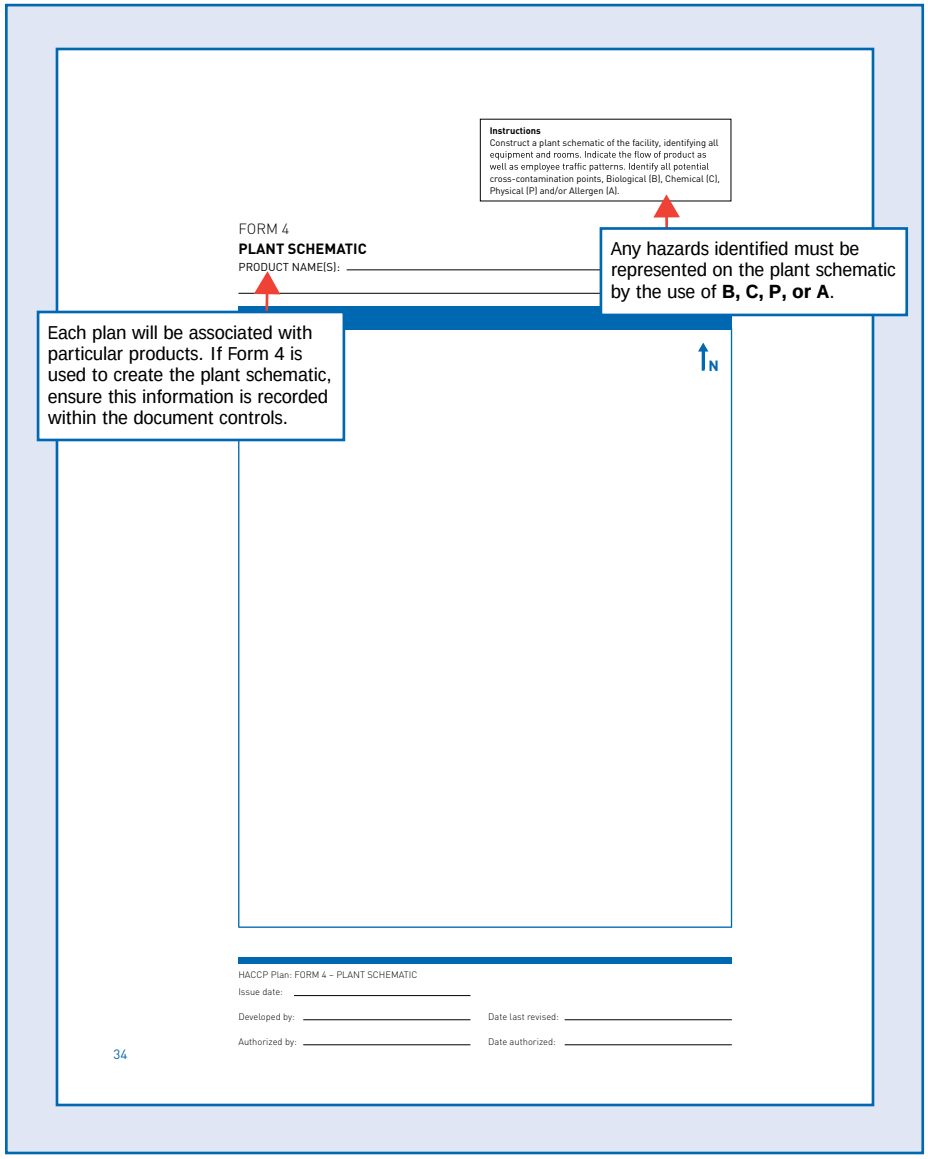


Flow Diagram – Example #2

Process Flow Diagram Form #3
Product Name(s): Example #2 – Generic Flow Diagram for Cooked Product



Form 4: Plant Schematic

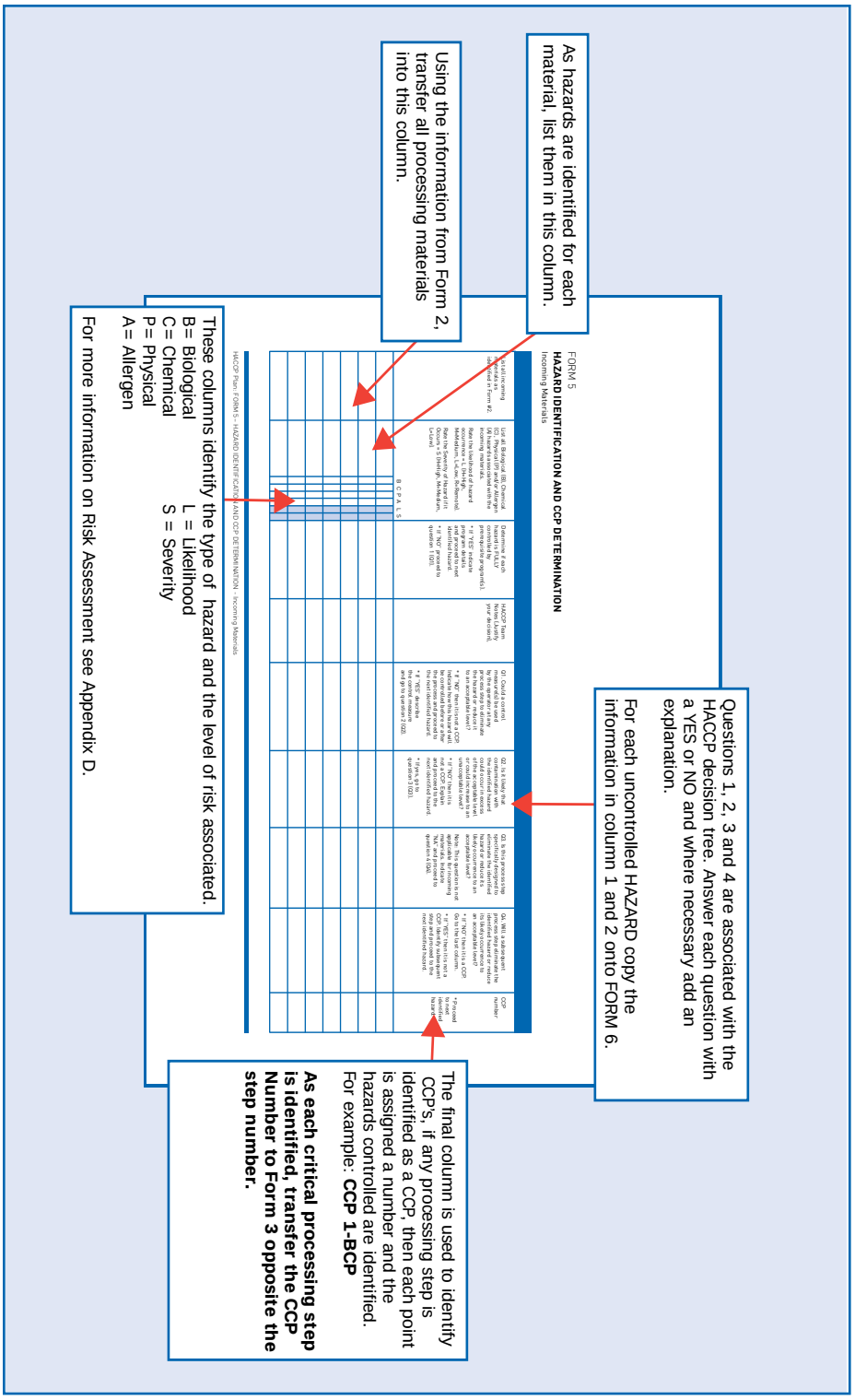


Form 4 is where the plant schematic is drawn. If more space is required, use a separate page or document (floor plan, architectural design). Record the necessary information to associate the document with the remainder of the HACCP plan.

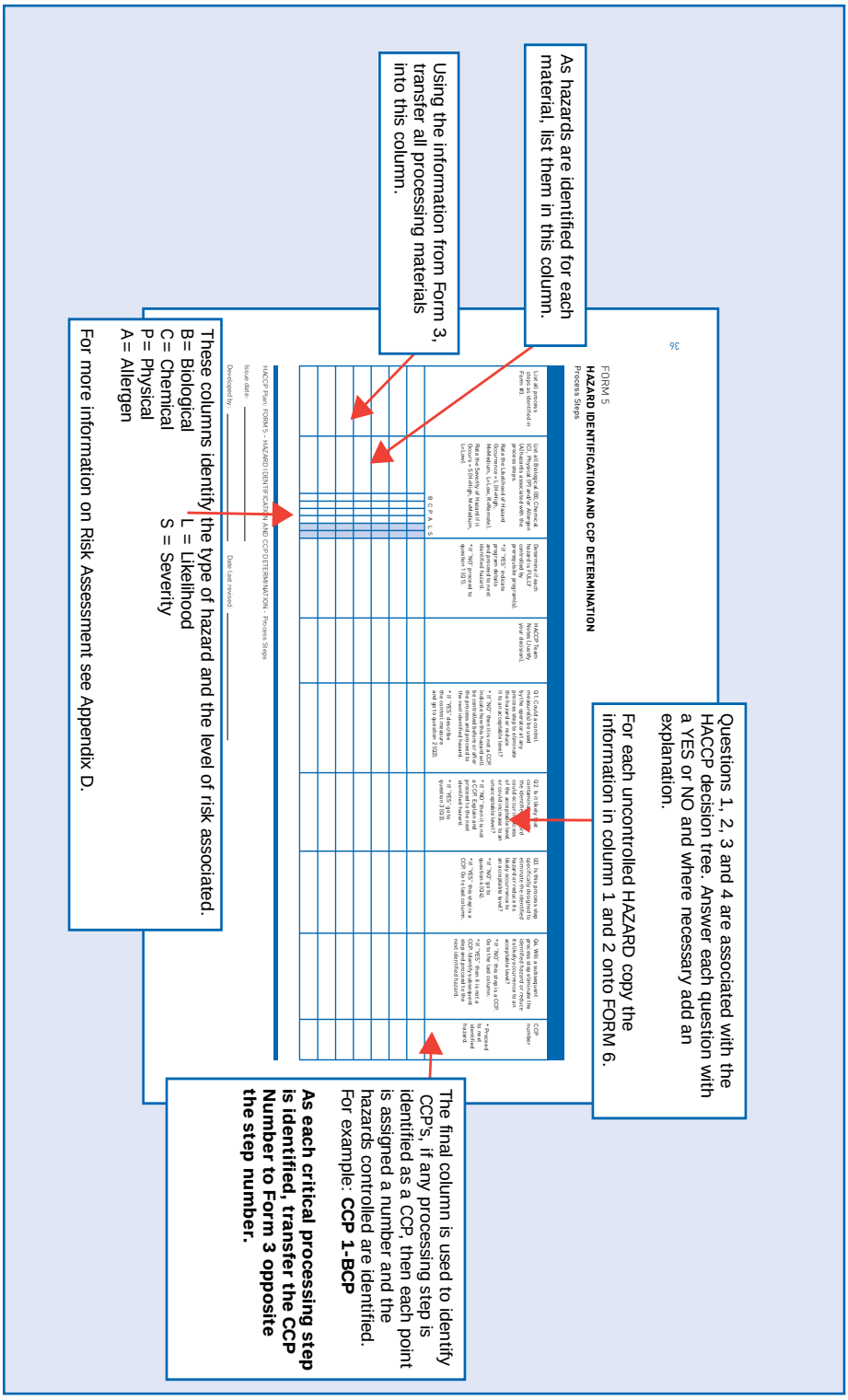
Plant schematics come in various forms. Some include graphics of equipment placement, and others just show the areas or rooms where they are placed. The amount of information the HACCP team needs will determine format and complexity of the plant schematic. The most useful plant schematic will include:

- All equipment and rooms within the facility;
- Flow of product, people and waste; and
- Potential cross-contamination or hazard points.

