
A QUALITY AND FOOD SAFETY GUIDE FOR SEAFOOD PROCESSORS

Supporting access to new markets
by enhancing quality and food safety
knowledge and skills of seafood
processors in Nova Scotia through
skills development and education.



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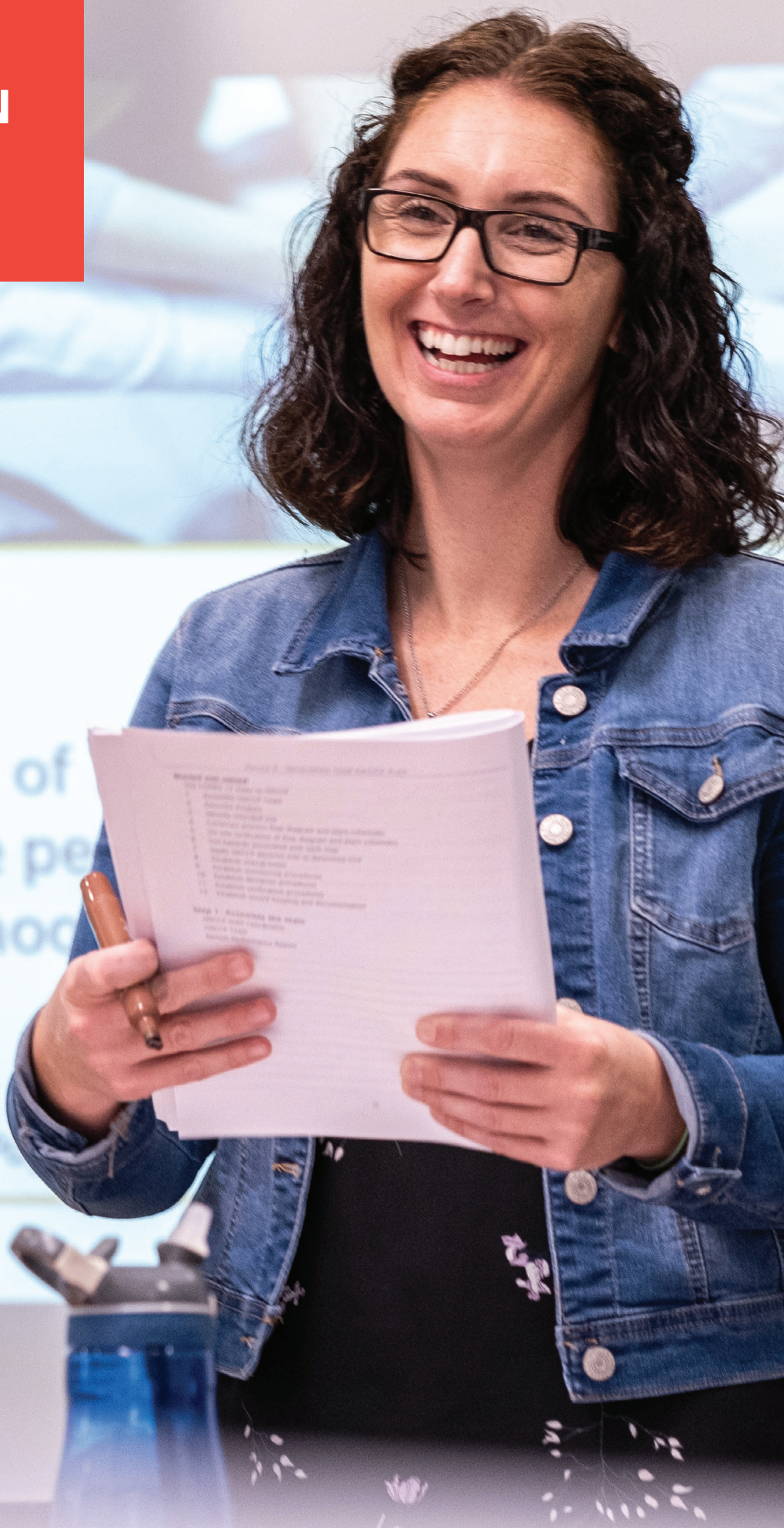
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INTRODUCTION

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Anyone who prepares and sells food is responsible for providing a safe product. Not only are customers expecting safe products, but they are also expecting high quality. Today's customers and retailers are requesting more from food processors such as supplier assurance guarantees, 3rd party certification or GFSI (Global Food Safety Initiative) certification, demonstrating that the food that is harvested, processed and/or stored is safe for consumption and of good quality. These requests can feel overwhelming to small and large seafood processors alike as they already have to comply with regulatory programs.