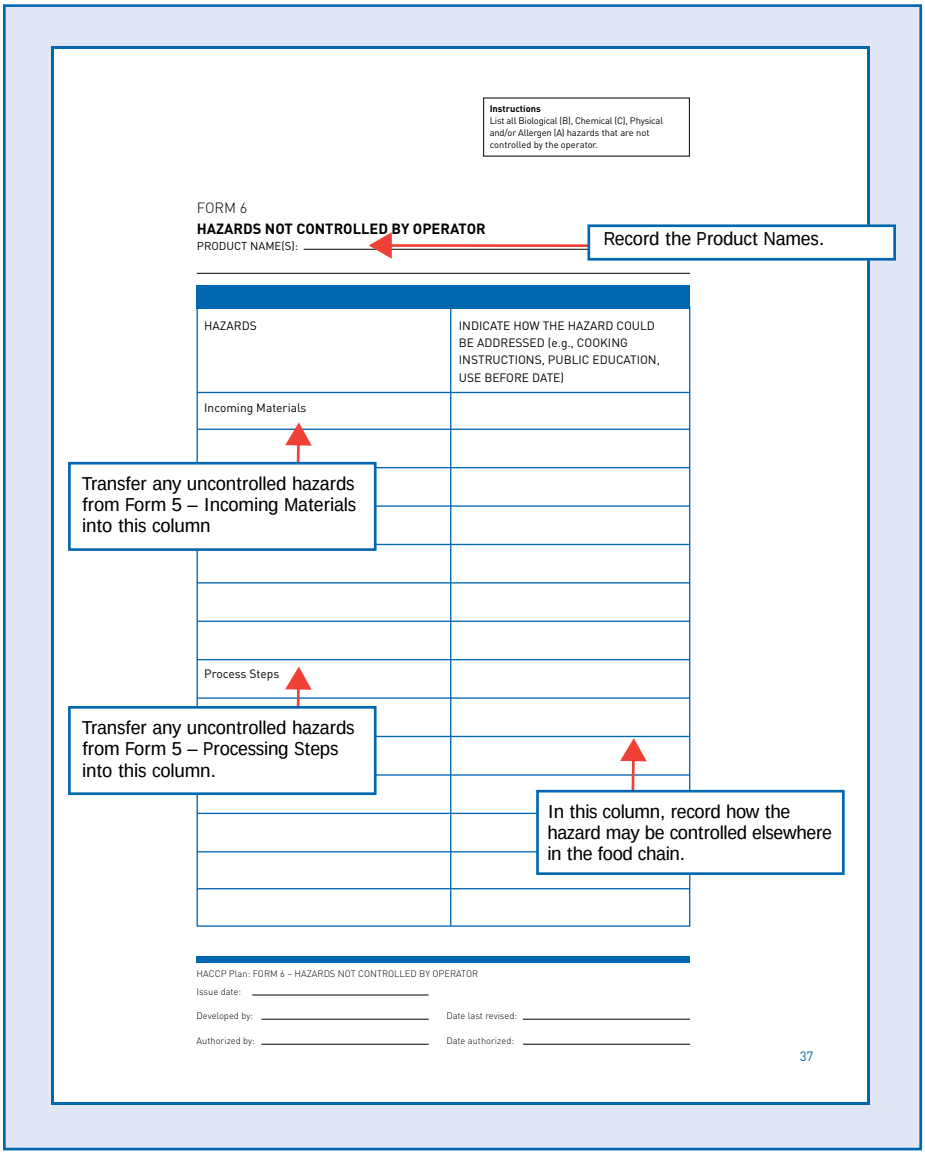
Form 5a: Hazard Analysis – Incoming Materials



Form 5b: Hazard Analysis – Processing Steps



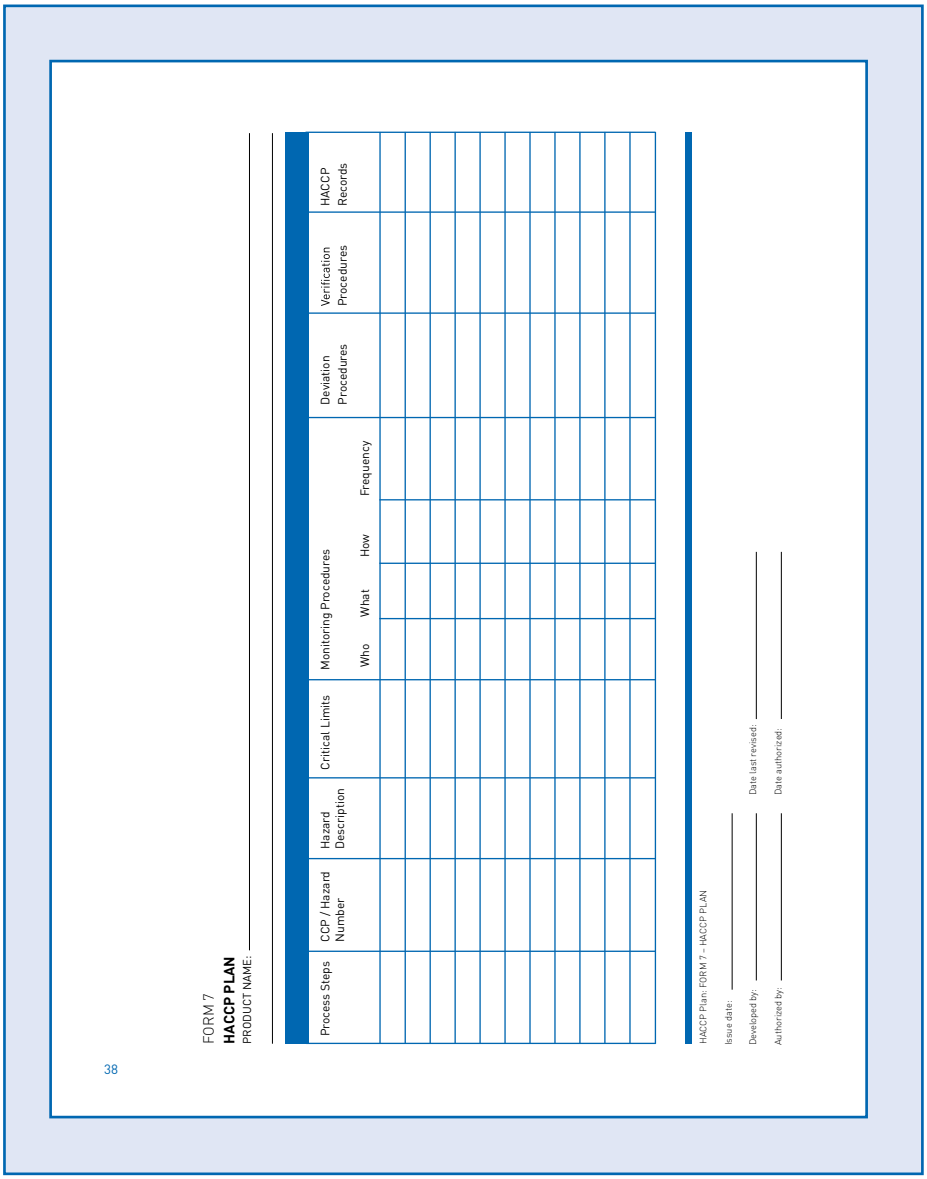
Form 6: Hazards not Controlled by Operator



The primary purpose of this form is to show due diligence of the food processor and helps the processor to find uncontrolled hazards. In the first column, copy the information from columns 1 and 2 of Form 5. In the second column, record how the hazard may be controlled elsewhere

in the food chain (e.g. supplier, consumer instructions, further processing). Any hazard that is listed on Form 6 and is not controlled at some point during the food chain should result in re-assessment of the production process and inclusion of appropriate controls.

Form 7: The HACCP Plan



FORM 7
HACCP PLAN
PRODUCT NAME: _____

Process Steps	CCP / Hazard Number	Hazard Description	Critical Limits	Monitoring Procedures				Deviation Procedures	Verification Procedures	HACCP Records
				Who	What	How	Frequency			

HACCP Plan: FORM 7 – HACCP PLAN

Issue date: _____ Date last revised: _____

Developed by: _____ Date authorized: _____

Authorized by: _____

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Form 7 is used to document HACCP principles 4 to 7. Each column breaks down the monitoring, deviation, verification, and record keeping required at each CCP. The following page outlines how to fill in each column.

Column 1. Process Step – Enter in a description of each processing step for which a CCP has been identified on Form 5a or 5b.

Column 2. CCP Hazard Number – Copy the number assigned to each CCP into this column.

Column 3. Hazard Description – This column identifies the type of hazard that this CCP deals with.

Column 4. Critical Limits – Use this column to identify unacceptable limits, which if exceeded, would lead to production of unsafe product. These limits must be clearly defined, unbiased and measurable.

Column 5. Monitoring Procedures – This column is further broken down into four new columns. This creates a matrix to identify how your monitoring procedures are to be used on the production floor. Each monitoring procedure must indicate:

i. Who will perform the task (recorded in WHO column);

ii. What will be monitored (recorded in WHAT column);

iii. How it will be monitored (recorded in HOW column); and

iv. Frequency it will be monitored (recorded in FREQUENCY column).

Column 6. Deviation Procedures – This column may be used to record deviation procedures. It can also be used to describe what documents contain deviation procedure instructions. You must record deviation procedures showing:

i. Who will perform the task;

ii. What the task is;

iii. How the task is to be performed;

iv. Where this information will be recorded; and

v. The cause for the deviation (if known).

Column 7. Verification Procedures – This column may be used to record verification procedures, or to state what documents contain verification procedures.

Verification procedures should include:

i. What is being tested or examined;

ii. Why this is being tested or examined;

iii. Who is responsible for the activity;

iv. How the activity is being carried out;

v. When (how often) the activity is being done; and

vi. Where the results or information are being recorded.

Column 8. HACCP records – This is a list of all records related to this CCP. To help plant employees, include information on where each record can be found.

5.0 COMMUNICATION

Whether an outside consultant is hired to develop the HACCP plan, or whether it's done in-house, good communication is needed for the food safety system to work smoothly. Good communication ensures that facility workers understand the food safety system and their role in it.

5.1 Communication Guidelines for HACCP

The following communication guidelines will help in setting up and running a HACCP system.

Guideline 1: Ensure everyone is informed and educated.

All those involved in the process must understand:

- Why HACCP is important; and
- What their role in the HACCP system is.

Communication should include everyone connected with production of the food product. This includes in-house maintenance staff, contractors, raw material suppliers, production staff and others.

Guideline 2: Personal and direct communication develops better understanding.

At first communication may seem centred around the HACCP plan development team. However, in time it will be necessary to communicate information one-on-one with employees in production and other areas.

Guideline 3: All messages must be consistent.

Delivering a consistent message is very important in setting up and running a HACCP plan. Some may feel that to be successful, a food safety system should be flexible. However, it is important that key principles, methods, and requirements are communicated in a consistent manner. This will improve confidence and increase trust in the HACCP team.

Guideline 4: Ensure communication channels are two way.

Promoting two-way communication with all employees gets those people who are doing the actual food processing involved.

Guideline 5: Information must be up to date, accurate and understandable.

The technical words and language connected with HACCP may scare some people off. It's best to introduce people to the HACCP plan in stages. Once everyone understands their role and the process, keep them updated on changes to the system.

Guideline 6: Support words with actions.

Management actions must support the principles, or basic ideas and requirements of HACCP. People like to see a system working at all levels before they support it fully. A food safety system depends on everyone involved to make it work.

Guideline 7: All HACCP documents must be clear, concise and use language everyone understands.

When it comes to developing HACCP documents and records, follow the KISS rule: Keep It Short and Simple. Where possible, use bulleted points and flow diagrams that provide clear and direct information.

See Chapter 3 for further information on how to document HACCP effectively.

See Appendix E for the HACCP Forms 1-7.

HACCP Generic Models – the Canadian Food Inspection Agency has created comodity-specific HACCP models to asssit processors in adopting a HACCP system in their operations. Find them online at: *www.inspection.gc.ca/food/safe-food-production-systems/haccp-generic-models-and-guidance-documents/eng/1374992202076/1374992233926*

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Chapter 15

MANAGING AND MAINTAINING THE HACCP SYSTEM

1.0 VALIDATING THE HACCP SYSTEM

2.0 VERIFICATION
- 2.1 HACCP Verification
- 2.2 Verification Records

3.0 AUDITS
- 3.1 Setting Up Audit Systems
- 3.2 Audit Records

4.0 HACCP TRAINING

5.0 CORRECTIVE ACTION FOLLOW-UP

6.0 DOCUMENTATION

7.0 HACCP MANAGEMENT AND MAINTENANCE FORMS

8.0 SOURCES OF INFORMATION

The HACCP system is recognized worldwide as one of the best systems of food safety. However, there are challenges in managing detailed food safety systems. Managing the HACCP system involves effective control of all facility programs.

Once HACCP plans are developed and started, work is still needed to keep them going. To control food safety hazards, the facility's HACCP system must stay 'in good repair'. It must be fine tuned to keep up with what's happening inside and outside the facility. HACCP systems need frequent updates and changes.

Effective HACCP maintenance depends on top management commitment. During HACCP development stages, management needs to show commitment to HACCP by supplying resources, time and money. Once the HACCP system is running, management must show its commitment through regular support of in-house activities (e.g. training, posted policies and continual improvement).

HACCP system maintenance activities include:

- Ongoing verification throughout the life of the HACCP system;
- Validation activities;
- Regular, pre-planned audits of the HACCP system, done by trained in-house or outside (third party) personnel;
- Follow-up and completion of corrective actions noted in earlier audits;
- Updating the HACCP system to deal with changes to the facility, products or processing operations;
- Revising the HACCP system to deal with new scientific information and/or new hazards;
- Keeping a log of all changes within the HACCP system;
- Altering the HACCP system to deal with changing regulations; and
- Ongoing training so that all personnel involved have necessary skills and know-how.

Verification asks: 'Is what should be done, getting done?'

Validation asks: 'Is this the right thing to do? Does it still work?'

Do not confuse verification and validation with routine monitoring activities for critical limits.

The meanings of 'Verification' and 'Validation' often get confused and are used incorrectly.

Verification is the application of methods, tests, procedures and other evaluations to determine CONFORMITY with the HACCP plan. Verification is done in addition to monitoring. (e.g. A HACCP coordinator checks the line supervisor's records to ensure that correct cooking temperatures are being met.)

Validation is obtaining EVIDENCE (e.g. testing, experimenting, or statistical analysis) that prove that the elements of the HACCP plan are WORKING EFFECTIVELY. (e.g. Statistical validation on how often a milk pasteurizer can be used without doing a Clean in Place).

1.0 VALIDATING THE HACCP SYSTEM

It is the responsibility of the manufacturer to validate its activities. Validation helps to confirm that the manufacturer can maintain control of a process. It confirms that the measures being used will control the hazards related to the food product.

Validate the following steps of HACCP plan development:

- CCPs;
- Critical limits;
- Monitoring activities; and
- Corrective actions (frequencies, methods and tasks).

Validation may require hiring people with professional skills or special training (e.g. food safety consultants) and may take time and money.

Do a new hazard analysis each time the system is changed or a new product is developed. It's necessary to check over the results of this new hazard analysis and how well the (new or old) control measures are working. For this reason, validation therefore becomes part of the HACCP maintenance system.

Validation may involve a scientific and technical review of every part of the HACCP plan – from hazard analysis to CCP verification strategies. One of the most important parts of HACCP program development is the original validation of the HACCP plan to make sure it's based on sound science and technology.

There are several ways to validate the HACCP plan. Some examples of validation include:

- Reliance on expert opinion, and scientific facts;
- Statistical evaluation of process parameters;
- Statistical analysis of a cooking step within the process; and
- Analysis of laboratory results (often using statistics) to check if a process is controlled.

One of the most important parts of HACCP program development is the original validation of the HACCP plan.

Ask the following questions when validating the HACCP plan:

1. Have all hazards been identified?
2. Do the implemented control measures remove significant hazards or reduce them to acceptable levels?
3. Do corrective actions restore control?
4. Are there procedures to ensure unsafe products do not reach consumers?
5. Has there been any new equipment incorporated into the process?
6. Have any new products been developed?
7. Have any new ingredients been sourced?

See Form HACCP Plan Validation Checklist.

How often the facility uses the validation program will depend on:

- Changes to raw materials, packaging materials or suppliers;
- Changes in product or process;
- Changes to the facility or equipment;
- New scientific information on hazards or control measures;
- New practices for handling distribution or consumer practices; and
- The risks associated with the facility's products.

2.0 VERIFICATION

Verification activities should cover all parts of the HACCP system including prerequisite programs. Examples of verification include:

- Watching employees to ensure that they are doing their job effectively, and comparing these findings to the written SOPs;
- Checking if records have been filled out accurately;
- Random tests to make sure that equipment is functioning as intended;
- Microbial or allergen testing to make sure cleaning and sanitation have been done correctly;
- Calibration or checking of monitoring devices;
- Checking for trends by reviewing calibration and other prerequisite program records;
- Targeted sampling and testing;
- Review of CCP (critical control point) records; and
- Audits or inspections by a regulatory agency.

Important factors to consider when developing the verification program:

- Verification processes need to be developed as a part of the HACCP plan. Write the verification processes, including how often they're done and who performs the activities, in a format similar to the rest of the HACCP plan.
- If the facility plans to do only in-house audits, using its own staff, ensure the personnel have the skills and knowledge needed. Make sure they can assess and understand the results and can perform the activities.
- Verifiers or auditors must be objective (unbiased). *Do not use the same people who developed the HACCP system to verify and audit that system*. Separating HACCP development from HACCP verification and auditing will prevent bias. It also helps in finding inconsistencies or problems within the programs.
- The same person cannot verify and monitor the same activity. To ensure that verification procedures are objective (unbiased) and credible (reliable), never have the same person who monitors a process or maintenance activity, also verify that same activity.

- Management must ensure that failures found in the system are dealt with. They must make sure the necessary corrective actions are taken. Management must continue to show commitment to the HACCP system.

Figure 1: Direct and Indirect Ways to Verify the Effectiveness of Food Safety Controls

	What is Evaluated		Methods Used?
Producer ↓	Knowledge Attitudes Behaviour Ownership Training	Of Operators and Managers	Questionnaires, Attitude, Scales, Audit, Observations
HACCP Plans And GMPs ↓	Quality of Plans	Design and Implementation	Audit, Inspections
Surfaces Equipment Plant ↓	Design Construction Cleanliness Cleaning Programs		Audit, Observation ATP Bioluminescence Microbiological Testing
Food Produced ↓	Microbiological & Chemical Quality		Microbiological and Chemical Testing, APC Indicator Organisms Presence of Pathogens or Chemical Contaminants
Health of the Public	Foodborne Illness Trends And Risls		Epidemiological Surveillance

2.1 HACCP Verification

Four methods most commonly used for HACCP verification are:

1. Equipment calibration;
2. Calibration record review;
3. Targeted sampling and testing; and
4. CCP record review.

If a monitoring procedure is not as strict as it needs to be, combine it with a strong verification strategy.

Verification reports should include:

- Mention of related HACCP plans;
- Direct monitoring of the CCPs (on-site observations);
- Direct monitoring of operators responsible for the CCP (where appropriate);
- valuation of records related to CCP monitoring;
- Certification that monitoring equipment is calibrated accurately;
- Deviations and corrective actions; and
- Modifications to the HACCP plan.

Calibrations are performed:

- *On equipment and instruments used in monitoring or verification;*
- *Often enough to ensure accuracy of measurements; and*
- *By checking the accuracy against a recognized standard (at or near the equipment's normal functioning condition).*

Equipment Calibration

Although this part of the HACCP system is covered in the equipment prerequisite program, it's also an important part of HACCP verification. Calibration of CCP monitoring devices helps to confirm the accuracy of measurements taken at each CCP.

If equipment is out of calibration, the CCP is considered to be out of control since the last time it was calibrated. How often calibration is done depends on the sensitivity of the equipment. It also depends on the risks related to loss of control.

Calibration Record Review

Calibration review involves going over equipment calibration records to check dates, methods and results of recent calibration activities. This is generally done as part of an internal (in-house) audit of the HACCP system, or as part of annual HACCP system maintenance.

For more information on equipment calibrations see Chapter 6: Developing An Equipment Program.

Targeted Sampling and Testing

An internal supplier compliance assessment (checking to see that suppliers are following food safety procedures) is a good example of verification using targeted sampling and testing. Supplier compliance is most often checked by taking a sample of the material being supplied. These test results are then compared with the safety specifications for that material.

For more information on supplier compliance see Chapter 12: Supplier Food Safety Assurance Program.

CCP Record Review

For each CCP, at least two kinds of records are produced. They are monitoring and corrective action records. (These may be separate documents, or combined into one.) Records alone are meaningless unless someone in a supervisory, quality assurance or management role reviews them. They must check that the HACCP plan is being followed. These records are very helpful for showing that CCPS are operating within safe limits. They also show whether all deviations or unusual situations are handled safely and effectively.

At set times the verifier will review, sign and date all records to confirm that they are complete and accurate. Write down any deviations found during the verification. Also write down what corrective actions were taken.

2.2 Verification Records

Create and keep records of all verification activities. The following table shows how to simplify verification recording activities.

WHAT	WHY	WHEN	HOW	WHO	RECORD
Product Test for Coliforms	Assess product cook-kill step.	End of each batch	Lab – instructions	Lab Tech	Finished Product Testing
Monitoring Trends	Implement improve-ments and catch deviations	End of each month	Review of documents – Graphs	QA Manager	Document Trend Review

3.0 AUDITS

Audits compare the actual practices and procedures of the HACCP system with what is written in the prerequisite programs and HACCP plans.

Audits:

- Are systematic, organized, and independent examinations that may involve both paper reviews and on-site checking;
- Check into whether an operation is conforming to, or following, the rules of the food safety system; and
- Are a way to reinforce strengths and find weaknesses in the food safety system.

Unlike traditional inspections, audits are more than just a snapshot of one point in time. They review everything from management commitment to employee practices.

Figure 2: The following charts describe some ways to develop an Auditing System.

Prerequisite Program Audit	
Program Audited	Methodology
Are prerequisite programs being carried out as defined by the plan?	Visual Observation
Have all procedures been carried out consistently since the last audit?	Record Review
Are staff members aware of the requirements?	Discussion / Interviews with new and existing employees
Are the prerequisite programs effective?	Review of consumer complaints, facility problems attributable to prerequisite programs • Record Review Waste, rework, or returns associated with GMP issues • Record Review

HACCP Plan Procedures	
Program Audited	Methodology
Have CCPs been consistently documented within the critical limits and the monitoring frequencies required by the HACCP plan?	Record Review
Have deviations and corrective actions been noted accurately? Was the product and the process corrected prior to further manufacturing	Record Review
Have verification procedures on CCPs been carried out consistently?	Record Review
Are CCPs managed properly on the floor today?	Visual Observation
Are line operators aware of the HACCP plan's requirements?	Discussion / Interviews with new and existing employees
Has the HACCP plan been effective?	Review of deviation records. Was effective corrective action taken? Are there repeat problem areas? Is deviation frequency increasing or decreasing?
Is there any new information or evidence from scientific journals or other sources that suggest the plan should be modified?	Literature search and review

3.1 Setting Up Audit Systems

Checklists are very helpful in keeping the audit process consistent. These checklists may be based on standards from which the food safety system was developed. Some food processors prefer that audit checklists suit their own facility and special concerns. To make customers more confident, some facilities use the same audit checklists as their customers.

Whatever method is used, keep the following in mind when developing the audit checklist:

- **Scope of the audit**
  Will the entire system be assessed or just parts of it?
- **Use written procedures to gather objective evidence**
  As with any part of a food safety system, set down the requirements of the auditing plan to ensure consistency.
- **An annual auditing timetable**
  Develop a yearly plan for when each audit is to be done and who does it. Modify the auditing schedule when it makes sense.
- **Follow-up and corrective actions**
  Create a procedure that not only allows for follow-up on corrective actions, but also shows the results of those actions.
- **Reporting procedures**
  The watchwords for HACCP are 'document, document, and document'. Find the best way to report auditing activities.

Many believe that for a HACCP system to be credible, or trustworthy, an independent review or audit is needed. Independent reviews can offer unbiased opinions. Some customers and regulatory agencies require confirmation that the HACCP system works well. They want to see documented activities showing that a facility's food safety hazards are being dealt with effectively.

Independent audits or assessments can be done by third parties. When selecting someone to assess the facility, make sure they are honest, reliable and skilled in auditing and inspection of the products being produced.

The frequency for auditing prerequisite programs and HACCP plans will depend on the special features of the facility. Record any changes to the annual audit schedule and the reasons for them in the HACCP log. When repeated compliance is confirmed, it may be possible to audit less often.

Here are some examples of when to modify or increase auditing schedules:

- When the process changes (new equipment, new products);
- Research indicates a new hazard;
- Customers have new requirements; and/or
- An unusual number of non-conformities or corrective actions are noticed.

3.2 Audit Records

Use audit results as a tool to encourage communication between facility staff – from management to floor workers. Many facilities use an easy-to-read, shortened audit report that can be posted in the employee lunchroom. It can also be reviewed at management meetings.

4.0 HACCP TRAINING

Employee buy-in is the key to maintaining a good HACCP system. Management support is also of key importance. Many facilities that have used HACCP consultants may forget this. They may also overlook the need for both initial and ongoing HACCP training.

Maintenance of the HACCP system should include ensuring that employees are well trained. Make sure they can carry out their tasks well. Training needs will differ throughout an organization. Keep staff motivated by developing their technical knowledge and expertise. This helps ensure that the HACCP system is successful.

Whether the facility is just beginning employee training, or adding to it, a good HACCP training program should include:

- Explanation of the importance of food safety to the facility, the consumer, and even the employees involved;
- Visual demonstrations of all steps and procedures;
- Chances for employees to practice;
- Opportunities for employees to provide feedback;
- Tests to reinforce the information being taught;
- Making the training and learning appealing for all employees;
- Setting down how often (at least yearly) to do reviews or refresher training with employees; and
- Follow-up on the training to ensure that it is effective.

For more information on employee training see Chapter 7: Developing a Personnel Training Program.

5.0 CORRECTIVE ACTION FOLLOW-UP

During HACCP audits or internal verification activities, non-conformances or shortcomings that require corrective action, may be noticed. A corrective action plan must be developed to deal with all issues. It should explain the action to be taken and a set time for doing it. Record all deviations and corrective actions. Include them as part of the HACCP documents.

6.0 DOCUMENTATION

As with every part of the HACCP system, HACCP maintenance is a documented process. There must be a plan that describes who is responsible for maintenance of the system.

Record all changes to the HACCP system. The easiest way to do this is with a HACCP system logbook. It provides an ongoing history of the facility's HACCP system. The logbook may be as simple as a coil-bound booklet with headings. It may also be a more advanced computerized HACCP database.