This guide has been developed to assist seafood companies in improving their existing quality and food safety management systems. It covers continuous improvement, food defense, food fraud, environmental monitoring, corrective action plans and more.

As always, if you have questions, feel free to contact our Quality and Food Safety Specialists. We are here to help.

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IMPORTANCE OF A QUALITY AND FOOD SAFETY MANAGEMENT SYSTEM

It is estimated that approximately 4 million (1 in 8) Canadians are affected by a food-borne illness annually. Of these 4 million, 11,600 will be hospitalized, and 238 will die. Food-borne bacteria, parasites and viruses are the main culprits in food-borne illnesses. Most people will not experience life-threatening symptoms from a food-borne illness, however, there are populations that are more susceptible. These include infants and young children, pregnant women, the elderly, those with weakened immune systems (i.e., people with diabetes, liver or kidney disease, alcoholism, etc.) or those who suffer from food allergies.

Robust quality and food safety management systems help prevent food safety hazards and reduce the likelihood of contaminated food. This is the most crucial reason to implement a quality and food safety system, not to mention it's the law. However, a quality and food safety system does come with additional benefits. These programs will not only help you meet consumer expectations and gain a loyal customer following but they will also help you gain access to new markets. As a result of a properly developed and maintained quality and food safety program, you will experience reduced customer complaints, recalls, rework, waste and legal liability – all of which are costly ordeals. A quality and food safety system equals due diligence and protects your brand.

Although consumers are responsible for handling their food with care (i.e., proper storage temperatures, avoiding cross-contamination/cross contact etc.), the assurance that a food product will not cause harm to a consumer largely remains the responsibility of those processing, manufacturing, storing, and transporting the food. This guide will help seafood processors implement and/or strengthen their current quality and food safety management system to contribute to safe food for customers.

FOOD SAFETY HAZARDS

The biggest food safety concerns with seafood production and processing are biological, chemical and physical hazards. Biological hazards include bacteria, viruses, parasites, or fungi (yeast and moulds) that can cause food-borne illness if they or their toxins are ingested.

Biological hazards can be found anywhere that conditions favour their growth. Such conditions include ideal: temperature, humidity, pH, water activity and oxygen availability. Bacteria can be found in soil, mud, air (i.e., aerosols or dust suspended in air), water, decaying matter, fecal matter, sewage, the gut of warm-blooded animals and even in our nose, mouth and on our skin. Fungi are typically found in warm and humid environments.

Chemical hazards can fall into three broad categories; naturally occurring toxins and allergens (i.e., shellfish toxins and mycotoxins); chemicals intentionally added to food (i.e., water, preservatives and additives); and chemicals unintentionally added to food (i.e., chemicals from packaging material, chemicals used for cleaning, maintenance or therapeutants). Chemicals that are intentionally added to food are not intended to be hazardous, however higher than desired amounts may render them harmful to human health.

A physical hazard is any extraneous or foreign material or object that can cause injury or illness to a consumer, such as (but not limited to) bones, glass, plastic, metal, wood, animal droppings or insects.



PREVENTIVE CONTROLS/ PREREQUISITE PROGRAMS

QUALITY CONTROL

Location: _____
Date of inspection: _____
Time of inspection: _____
Inspected by: _____

CTIONS

Sample

Observations

Admit

Yes

No

PREVENTIVE CONTROLS/PREREQUISITE PROGRAMS

Implementation of Preventive Controls/Prerequisite Programs is a means of being proactive in managing the quality and safety of food products. Preventive Controls are essentially good manufacturing practices and are the foundation of the HACCP plan. They must be sufficient and effective. As part of the preventive controls, steps and procedures are developed to control operational conditions within the facility that will help create a safe environment for food processing. Employees responsible for preventive control tasks must be trained and understand what is expected to maintain food quality and safety.