All entries should include:

- The program or part of the system that was changed;
- Why it was changed;
- What change was made;
- Who made the change; and
- Initials of the employee making the change.

There should also be a column to mark verification or validation of the change. For example, if changes are made to a CCP, it may be necessary to re-validate the effectiveness of that CCP.

Example of HACCP System Logbook Entry:

Date	Prerequisite Program or HACCP Plan	Change Made	Verification or Validation Activities	Initials
May 23, 2006	E1 – Sanitation	Restroom re-stocking schedule increased to twice per day.	Records check shows a decrease in necessary corrective actions associated with this activity.	RB

Note: The above change is very simple and does not indicate all the records involved. Any changes to prerequisite programs or HACCP plans that are recorded in the logbook should also be noted in the written control program. These changes should also be recorded in any documents where monitoring and corrective actions are tracked.

7.0 HACCP MANAGEMENT AND MAINTENANCE FORMS

- HACCP Revision Log
- HACCP Plan Validation Checklist
- HACCP Plan Internal Audit Report

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Appendix A

GLOSSARY OF FOOD SAFETY RELATED TERMS

- A -

Abattoir:	Any premises or facility where live animals are slaughtered or and any or all of the following take place: meat is cut, wrapped, frozen, cured, smoked or aged.
Acceptable Limit:	A point that separates satisfactory conditions from unsatisfactory conditions relative to food safety.
Accredited:	A facility that has been recognized by an authoritative body based on a set of requirements that is logical, fair, sensible and rational.
Adequately Controlled:	A situation in which an identified hazard is eliminated or reduced to an acceptable level that meets requirements and is in line with what is logical, fair, sensible and rational.
Adulterated Food:	Food that has been contaminated so that it is considered unfit and unsafe for human consumption.
Agent:	A substance or condition that exerts some effect on food safety.
Allergen Clean:	Free of any residue that may lead to an allergic reaction in a sensitive consumer.
Allergens:	Substances that cause an exaggerated immune response in some people and that may result in a runny nose, watery and/or itchy eyes, a rash, wheezing, serious illness or (occasionally) death.

Allergen Control Program:	Food safety program to reduce, eliminate, or control allergen hazards within a food-production or processing facility.
Applicant:	An operator or facility that applies for certification or recognition.
Assessment:	The act of judging or documenting (often in measurable terms) the knowledge, skills, successes and policies a person or facility has relative to the Alberta HACCP Advantage Standard or another acceptable food safety system.
Audit:	Systematic organized and independent examination that may involve both paper reviews and on-site checking of a food-processing facility to determine whether the operation is following the rules of its food safety system. An audit looks for proof that you do what you say you do, and it is appropriate.

- B -

Bacteria:	Single-celled organisms that live in and around humans and other hosts, and that are too small to be seen with the naked eye.
Baseline:	A measurement, calculation, or location used as a starting point or condition against which to measure future changes.
Batch Number or Lot Number:	A distinct identification code for each product or batch. It may be in the form of a distinctive combination of letters, numbers or both assigned to a specific identifiable batch/lot of production. It is usually found on each individual container.
Biological Hazard:	Any danger to food safety by the contamination of food with illness or disease-causing organisms.

- C -

Calibrate:	To adjust an instrument for accuracy relative to an established standard.
Canadian Food Inspection Agency:	The federal government agency responsible for delivery of all federal inspection services to protect public health relative to food safety, from the farm gate to the consumer's plate. The agency safeguards the food supply as well as the plants and animals upon which availability of safe and high-quality food depends.
Certification:	The status obtained after being successfully certified under a food safety certification audit. The facility receives certification once it has provided evidence to that its food safety system meets the specified requirements of the food safety standard.
Certification Body:	An organization that is licensed to conduct audits and provide official recognition of compliance to certain standards.
Certificate of Analysis:	Documentation that is based on a scientific examination and states that a food product has certain qualitative and/or quantitative properties.
Chemical Sanitizing:	A method of sterilizing a surface using a chemical that has been approved by the Canadian Food Inspection Agency at a specified concentration and contact time.
Chemical Hazard:	Any chemical that through contamination presents a danger to food safety.
Clean:	Free of soil particles and other foreign material (See also 'Soil').

Code:	A systematic collection of regulations and rules of procedure or conduct (e.g. General Principles of Food Hygiene or the Food Retail and Foodservices Code).
Codex or The Codex Alimentarius Commission:	An organization formed by the World Health Organization (WHO) and Food and Agriculture Organization (FAO). Comprised of representatives from 165 countries, it develops internationally accepted food safety standards.
Cold Chain:	The process of maintaining proper refrigeration or freezer temperatures during transportation to prevent deterioration of food products or ingredients.
Communicable Disease:	An illness that is caused by an organism, microorganisms or its toxins. It is transmitted directly or indirectly from an infected person or animal, or through the environment by water, air or other means.
Conformity:	Ability to meet set standards.
Contamination:	A condition that can affect food that has been exposed to and faced introduction of foreign matter, including filth, a poisonous substance or pests, disease-causing microorganisms or parasites, or toxins.
Control Measure:	Any action or activity that can be used to prevent, reduce or eliminate a food safety hazard.
Control Point (CP):	Any step at which biological, physical, allergenic or chemical factors can be dealt with through operational conditions to prevent food safety hazards and to support producing safe food that will not result in an unacceptable health risk.

Corrective Action:	Procedures or activities to address a deviation, restore to normal conditions, and to prevent the deviation from happening again.
Corrosion:	Deterioration due to the chemical reaction of water, air or acid (A metal or alloy that is likely to be damaged or destroyed, especially by oxidation or chemical action, is 'corrodible').
Corrosion-resistant Materials:	Materials not susceptible to deterioration due to the chemical reaction of water, air or acid.
Criterion:	A requirement on which a judgement or a decision can be made.
Critical Control Point (CCP):	A point, process step, or a site where an action or procedure can be applied to prevent, eliminate or reduce a food safety hazard to and acceptable level.
Critical Limit:	The maximum or minimum level to which an allergenic, biological, chemical or physical hazard has to be controlled to prevent, eliminate or reduce its occurrence to an acceptable level.
Cross-contamination:	A situation that occurs when micro-organisms, allergens, chemicals or other hazards that are carried by utensils, hands, towels or other food are transferred from one food, ingredient or surface to another.

- D -

Danger Zone:	The temperature range that bacteria and spoilage organisms grow most quickly. The Danger Zone is between 4º C and 60º C.
Dairy Processor (Alberta):	Any person or firm that processes (for sale) 50 litres or more of milk or dairy product daily. It does not include retail outlets that operate or use a freezing device to freeze a frozen dairy product mixed or manufactured by a processor.
Deviation:	A variation from the standard or norm. In a food safety system, a failure of or departure from the standard operating procedures (SOP), is one example.
Disposition (or Product Disposition):	The final outcome or action taken in dealing with a particular food product. The action usually is associated with held, suspect or returned food products. Examples of disposition include disposal, reworking into future products or donation to charity.
Document:	To write down or record information. A file that contains information or accounts of food safety policies or activities (e.g. forms, records).
Documentation:	Permanent policies and work instructions that define systems, processes and procedures. The recording in a permanent format of information derived from food safety activities.
Documentation Review:	A process that verifies an applicant has developed and provided all necessary documentation for the certification process to proceed.
Due Diligence:	The degree of prudence that might be expected from a reasonable person, group or organization in the same circumstances.

- E -

Edible Product:	Any substance that may be used as food.
Endospore:	A resting stage of some bacteria, during which the bacteria is resistant to unfavourable conditions. An endospore serves a purpose similar to the seed of a plant.
Environmental Contamination:	The presence of hazardous substances in the atmosphere or surroundings.
Eradication:	Steps/measures taken to totally eliminate a pest or weed from an area.
Establishment:	Any building or facility, including the surrounding areas that food is processed or handled.
Exit Criteria:	The standards, measures or expectations used to evaluate a learning experience.

- F -

FIFO First In, First Out Policy:	An effective food rotation system in which the first lot of product received is used up before using lots received on later dates.
Flow Diagram:	A systematic illustration or graphic of the sequence of steps or operations to produce or manufacture of a food item.
Food:	Any substance, including water and ice, manufactured, sold or intended for use in whole or in part as food or drink for human consumption. It does not include drugs, medication or health-related products regulated under the Pharmaceutical Profession Act or the Food and Drugs Act (Canada Public Health Act).
Food-Contact Surface:	The surface of equipment or utensils that food normally touches.
Food Establishment:	A place, premises or vehicle where food intended for public consumption is sold, offered for sale, supplied, distributed, displayed, manufactured, prepared, preserved, processed, packaged, served, stored, transported or handled.
Food-Grade Packaging:	Any wrapping or container material that will not transfer noxious or toxic substances into food and has been approved by the Canadian Food Inspection Agency.
Food Handler:	A person involved in any activity that relates to food processing, transportation or storage, or who works with a surface likely to come into contact with food.

Food Hygiene:	All measures necessary to guarantee the safety of food at all stages of the food chain.
Food Safety Plan:	The documented practices and procedures undertaken by a business or food establishment to protect food products, prevent contamination and to control microbial growth.
Food Safety:	Activities to protect the food supply from microbial, chemical, allergenic and physical hazards that may occur during all stages of food production and handling.
Food Safety System:	A set of procedures or plans designed to ensure that food is protected and wholesome to eat. In food processing, a set of independent but interrelated control elements to ensure compliance with all legislated food safety regulations, the product protection plan or the HACCP plan used, or proposed by a food processor or applicant.
Foodborne Illness:	Sickness or injury caused by eating food containing a microbiological, chemical or physical hazard(s).
Foreign Material:	Any substance or object that does not naturally or normally belong in a food product.
FSEP (Food Safety Enhancement Program):	Canada's national 'food safety standard.' It applies HACCP principles in federally registered food-processing establishments.

- G -

Gap Assessment Audit (GAP Audit):	A systematic examination of a food-processing program (including the applicable management, production, training and related systems, as well as their records to identify any shortcomings in the program).
General Principles of Food Hygiene (GPFH):	A recommended international code of practice adopted by Codex Alimentarius Commission in 1969 and revised in 1997. This code consists of prerequisites and Control of Food Hazards, similar to the seven principles of HACCP used in development of HACCP plans. The GPFH code contains guidelines for application of both prerequisite programs and Control of Food Hazards Plans in a variety of situations from production through to the consumer. The Canadian (GPFH) Code is based on the Recommended International Code of Practice – General Principles of Food Hygiene noted above. It provides a firm foundation for good manufacturing (GMP's) and hygienic practices to be applied by the food industry in Canada.
Generic HACCP Model:	Generalized HACCP plans designed for a specific product or product category that can be used as an example or guideline for developing a plant-specific HACCP plan.
Good Agricultural Practices (GAP's):	This refers to an integrated management system and the resulting 'best-practices' designed to ensure the efficient production of safe agricultural products.
Good Manufacturing Practices (GMP's):	General procedures to reduce food safety hazards.
Good Hygienic Practices (GHP):	The basic rules for the clean and healthy handling, storage, processing, distribution and final preparation of all food along the food production chain.

- H -

HACCP (pronounced 'HAS-sip'):	Acronym of 'Hazard Analysis Critical Control Point', a systematic approach used in food production as a risk-based means to ensure food safety. A system that identifies, evaluates and controls hazards that are significant for food safety.
HACCP Coordinator:	Leader for the development and maintenance of a HACCP system.
HACCP Plan:	A written document that is based upon the seven principles of HACCP and that defines the procedures to be followed. A HACCP plan includes an evaluation of a product that is being processed and then specifies procedures to address hazards through prerequisite programs, control points and critical control points.
HACCP Reference Standard:	A written standard that provides all of the details necessary to implement a food safety program based on HACCP. It is an effective means of assuring food safety.
HACCP System:	A HACCP system is a science-based and systematic strategy that identifies specific hazards and measures for their control to ensure food safety through control points or critical control points. The system includes prerequisite programs and HACCP plans.

Hand-washing Station:	A means by which hot and cold running water are provided for the washing of hands. This station unit, which is directly connected to the facility's sewer system, has in its immediate vicinity: a. A dispenser for the provision of soap or is otherwise equipped with soap in a container; and b. A method of hand drying that uses single service products or a mechanical hand dryer.
Hazard Analysis:	Collecting and evaluating information on agents in or conditions of food with the potential to cause a significant adverse health effect or injury in consumers, and that must be addressed in the HACCP plan.
Hazard Identification:	Detection of known or potential health effects associated with a particular agent.
Hazard Characterization:	The evaluation of the nature of the harmful effects associated with biological, chemical, allergenic and physical agents present in food.
Hazard:	Agents in or conditions of food that have the potential to cause an adverse health effect or injury in consumers. A biological, chemical, allergenic or physical agent that is reasonably likely to cause illness or injury in the absence of a control.
Hygiene:	Conditions and practices followed to maintain health including sanitation and personal cleanliness.

- I -

Immune Response:	A bodily defence reaction that recognizes an invading substance (such as a virus, bacteria or allergen) and produces antibodies to counter the invader.
Immunodeficiency:	Impairment of the immune response that makes a person susceptible to infection and certain illnesses.
Implementation:	The process of putting into place program functions and activities.
Infective Dose:	The amount of a pathogen that is required to make someone sick.
Integrated Pest Management:	A decision-making process to foresee and prevent pest activity and infestation. The built-in process combines several means to achieve long-term solutions including staff education, proper waste management, building repair, maintenance as well as biological and mechanical control methods.
ISO:	International Organization for Standardization, a worldwide federation of national standards bodies (ISO- member bodies). The work of preparing national standards is normally carried out through ISO technical committees. Members of technical committees can be international organizations, governments and non-government groups.

- L -

Label:	Any legend, word, ticket, tag, sign or mark attached to, included in, belonging to or accompanying any food or food package.
Letter of Recognition:	A document awarded to a producer organization or processor following the successful completion of the 'Recognition Audit Process.'
Lot Number:	A distinct code for each product, batch or container. A distinctive combination of letters and/or numbers assigned to a specific identifiable batch of production.
Low-Risk Food:	Food that is unlikely to contain pathogenic micro-organisms and that (normally) will not support their growth due to the characteristics of the food (e.g. un-cooked grains and cereals, bread, carbonated beverages, sugar-based confectionary, alcohol).

- M N -

Management Commitment:	A pledge or promise by a senior individual within an organization to ensure that adequate resources are consistently provided to the food safety system.
Meat Facility Standards:	A regulatory standard for 'Alberta Licensed Meat Facilities' that is supported by the Meat Inspection Regulations. This standard includes **eight** programs: **seven** based on FSEP prerequisites and **one** that details the 'seven principles of HACCP.'
Medium-Risk Foods:	These foods may contain pathogenic micro-organisms but will not normally support their growth due to the characteristics of the food. Usually they are acidic, dried or high in salt (more than 20%) or sugar (more than 50%).
Microbial Hazard:	Microscopic organisms associated with foods that have the potential to cause an adverse health effect or injury to consumers.
Microbial:	Of or relating to micro-organisms, or to any life form too small to be seen with the naked eye.
Mock Recall:	A process designed to assess the effectiveness of a food processor's recall program and the readiness of the recall team. Mock recalls help to identify any gaps in traceability or problems that might have developed (e.g. new employees not following established protocols).
Mould:	A small multi-celled plant-like organism (classed a fungi) that generally reproduces by spore formation. These spores are very light and easily carried by air currents. They are also very resistant to drying and freezing, but are easily destroyed by heat.

Monitoring:	A planned sequence of observations or measurements to determine if Standard Operating Procedures (SOP's) are being followed or if critical limits are being met.
Multi-location Abattoir (Alberta):	An abattoir that is portable and that may be mounted on a vehicle.
Non-conformity:	Non-fulfilment of a requirement that is a stated, generally implied or an obligatory need or expectation.
Non-hazardous Food:	A food that has a shelf life greater than 90 days at room temperature.

- O -

On Farm Food Safety (OFFS):	Food safety programs developed to create the proper operating environment to minimize food safety risks on farms by implementing Good Agricultural Practices.
On-farm Food Safety Program:	A systematic, HACCP-based approach to promote the production of safe products at the farm level by a set of production practices including control measures, a producer's manual and a management manual.
On-site Verification:	The process of checking that the food safety system in an establishment has been implemented as written. This requires an audit of the operating food safety system to confirm it is implemented as designed and that the system is effective in meeting the requirements as set out in the reference standard.
On-the-job Training:	A teaching method that allows students or employees to gain practical (hands-on) experience while learning a trade or professional skill.
Operational Separation:	The act of dividing or disconnecting processing activities by non-physical means to ensure that incompatible processing activities do not cause product contamination. Examples include separation by time, or by sanitation activities.
Operator:	A person controlling, causing to function or engaging in a food-processing business.
Overhead Structure:	A piece of equipment or other entity that may be positioned over the employees' normal work station or traffic area.

- P -

Package:	Anything that food is wholly or partly contained, placed or packed.
Packaged Ice:	Potable frozen water that is sealed in a container or package and intended for human consumption.
Parasite:	An organism that lives in or on the living tissue of a host organism at the expense of that host.
Pathogen, Pathogenic Bacteria or Pathogenic Microorganism:	Any bacteria, virus, mould or other form of life that is too small to be seen by the naked eye and that is capable of causing disease, illness or injury.
Perishable:	Any food product or ingredient that is susceptible to deterioration or loss of quality when subjected to temperature abuse.
Personal Hygiene:	The combination of an individual's practices and style that relates to cleanliness. For example, healthy habits that include bathing, wearing clean clothing and, most importantly, washing hands frequently before handling to insure food safety.
Pest:	Any animal or insect of public health importance, including, but not limited to birds, rodents, roaches, flies and larvae that may carry pathogens that can contaminate foods.
Pesticide:	A substance used to prevent, destroy or repel any insect, nematode, rodent, predatory animal, parasite, bacteria, fungus, weed or other form of plant or animal life.

pH:	Scale that the acidity and/or alkalinity of a food is measured. The lower the pH number, the more acid there is in the product. pH values range from 0 to 14.
Physical Hazard:	Any danger to food safety by the contamination of food with any foreign materials that are not normally found in food.
Physical Separation:	The act of dividing or disconnecting processing activities by physical means to ensure that incompatible processing activities do not cause product contamination. Examples include walls, curtains and separate rooms.
Potable:	Any liquid suitable for drinking.
Potable Water:	Water that is safe for human consumption and that meets provincial water-quality standards.
Potentially Hazardous Food:	Food capable of supporting the rapid and progressive growth of pathogenic micro-organisms or the production of toxins. These products tend to have a pH greater than 4.6 and a water activity (a_W) of 0.85 or more.
Premises:	All elements (interior and exterior) in the building and surrounding property including driveway(s), parking lot(s), drainage, sanitary facilities, waste management or other related structures.
Pre-packaged Product:	Any product that is packaged in a container that will be normally sold to or used by a consumer without being re-packaged.
Prerequisite Programs:	Procedures that must be established to manage the basic conditions throughout the food chain, and the activities and practices that must be performed in order to establish and maintain a hygienic environment.

Preventative System:	A management system consisting of a number of programs and procedures designed to control food safety hazards. When properly implemented, such a system ensures that products are handled and/or processed so as not to pose a risk to human health.
Proactive:	Acting before a situation becomes a crisis or emergency affecting food safety.
Product Flow:	Sequential steps or procedures performed in the manufacturing of a processed food product.
Product Protection:	Program or procedures documented and implemented to ensure critical factors to food safety are controlled.

- R -

Ready-to-eat Foods:	Foods that require no further preparation before consumption (e.g. chocolate bars, salami).
Recall:	Process of removing from sale food products that do not meet legally required safety or company standards.
Record:	Documented evidence that a specific action or procedure has been performed. The information that results from documenting an action or procedure.
Record or Document Control:	Procedures and policies to ensure that the right people have the right copy of the right document at the right time.
Record Keeping:	A process of filling in forms to provide proof that policies are being followed or activities are being performed. It demonstrates that processes and procedures are being conducted properly.

Rework:	Manufactured products or processing materials that have failed a usability test and require the addition of labour or materials to avoid being scrapped. Generally used in connection with re-incorporating the materials into the production of future finished products.
Risk:	The likelihood of an occurrence and the size of the consequences of an adverse event. A measure of the probability of harm and the severity of impact of a hazard.
Risk Analysis:	A process that includes risk assessment, risk management and risk communication.
Risk Assessment:	The process of identifying a hazard and characterizing the risk presented by that hazard in qualitative or quantitative terms.
Risk Communication:	An open exchange of information and opinion leading to a better understanding of risk and risk-related decisions.
Risk Management:	The process of identifying, evaluating, selecting and implementing alternatives for mitigating or lowering risk.

- S -

Sanitation/ Sanitizing:	The application of some method or material to destroy all disease producing pathogens and other harmful organisms. Such treatment should result in a surface that is safe from a public health standpoint and that contributes to food protection and an extended shelf life.
Sanitation Program:	Written procedures outlining cleaning and sanitizing steps and methods.
Segregation:	The separation of the two activities, products, or equipment to prevent likely cross-contamination or contact.
Sell:	To offer for sale, to expose for sale and/or to have in possession for sale and distribution.
Shelf Life:	The period of time that a product can be stored under specified temperature conditions and remain suitable for use.
Shelf Stable:	Refers to foods that do not require refrigeration and that can be stored safely at room temperature without deterioration in quality within a specified time period.
Soil:	The material remaining on the surface of food equipment after processing.

Specification:	A detailed, exact statement of prescribed requirements for incoming materials or finished products.
Spoilage Bacteria:	Bacteria that break down foods so that they look, taste, and smell bad. Spoilage bacteria primarily affect the quality of food but also may affect product safety.
Standard Operating Procedure (SOP):	A written description of a particular task or procedure to ensure safe food handling. A set of instructions describing the activities necessary to complete a task that reduces the risk of foodborne illness.
Standard:	A set of rules or requirements established by authority, custom, or general consent as a model, example or point of reference.
Standards Council of Canada:	An agency that carries out a variety of functions intended to ensure the effective and coordinated operation of standardization in Canada.
Sterilize:	To completely eliminate microbial viability by approved means. To make free from all forms of life, including bacteria, usually using chemical or heat methods.
Supplier Food Safety Assurance:	A situation established when a processor enters into a formal agreement with its suppliers to ensure they provide their products under a stated set of conditions.
Systems Audit:	A procedure that verifies the applicant's written food safety system contains all of the required components and that each component meets or exceeds the requirements in the reference standard.

- T -

Temperature Abuse:	A situation that arises when food is not held at the proper temperature (e.g. keeping raw meat at room temperature for more than two hours before cooking).
Temperature Log:	An ongoing record of food temperatures.
Thermal Sanitation:	Sanitation method using hot water or steam for a specified temperature and contact time.
Third-party Audit:	A systematic examination by an outside person or firm to assess the effectiveness of the documented food safety system to determine if the requirements of the written program have been met.
Time/ Temperature Rule:	Rule stating that the growth of micro-organisms in food is affected by the temperature that the food is held as well as by how long the food is at that temperature.
Traceability:	To check the history, application or location of a food item by means of recorded information by tracking a food item forwards or backwards through the food-supply chain.
Trace-Back:	The ability to identify and trace the origin of problems when they occur.
Trace-Forward:	The ability to identify and follow the sale and/ or use of an affected product and provide information to those customers affected.
Tracing/ Tracking:	Identifying the origin of an item or group of items through records back or forward through the food-supply chain.

- U V W -

Utensil:	Equipment that is used in the preparation, processing, service, storage and dispensing of food. It does not include tabletops, counter tops or similar working surfaces.
Validation:	The process of obtaining evidence that the elements of your HACCP plan are effective. Validation involves obtaining confirmation that the elements of the HACCP system, including critical control points are complete and effective in controlling biological, chemical, and physical and allergen hazards. This may include challenge studies, heat distribution and process validation studies. *Validation Asks: 'Is this the right thing to do? And does it still work?'*
Verification:	Verification is the use of methods, procedures, tests and other means to check whether the HACCP system is correctly in place and if it is being followed (e.g. checking to make sure the temperature has been reached). Although the validation and verification activities may be similar, results from verification activities are not intended to be used to make decisions on the acceptability of products. Instead, the verification results are used to check the adequacy of food safety controls or how well they are working. *Verification Asks: 'Is what should be done, getting done?*'
Virus:	Any simple sub-microscopic parasites of plants, animals and bacteria that often cause disease and essentially consist of a core of RNA or DNA surrounded by a protein coat. Since they are unable to reproduce without a host cell, viruses typically are not considered living organisms.

Waste Management:	The collection, transport, processing or disposal of waste materials – including solid, liquid, gaseous or plasmic waste.
Water activity (a_W):	The amount of free water in food that is available to pathogens. Denoted by the symbol a_W. Pure water has a water activity of 1.0.
Water Treatment:	The use of chemicals or filtration to make water potable or suitable for boiler use.

Appendix B

QUESTIONS TO ASK WHEN CONDUCTING A HAZARD ANALYSIS

For each of the following 12 sections listed below, there are a useful questions that will help identify hazards connected with incoming materials and process steps at a facility.

1.0 INGREDIENTS

2.0 INTRINSIC FACTORS

3.0 FOOD PROCESSING STEPS

4.0 MICROBIOLOGICAL PROFILE OF INGREDIENTS OR FOOD

5.0 FACILITY DESIGN

6.0 EQUIPMENT

7.0 PACKAGING

8.0 SANITATION

9.0 WORKER HEALTH, HYGIENE AND TRAINING

10.0 CONDITIONS OF STORAGE
(FROM PACKAGING THROUGH TO THE END USER)

11.0 INTENDED CONSUMER USE

12.0 INTENDED CONSUMER

1.0 INGREDIENTS

1. Does the food or ingredient contain any:
    a. Microbiological hazards
    (e.g. Salmonella, Staphylococcus aureus);
    b. Chemical hazards
    (e.g. aflatoxin, antibiotic or pesticide residues); or
    c. Physical hazards (e.g. stones, glass, metal)?
2. Are ice and steam used in formulating or in handling the food?
    a. Is it made from potable water
    (water fit for human consumption)?
3. Does the geographical region or the supplier play a role in the hazards associated with the ingredients?

2.0 INTRINSIC FACTORS

Intrinsic factors are any chemical or physical characteristics that affect the microbial or chemical stability of the food, either during or after processing. These physical or chemical characteristics prevent the growth of bacteria to high levels. They also suppress toxin production.

Intrinsic factors can include:

- Acidity;
- Types of acidifying agents;
- Salt concentration;
- Carbohydrate type and concentration;
- Water activity (available free water); and
- Types of preservatives used.

1. What hazards could result if the chemical or physical requirements of the food are not met?
2. During processing or before the finished-product state, is there a likelihood of microbial growth that might contribute to the presence of toxins, or high levels of bacteria, resulting in unsafe food?

3. Does the finished product support the survival or growth of pathogens or toxin production in last stages of food handling, storage or consumption?

4. Can you compare your product to one that is already on the market? What hazards are associated with the existing product?

3.0 FOOD PROCESSING STEPS

1. Is there one step that is effective in killing pathogens? Does this step destroy vegetative and spore forms of the pathogen? If so, this will be the critical control point for biological hazards.

2. Is recontamination likely (usually through packaging or product handling) once the product is dealt with by the critical process? If so, what hazards (biological, chemical or physical) could result in recontamination of the product?

4.0 MICROBIOLOGICAL PROFILE OF INGREDIENTS OR FOOD

1. What are the usual associated pathogens or spoilage bacteria in the ingredient/food?

2. What is the likelihood of a pathogen being present in the ingredient/food before and during processing?

3. What is the severity of the pathogen presence in the ingredient/food before and during processing?

4. How does the ingredient/food's microbial profile change over time? How does it change:

    - Before consumption?
    - During normal shelf life?
    - During other conditions?

5. Is there a hazard from a change in the food's microbial profile over its normal storage? Could this affect the safety of the ingredient/food?
6. What is the likelihood of a pathogen being present in the food when it's consumed?
7. What is the severity of pathogen presence in the food when it is consumed?

5.0 FACILITY DESIGN

1. Are there concerns associated with facility layout with possible contact between raw materials and the finished products (e.g. cross-contamination)?
2. Are employee flow or equipment location possible sources of recontamination?
3. If producing ready-to-eat (RTE) foods, is there a risk of cross-contamination?
4. Is there a possibility of recontamination with pathogens? By what pathogens?
5. What hazards should be considered as possible contaminants of finished products?
6. In areas where finished product is handled, is positive air pressure needed for product safety?

6.0 EQUIPMENT

1. Is the equipment designed to deliver the necessary treatment (e.g. time and temperature) in order to produce safe food?
2. Is the equipment designed for the volume of food that is being processed?

3. Does the equipment operate without breakdowns? If it does breakdown, do alarms alert the operator?
4. Does the installation of the equipment allow for sanitation and ease of maintenance?
5. Does the design of the equipment allow for easy cleaning and sanitizing?
6. How likely is contamination from the equipment? Is there a chance of physical hazards (e.g. metal fragments, shavings), and/or chemical hazards (e.g. oils and lubricants)?
7. Does the use of the following pieces of equipment reduce the likelihood and severity of biological, chemical or physical hazards in food?
    a. Metal detectors
        - What are the metal hazards associated with the ingredients and the processing facility (ferrous, non-ferrous, stainless steel)?
        - Is the metal detector designed and calibrated for the product characteristics?
    b. Magnets
        - Is the magnet design effective for the process parameters?
    c. Sifters
        - Is the sifter regularly maintained?
        - Is it the appropriate opening size?
    d. Filters
        - Is the filter design effective for the process/product? Is it working well?
        - Are the filters regularly maintained?

e. Screens

- Are screens regularly maintained?
- Is it the appropriate opening size?

f. Thermometers

- Is the thermometer designed to be used for the process parameters?
- Is it calibrated?

g. Bone removal devices

- Is the bone detector designed for the process parameters?

8. Does normal equipment wear-and-tear contribute to the increased likelihood and severity of a physical hazard in the finished product?

9. Does equipment design allow for safe production of allergen and non-allergen containing ingredients? Also, does it allow for easy and effective cleaning and sanitizing? If not, what controls are needed to control these chemical hazards?

7.0 PACKAGING

1. Does the packaging affect the growth of bacteria and/or toxin formation?

2. Does the package include instructions on how to maintain product safety?

3. Are there clear and important instructions for the consumer to follow to ensure safe food preparation?

4. Is the packaging material resistant to damage? Or is it protective enough to minimize any packaging damage that might allow microbial contamination or possibly microbial growth?

5. Are there features to clearly indicate, or prevent, product tampering?

6. Is each package clearly labeled to allow for product tracking or recall?

7. What is the likelihood that a product will not be labeled with ALL necessary information? As a result of this, could it allow an allergenic product to get to consumers (without their knowledge of the allergen)?
8. Is the label correct for the actual packaged product? Does the label clearly identify the presence of allergens and ingredients?

8.0 SANITATION

1. Can sanitation procedures affect the safety of the food?
2. Are the facility and equipment designed for easy cleaning and sanitization?
3. Can the sanitation program be delivered effectively? Can it react to situations where ongoing sanitation is needed?

9.0 WORKER HEALTH, HYGIENE AND TRAINING

1. Can employee health or personal hygiene practices impact the safety of the food being processed?
2. Do employees understand the process and the factors they must control to ensure preparation of safe foods?
3. Will the employees tell management about any problem that could impact food safety?

10.0 CONDITIONS OF STORAGE - FROM PACKAGING THROUGH TO THE END USER

1. What is the likelihood that the food will be temperature abused during transport and storage (exposed to temperatures above the desired temperature)? What is the likelihood of this leading to unsafe food? What is the severity of this hazard?
2. What is the likelihood that the food will be exposed to hazards (biological, chemical and/or physical) during transport or storage? And will this contribute to contamination?

11.0 INTENDED CONSUMER USE

1. What is the likelihood that the consumer will not heat the product enough if heating is required? What are the risks of such an action, or lack of action?
2. What are the risks if the product is consumed past its listed shelf life?
3. If leftovers result, what is the likelihood that the product will become unsafe? How severe are the consequences of this?

12.0 INTENDED CONSUMER

1. What consumer is the food intended for? Is it intended for:
   a. General public (healthy population);
   b. Infants;
   c. Children;
   d. Elderly; and/or
   e. Immuno-compromised individuals?
2. What is the likelihood that the food intended for the general public is consumed by someone more inclined to illness (infants, immuno-compromised, the elderly)?

3. Where will the food be prepared for consumption?
    a. Consumer's home;
    b. Food service;
    c. Restaurant; or
    d. Institution (e.g. hospital)?

Appendix C

BASIC FOOD MICROBIOLOGY

1.0 MEET THE CULPRITS
- 1.1 Bacteria
- 1.2 Viruses
- 1.3 Parasites
- 1.4 Yeasts, Moulds, and Other Fungi

2.0 FACTORS AFFECTING GROWTH
- 2.1 Food
- 2.2 Acidity
- 2.3 Temperature
- 2.4 Time
- 2.5 Oxygen
- 2.6 Moisture

3.0 SOURCES OF INFORMATION

Microorganisms are tiny life forms capable of rapid reproduction under some growth conditions. Many have been found to be useful to the food industry. Examples include bacteria used in the production of yogurt and cheese, or yeast for bread production. Many have also been found to cause problems such as food spoilage and illness.

According to public health and food safety experts, millions of illnesses in the United States can be traced to foodborne bacteria each year. The U.S. Public Health Service has identified the following microorganisms as being the biggest culprits of foodborne illness either because of the severity of the sickness or the number of cases of illness they cause. Beware of these pathogens:

- CAMPYLOBACTER – raw and undercooked meat and poultry, raw milk and untreated water.
- CLOSTRIDIUM BOTULINUM – honey, root vegetables, home prepared foods.
- E.COLI O157:H7 – undercooked meat, produce, raw milk.
- LISTERIA MONOCYTOGENES – dairy products, soil, water, deli meat products, poultry and seafood, and produce.
- NOROVIRUS – any food if handled by someone who is infected, or in a water storage system.
- SALMONELLA – raw and undercooked eggs, undercooked poultry and meat, dairy products, seafood, produce.
- STAPHYLOCOCCUS AUREUS – cooked foods high in protein, commonly found on human hands.
- SHIGELLA – salads, dairy products, and unclean water. Poor hygiene allows shigellosis to easily be transmitted from person to person to food.
- TOXOPLASMA GONDII – primarily pork products.
- VIBRIO VULNIFICUS – raw or undercooked seafood.

Least Wanted Foodborne Pathogens fightbac.org, the website of the Partnership for Food Safety Education (PFSE), is your resource for Fight BAC! food safety and safe food handling campaign information. © 2006 http://www.fightbac.org/content/view/14/21

Microbes are everywhere. They are found in:

- Air;
- Water;
- Food;
- Soil;
- Humans (nose, gut, skin, etc.); and
- Surfaces.

Although many are found in locations where environmental factors are ideal to support their multiplication, many also are able to survive and even multiply outside their natural surroundings.

1.0 MEET THE CULPRITS

There are more than 200 known illnesses that a person can get from eating contaminated food. These illnesses can result from disease-causing bacteria, viruses, toxins and parasites. These harmful microorganisms are known as pathogens.

Pathogens can cause illness in three ways:

- Pathogens found on contaminated food infect intestines causing illness;
- Pathogens on contaminated food produce toxins that cause poisoning; and
- Pathogens found on contaminated food infect intestines and produce toxins that cause illness.

1.1 Bacteria

These microorganisms are small, living, single-celled life forms that are easily carried by food, water, humans, insects and air. They can reproduce rapidly when exposed to ideal conditions and can be hard to control. Some bacteria can survive freezing, some grow easily when food is cold, and some can form endospores (change their structure to create very tough, resistance outer coatings etc.).

When bacteria first come into new surroundings (e.g. food source), they go through an adaptation phase. During this time, they do not multiply. This lag phase is a key time to use controls, such as temperature acidity, to inhibit bacterial growth. The next stage is called a logarithmic growth phase. This is when bacteria rapidly multiply under ideal conditions. (can double in number every 15 minutes). During this multiplication, by-products like acid and a reduction of food resources lead to a gradual slow-down and eventually limit further reproduction. Toxins are most commonly produced at this point. Since toxins can form before the bacteria are able to cause visible changes to the food, food that looks fine may cause poisoning and illness.

1.2 Viruses

Viruses are extremely small life forms that need living cells to grow. Viruses can also be described as a packet of genetic material that needs a host to reproduce. Infection can occur with very few viruses, which usually contaminate food through poor staff personal hygiene. All foodborne viruses have been shown to originate from the human gut, and therefore tend to affect the gut. Viruses have been known to survive cooking and freezing.

1.3 Parasites

Like viruses, parasites need to live in or on a host organism to survive and refer most commonly to toprotozoa or parasitic worms, which are too small to be seen with the naked eye. Many of these parasites have complicated life cycles where a human host is only one step. Commonly infected organs include muscles, the brain, eyes and the gut.

1.4 Yeasts, Moulds, and Other Fungi

These organisms are more commonly connected with food spoilage than food-related illnesses. However, a few moulds can cause illness in humans. Often this is due to the production of toxins during growth. These toxins have been shown to be able to cause cancer, hay fever and some forms of asthma.

2.0 FACTORS AFFECTING GROWTH

All microorganisms, like any other living organism, depend on their environment to survive. Unfavourable conditions have been shown to alter their reproductive rates or even kill them. By influencing what microorganisms need for growth, processors can gain control.

Toss the Sponge

Damp towels and sponges may provide the perfect environment for pathogen growth. Consider using paper towels for cleaning up surfaces or drying equipment and hands. If you use cloth towels, wash and sanitize them often.

Your company can take several steps to prevent or control food contamination by potentially harmful organisms. The most common controls involve altering one or more of the following:

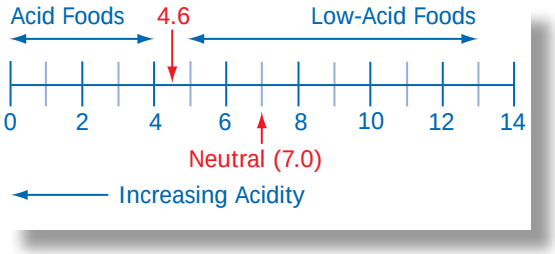
- Food;
- Acidity (pH);
- Temperature;
- Time;
- Oxygen; or
- Moisture.

2.1 Food

Like all animals, microbes require food or nutrients for growth and survival. The easiest method of control is cleaning. Cleaning removes visible soil and food residue from equipment and surfaces. Food residue left on equipment is a source of food for bacteria. If equipment and surfaces are not cleaned properly, these organisms multiply and contaminate the next batch of food.

2.2 Acidity

Bacteria do not like living in very acidic or low-acid, or basic (alkaline) environments. Many pathogenic organisms grow well somewhere between a pH of 4.6 and 7.5. Many foods are preserved by adding acid to their ingredients.



Acidic foods have pH values below 4.6. These foods include pickles, most fruits, and jams and jellies made from fruit. Acidic foods contain enough acidity either to stop the growth of bacteria or destroy the bacteria more rapidly when heated.

Low-acid foods include red meats, seafood, poultry, milk, all fresh vegetables and some tomatoes. Low-acid foods have pH values higher than 4.6 and do not contain enough acid to prevent the growth of bacteria. When low-acid foods are used in formulations, it is important that they be properly acidified before they have a chance to spoil.

2.3 Temperature

Like acidity (pH), there are minimum and maximum temperature values for optimal pathogenic growth. Keep food out of the 'Danger Zone', the temperature range when bacteria and spoilage organisms grow most quickly: between 4º C and 60º C. When food is left in the Danger Zone, bacteria can grow fast and reach unsafe numbers in your food product. Follow the simple rule of keeping hot foods hot and cold foods cold to help ensure that your product will be safe for your consumers.

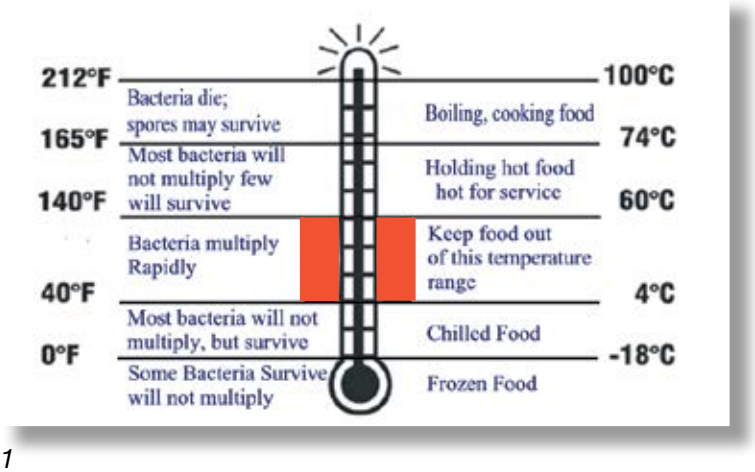


Figure 1

Courtesy the Marketing Food Safety – Farm Direct Advantage Manual developed in a partnership with Alberta Agriculture and Food and the Alberta Farmers' Market Association.

High-risk foods can support fast microbial growth and exposure to the Danger Zone should be minimized. These foods include:

- Meat, seafood, fish or poultry and foods that contain them, such as casseroles, deli meats, salads and sandwiches;
- Eggs and other protein-rich foods, like soybean products, and foods that contain these items;
- Dairy products and foods containing dairy products;
- Fresh-cut or peeled fruit or vegetables;
- Cooked vegetables, beans, rice and pasta dishes;
- Sauces, gravy, and other low-acid food products; and
- Sprouts, such as alfalfa and bean sprouts.

Appearance and touch are not reliable signs of safe temperatures. Taking food temperatures correctly and using a properly adjusted food thermometer is the only way to ensure that food is kept out of the Danger Zone.

Many foods companies use heat processing to ensure safe products. These products are usually foods where other controls do not work and involve placing the food in extreme temperatures for a longer time. For commercial sterility, this period must be long enough to reduce the number of organisms by a factor of 109. That means there are one billion times fewer organisms. Temperatures and processing times that destroy microorganisms may fail to get rid of enzymes and not destroy toxins that are heat stable. These toxins may cause illness in people who eat them. Thermal processing is no substitute for good quality raw materials, good raw-material safety and safe food handling and processing.

2.4 Time

If they remain in the Danger Zone for more than four hours, all pathogenic microorganisms can increase to unacceptable levels that can result in illness.

2.5 Oxygen

Microorganisms have different oxygen needs. Some need oxygen to grow, some will grow only when there is no oxygen, and some can grow with or without oxygen. Some packaging methods work by restricting or stopping availability of oxygen. These include modified-atmosphere packaging and vacuum packaging.

2.6 Moisture

Water is necessary for most life forms to grow. If a product is dry, then bacteria cannot grow as well as when there is water. Water in food that is not bound to food molecules can support the growth of bacteria, yeasts and moulds (fungi). The term water activity (a_W) refers to this unbound water.

The water activity of a food is not the same thing as its moisture content. Although moist foods are likely to have greater water activity than dry foods, it is not always so. In fact, certain foods may have exactly the same moisture content and yet have quite different water activities.

The Typical Water Activity of Some Food Products

Type of Product	Water Activity (a_W)
Fresh Meat and Fish	0.99
Bread	0.95
Aged Cheddar	0.85
Jams and Jellies	0.80
Plum Pudding	0.80
Dried Fruit	0.60
Biscuits	0.30
Milk Powder	0.20
Instant Coffee	0.20

The water activity (a_W) represents the ratio of the water vapour pressure of the food to the water vapour pressure of pure water under the same conditions. It is expressed as a fraction. If we multiply this ratio by 100, we obtain the equilibrium relative humidity (ERH) that the food product would produce if enclosed with air in a sealed container at constant temperature. Thus, a food with a water activity (a_W) of 0.7 would produce an ERH of 70 per cent. Maintaining a water activity of 0.85 or less holds back the growth of most pathogenic organisms that threaten public health.

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Appendix D

FOOD SAFETY RISK ANALYSIS

1.0 RISK IN FOOD PROCESSING
- 1.1 Risk Analysis
- 1.2 Risk Assessment
- 1.3 When to do a Risk Assessment
- 1.4 Risk Assessment and HACCP
- 1.5 The Health Risk Assessment Model

2.0 RISK MANAGEMENT
- 2.1 Steps of Risk Management

3.0 RISK COMMUNICATION

4.0 SOURCES OF INFORMATION

It's important to consider hazards and risks in food processing. Hazards are often thought of as the same as risks, however, hazards are quite different from risks. The differences between them are outlined in more detail in this appendix.

1.0 Risk in Food Processing

In food processing, a hazard is a biological, chemical, allergenic or physical substance that has the potential to harm. It may also be a condition (e.g. high humidity) that could cause harm.

Not all hazards are as serious, or as immediate a threat, as others. Some situations can be more 'hazardous' depending on the levels, sizes, quantities, or doses of unwanted substance or conditions.

When it comes to food and food processing, just how hazardous a substance or condition is may vary greatly. The level of danger can depend not only on the type hazard, but also on who might consume a food product. There usually is a threshold level below or above which the presence of a hazard is considered tolerable, or acceptable.

1.1 Risk Analysis

Risk is a measure of the likelihood of a hazard doing harm and how much harm the hazard could do. Or, another way of looking at it is to consider risk an estimate of the probability of a hazard being present.

All activities related to food production and handling involve some hazards. However, how we do something or what we do determines the level of risk.

By understanding how to reduce or eliminate food hazards, it's then possible to set up food safety controls. These will lower risks to consumers and these actions are an important part of risk analysis.

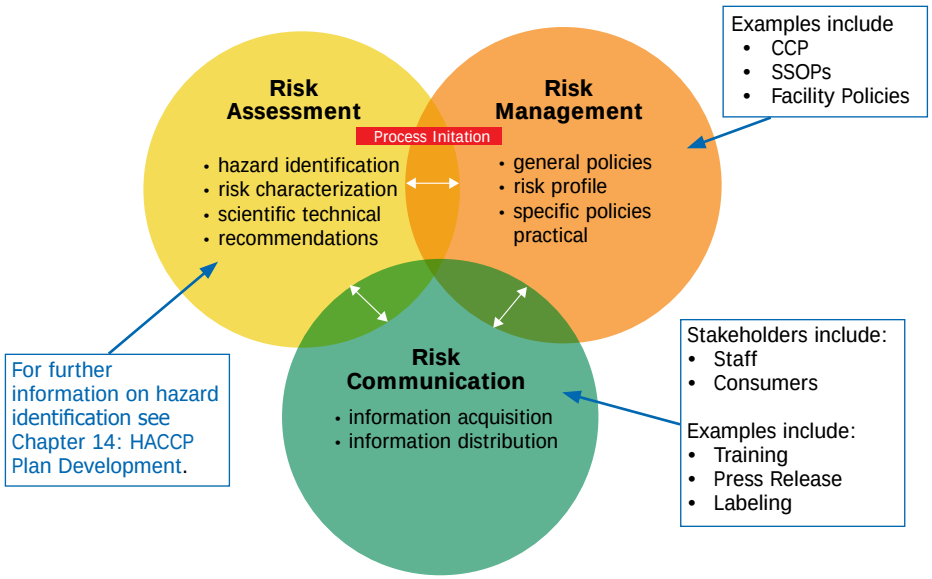
A food safety risk analysis directs time and attention to greatest safety concerns in a facility. Not every food safety issue will need a formal risk analysis. It may be possible to deal with many issues in-house with well-trained staff. Depending on the situation, the facility may need the knowledge or services of an outside consultant.

Risk is an estimate of the chance of a hazard being present and the chance of it causing harm.

Risk analysis deals with:

- Assessing the risk;
- Managing the risk; and
- Risk communication.

Figure 1: Schematic Diagram of Risk Analysis



Begin the risk analysis by identifying and describing any hazards, problems or situations in the facility and its food production process. Look for anything that could be a risk to human health.

To make this list of risks, use information from:

- Consumer feedback;
- Audit results;
- New scientific research; and
- Staff comments and input.

Potential risk factors might include the food processing operation, post-preparation handling or even food safety practices in the home of consumers.

The level of risk could also relate to how retailers and distributors handle, store and process the facility's products. Consider the cause and effect relationship between the identified substance, agent or event, and how this might affect food safety.

To find more information on food safety risk analysis, visit the University of Maryland's Joint Institute for Food Safety and Nutrition (JIFSAN) at their Online Resource for Food Safety Risk Analysis at www.foodrisk.org.

1.2 Risk Assessment

The first step in risk analysis is risk assessment. This helps the facility to decide on the level of risk for each hazard. Risk assessment should provide complete information to allow the risk management team to make the best possible decisions.

Begin the risk assessment by answering three basic questions:

1. What could go wrong?
2. How likely is the event to happen?
3. What would be the outcome or impact if this event happened?

A risk assessment is never exact. The results of the risk assessment point toward probable outcomes that describe the population risk (e.g. look into density, distribution, disease and/or death).

Always think about science and public values when looking at food safety.

1.3 When to do a Risk Assessment

Ingredients, processes, consumers and other product factors are important in deciding if a formal risk assessment is needed. In general, do a risk assessment for products, processes and activities that could result in an increase in a health risk. Do so for anything that could have a direct affect on food safety.

Examples might include:

- The use of new additives in the facility's food products;
- Facility changes that affect exposure and product safety;
- Environmental changes at the facility that could affect product safety;
- Changes to the process or facility that might affect the microbiological or chemical safety of food supplies or the food supply chain; and
- Assess existing facilities, procedures, processes and policies to improve existing risk prevention.

1.4 Risk Assessment and HACCP

Risk assessments can be very complicated and lake a lot of time. Don't hesitate to get help from an expert.

Risk assessment is very important in developing a HACCP (Hazard Analysis Critical Control Point) system.

Hazard Analysis is the first principle of HACCP plan development. A hazard analysis looks at the hazards that might affect a food product or raw ingredient in a processing operation. It includes collecting and evaluating information on each hazard and looks at the conditions that may cause the hazard to be present or to increase.

Once the facility decides that one or several hazards are present, do a food safety risk assessment. This will help to decide which hazards are great enough to affect food safety. These must be dealt with in the HACCP plan.

The facility's risk assessment should be based on the presence of the hazard, agent, or cause. It should also be based on how serious the hazard is, and how likely it is to reach unacceptable levels.

For example, the facility might come to the following conclusions:

- If an agent isn't present in the raw materials, production lines, or environment, it may be safe to assume it's not a hazard;
- If an agent is known to be in the facility's environment, but it can't contaminate the product, it may be safe to assume it's not a hazard;
- If the agent can contaminate the product it may become a hazard; and
- If the agent can survive, stay or increase, it may become a hazard.

This type of food safety risk assessment can often be done quickly. But sometimes the issue may be large and complicated. It may involve major health concerns and in these situations, the facility may need outside help.

1.5 The Health Risk Assessment Model

The Canadian Food Inspection Agency (CFIA) and Health Canada have developed a health risk assessment model. It lets the facility assess food safety by ranking risks on how severe they are. This assessment model offers a simple method that processors can use to look into food safety concerns.

The CFIA approach:

- Is based on current science;
- Allows for an assessment of the significance of any given risk; and
- Uses common sense.

When estimating health and safety matters, the CFIA assessment model takes into account:

1. Impact of consequences;
2. Probability; and
3. Population at risk.

CFIA Risk Assessment Summary

1. Identify the problem.
2. Determine if product safety is affected.
3. Identify the concern or hazard.
4. Evaluate the probable outcomes.
5. Determine if a sensitive population is likely to be affected.
6. Assess what controls are currently in place to deal with the hazard or concern.
7. Based on current controls, place a value to the chances of something harmful happening.
8. Decide whether the risk is remote, low, major or critical.

Identify the Problem

Keep in mind, studies have shown that 90 percent of problem solving is spent on:

- Dealing with the wrong problem;
- Describing the concern in a way that can't be answered; and
- Trying to get agreement on a solution before the problem has even been identified.

In deciding whether or not to do a formal assessment ask:

1. What is the concern or hazard?
2. Why is it a concern or hazard?
3. How urgent is this concern?
4. What do consumers think of this concern?

Determine if Product Safety is Affected

The CFIA has also developed a process to help decide what's most important. It looks at the immediate effect on human health and considers other possible impacts, like business reputation and financial impact.

The CFIA process gives the highest priority to figuring out the expected immediate impact on health. Give priority to anything where an expected emergency could immediately endanger human health.

To deal with this step, ask:

- What can go wrong?
- What disease agents, pests, hazards could be involved?
- What end results are concerns (e.g. infection, clinical disease, death, lost trade, recall)?

Evaluating the Outcome

To determine the probable outcome, look into both human concerns and financial impacts. In the CFIA assessment model, human concerns and financial impacts are noted on the X or horizontal axis (see Figure 1 on the next page).

The impact of a hazard affects not only consumers, but also the facility's business.

Health and Safety Concerns:

The health and safety effects of hazards on consumers (e.g. illness, injury, etc.) fall into one of the following groups:

- **Low** – no medical attention required;
- **Medium** – medical attention required, but recovery of the consumer expected; and
- **High** – medical attention required, no chance of recovery of the consumer expected.

The seriousness of a hazard might increase for people who are sensitive to certain situations or materials (e.g. allergens). For example, the outcome related to a hazard may be more serious if a product is used mainly by a sensitive population like newborns or the elderly.

The elderly, newborns, small children and people with severe allergies or poor immune systems are examples of sensitive populations.

Business Impact

The impact on the facility's business can be measured in dollars (e.g. lost sales or revenue). It can also be measured in reduced output. The impact of lost sales in a year can be grouped as:

- **Low** – minimal effect to sales, or costs for recovery;
- **Medium** – noticeable loss in sales, large expense for recovery; and
- **High** – loss or closing of the business.

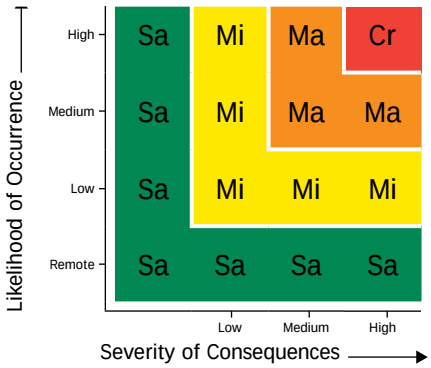
Likelihood of Occurrence

The Y or vertical axis of the assessment model (see Figure 1 below) lists the probability or chance of something happening. The chance of an undesirable outcome can be listed as:

- **High**
- **Medium**
- **Low**
- **Remote**

The chance of an unwanted outcome happening tends to increase as control over products and processes decreases.

Figure 2: CFIA Risk Assessment Model



Significance of the Hazard

Figure 1 shows how a food safety hazard is decided using the CFIA assessment model. By looking at each axis and combining their results, the facility can see different outcomes of the various combinations (Sa = Satisfactory; Mi = Minor; Ma = Major; Cr = Critical).

There are four levels in this risk assessment model:

- **Satisfactory** – a REMOTE (small) possibility of health or economic risk
- **Minor** – a LOW health or economic risk
- **Major** – a MODERATE health or economic risk
- **Critical** – a HIGH health or economic risk

2.0 RISK MANAGEMENT

Risk management was originally considered a separate part of risk analysis. However, risk analysis experts now realize that risk management and risk assessment overlap. Risk management is about choosing the best way to reduce the risk.

The main goal of food safety risk management is to protect public health. This is done by controlling risks as much as possible. Risk assessment results allow the facility to decide how to manage its own unique risks.

Since it isn't possible to eliminate risk, the facility must reduce it to an acceptable level.

2.1 Steps of Risk Management

The five steps of risk management are:

1. Evaluate the risk;
2. Determine a course of action;
3. Put a plan in place;
4. Monitor and review; and
5. Document all actions.

1. Evaluate the Risk

Most information needed for risk evaluation comes from the risk assessment. Next, use the following steps to decide how to reduce the risk:

1. Identify the food safety problem;
2. Put together a risk profile;
3. Rank each hazard for risk assessment priority (importance);
4. Rank each hazard for risk management priority; and
5. Consider the risk assessment result.

2. Determine a Course of Action

New control measures for one hazard might affect the probability of risks for other hazards. For each risk management option considered, evaluate how much the risk is reduced. Also look at how each change being considered could affect other processes and hazards.

The CFIA risk assessment model recommends making human health the priority. When human health is at immediate risk, it must be the facility's first concern.

Risk to human health must be managed through the facility's recall program. It will also be managed through the facility's product protection procedures or HACCP plans. After dealing with all human health concerns, consider other factors. Look at economic costs (e.g. lost profits), benefits (e.g. improved shelf life) and consumer preferences (e.g. use of preservatives).

3. Implement a Plan

Once the facility decides on the action to take, develop a plan. Set specific tasks and timelines. Make sure to carry out the plan.

4. Monitor and Review

Monitored and re-evaluate all activities so that that they achieve the facility's goals. The feedback from monitoring and reviewing the risk management program will let the facility know how well the program and process work.

5. Document Actions

As with all other parts of the facility's food safety system, thorough record keeping is important for risk analysis. Be clear in identifying and keeping records of all parts of the risk management process. Be sure to include the decisions made and the reasons for making them.

3.0 RISK COMMUNICATION

Risk communication lets the facility identify and weigh options during the risk analysis process. Open communication among all stakeholders (from employees to consumers) will improve the overall risk management. When the facility decides on a course of action, make sure that the decision and the reasons for it are explained clearly to everyone involved.

Risk communication is very important during food safety emergencies. However, to help make sure the message stays constant and clear, communication is also very important when there is no crisis.

The main goals of risk communication are:

1. Promoting awareness and understanding of risks (amongst employees, government officials and consumers);
2. Promoting consistency and clarity about the risk analysis process;
3. Providing an understanding for risk management decisions;
4. Strengthening good working relationships and promoting respect;
5. Promoting appropriate involvement of all stakeholders groups; and
6. Exchanging information, knowledge, attitudes, practices and perceptions of those involved.

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Appendix E

HACCP FORMS

1.0 FORM 1
Product Descripition

2.0 FORM 2
List of Product Ingredients and Incoming Materials

3.0 FORM 3
Process Flow Diagram

4.0 FORM 4
Plant Schematic

5.0 FORM 5
Hazard Identification and CCP Determination Incoming Materials
Hazard Identification and CCP Determination Process Steps

6.0 FORM 6
Hazards Not Controlled By Operator

7.0 FORM 7
HACCP Plan

FORM 1

PRODUCT DESCRIPTION

PROCESS / PRODUCT TYPE NAME: _____

1. PRODUCT NAME(S)
2. IMPORTANT PRODUCT CHARACTERISTICS (e.g., A_w, pH, PRESERVATIVES)
3. HOW IT IS TO BE USED
4. PACKAGING
5. SHELF LIFE
6. WHERE IT WILL BE SOLD
7. LABELLING INSTRUCTIONS
8. SPECIAL DISTRIBUTION CONTROL

Issue date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Instructions
Identify Hazards by placing a:
(B) Biological
(C) Chemical
(P) Physical, and/or
(A) Allergens
directly adjacent to the items listed

FORM 2

LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIALS

PRODUCT NAME: _____

List incoming raw materials and ingredients by product	List all incoming processing aids	List all incoming packaging materials
_____	_____	_____
_____	_____	_____

Issue date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Instructions
Construct a process flow diagram from incoming ingredients through to finished product. Number each step in the process and identify Biological (B), Chemical (C), Physical (P) and/or Allergen (A) hazards associated with each step, and if applicable, clearly identify each Critical Control Point (CCP).

FORM 3

PROCESS FLOW DIAGRAM

PRODUCT NAME(S): _____

Issue date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Instructions
Construct a plant schematic of the facility, identifying all equipment and rooms. Indicate the flow of product as well as employee traffic patterns. Identify all potential cross-contamination points, Biological (B), Chemical (C), Physical (P) and/or Allergen (A).

FORM 4

PLANT SCHEMATIC

PRODUCT NAME(S): _____

Issue date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

FORM 5

HAZARD IDENTIFICATION AND CCP DETERMINATION

Incoming Materials

List all incoming materials as identified in Form #2.	List all Biological (B), Chemical (C) , Physical (P) and/or Allergen (A) hazards associated with the incoming materials. Rate the likelihood of hazard occurrence = L (H=High, M=Medium, L=Low, R=Remote). Rate the Severity of Hazard if it Occurs = S (H=High, M=Medium, L=Low). B C P A L S	Determine if each hazard is FULLY controlled by prerequisite program(s). * If "YES" indicate program details and proceed to next identified hazard. * If "NO" proceed to question 1 (Q1).	HACCP Team Notes (Justify your decision),	Q1. Could a control measure(s) be used by the operator at any process step to eliminate the hazard or reduce it to an acceptable level? * If "NO" then it is not a CCP. Indicate how this hazard will be controlled before or after the process and proceed to the next identified hazard. * If "YES" describe the control measure and go to question 2 (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" then it is not a CCP. Explain and proceed to the next identified hazard. * If yes, go to question 3 (Q3).	Q3. Is this process step specifically designed to eliminate the identified hazard or reduce its likely occurrence to an acceptable level? Note: This question is not applicable for incoming materials. Indicate "NA" and proceed to question 4 (Q4).	Q4. Will a subsequent process step eliminate the identified hazard or reduce its likely occurrence to an acceptable level? * If "NO" then it is a CCP. Go to the last column. * If "YES" then it is not a CCP. Identify subsequent step and proceed to the next identified hazard.	CCP number * Proceed to next identified hazard.

Issue date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

FORM 5

HAZARD IDENTIFICATION AND CCP DETERMINATION

Process Steps

List all process steps as identified in Form #3.	List all Biological (B), Chemical (C) , Physical (P) and/or Allergen (A) hazards associated with the process steps. Rate the Likelihood of Hazard Occurrence = L (H=High, M=Medium, L=Low, R=Remote). Rate the Severity of Hazard if it Occurs = S (H=High, M=Medium, L=Low). B C P A L S	Determine if each hazard is FULLY controlled by prerequisite program(s). * If "YES" indicate program details and proceed to next identified hazard. * If "NO" proceed to question 1 (Q1).	HACCP Team Notes (Justify your decision),	Q1. Could a control measure(s) be used by the operator at any process step to eliminate the hazard or reduce it to an acceptable level? * If "NO" then it is not a CCP. Indicate how this hazard will be controlled before or after the process and proceed to the next identified hazard. * If "YES" describe the control measure and go to question 2 (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" then it is not a CCP. Explain and proceed to the next identified hazard. * If "YES" go to question 3 (Q3).	Q3. Is this process step specifically designed to eliminate the identified hazard or reduce its likely occurrence to an acceptable level? * If "NO" go to question 4 (Q4). * If "YES" this step is a CCP. Go to last column.	Q4. Will a subsequent process step eliminate the identified hazard or reduce its likely occurrence to an acceptable level? * If "NO" this step is a CCP. Go to the last column. * If "YES" then it is not a CCP. Identify subsequent step and proceed to the next identified hazard.	CCP number * Proceed to next identified hazard.

Issue date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

Instructions
List all Biological (B), Chemical (C), Physical and/or Allergen (A) hazards that are not controlled by the operator.

FORM 6

HAZARDS NOT CONTROLLED BY OPERATOR

PRODUCT NAME(S): _____

HAZARDS	INDICATE HOW THE HAZARD COULD BE ADDRESSED (e.g., COOKING INSTRUCTIONS, PUBLIC EDUCATION, USE BEFORE DATE)
Incoming Materials	
Process Steps	

Issue date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____

FORM 7

HACCP PLAN

PRODUCT NAME: _____

Process Steps	CCP / Hazard Number	Hazard Description	Critical Limits	Monitoring Procedures				Deviation Procedures	Verification Procedures	HACCP Records
				Who	What	How	Frequency			

Issue date: _____

Developed by: _____ Date last revised: _____

Authorized by: _____ Date authorized: _____