Detailed written programs such as standard operating procedures (SOPs) and/or policies are great, however, they will not be truly effective if they are not followed. This is where records of monitoring and deviation procedures become important. Record keeping offers proof that SOPs and/or policies are being followed. When creating records, remember to capture the information needed and to combine records where it makes sense. If the records are cumbersome or do not make sense, employees are less likely to fill them out or fill them out correctly. Records must be kept up-to-date, legible, accurate, and properly filled out in real-time and should not be recorded on scrap paper with the intent to be rewritten as they may become illegible or lost.

The next section will focus on preventive controls. Basic good manufacturing practices will be discussed, and there will be a focus on key differences that arise between different operations.

- Responsibility of Operator
- Sanitation, Pest Control and Non-Food Agents
- Conveyances and Equipment
- Conditions Respecting the Establishment
- Unloading, Loading and Storing
- Competency
- Hygiene
- Investigation, Notification, Complaints and Recall

SAFE FOOD FOR CANADIAN REGULATIONS (SFCR)

The SFCR came into effect on January 15, 2019. Check out Perennia's website (link in Resources) for a fact sheet containing more information and guidance on the SFCR.

RESPONSIBILITY OF OPERATOR

The operator must maintain and operate an establishment so that all preventive controls prevent food safety hazards and reduce the likelihood of contaminated food. Although senior management commitment is not referenced directly in the SFCR, an establishment cannot meet all the requirements of the preventive controls if resources are not available. Also, regulatory quality and food safety management systems are based on HACCP Codex Alimentarius. In the fall of 2020, HACCP Codex Alimentarius revised the Code of Practice (General Principles of Food Hygiene (CXC 1-1969) and its HACCP annex) which now includes Management Commitment to Food Safety.

Examples of senior management commitment to food safety may include:

- Providing the necessary time required for the development, implementation and effective maintenance of the quality and food safety management system
- Providing the financial resources to ensure overall maintenance of the construction of the premises (internal and external) and that equipment is in sound condition
- Providing the necessary time and financial resources for training (i.e., HACCP, sanitation, maintenance, technical, etc.)
- Designating trained and qualified staff and giving them the authority to oversee the development, implementation and effective maintenance of the quality and food safety management system

HOW TO MEET THIS REQUIREMENT

Develop a written statement of commitment that depicts how the company plans to provide safe, quality products, provide necessary resources, meet regulatory and customer requirements, and appoint a trained and qualified food safety team leader. This statement of commitment should be communicated to all staff members, signed, dated and posted.

SANITATION

KEEPING YOUR FACILITY AND EQUIPMENT CLEAN

There are two types of surfaces that need to be kept clean: food contact and non-food contact surfaces. Food contact surfaces are surfaces in direct contact with food, food packaging or other food contact items such as knives, utensils, cutting boards, skimmers, gutting and heading troughs/tables, containers, rollers and other equipment. Surfaces above food contact areas are also considered to be food contact surfaces. Non-food contact surfaces are surfaces that are not, or should not be, in direct contact with food or food materials, i.e., floors, equipment legs, mop buckets, brooms, walls and pallets.

The sanitation program should include documented procedures on how the cleaning is to be carried out for all areas and equipment; frequencies of cleaning activities; housekeeping and sanitation procedures required during operations; a means of conducting a pre-operational inspection prior to start of production; corrective actions to be taken for non-compliant situations observed; and finally, records that are to be kept.

Chemicals for cleaning and sanitizing food contact surfaces must be suitable for the intended use and not contaminate the food product. Cleaning and sanitizing chemicals for food and non-food contact surfaces must be differentiated and applied using the manufacturer's instructions (i.e., concentration, contact time, water temperature). Ensure all food or packaging material is protected before using any cleaning and sanitizing chemicals.

A master sanitation schedule should be developed and include all items, including walls, ceilings/overheads, drains, exterior premises, and the frequency of cleaning. Cleaning may be daily or weekly, monthly, or less frequent depending on use and debris accumulation. The master sanitation list helps to schedule and track when cleaning is done and should be in place to ensure areas and equipment do not get missed. Similar to a preventive maintenance schedule, this can be as easy as using an electronic calendar reminder or documenting it on a spreadsheet. Records must be kept of all cleaning activities.

WHY DO YOU NEED TO CLEAN?

If surfaces are not cleaned, it will cause:

- bacteria growth causing food spoilage which can affect product quality (i.e., taste, appearance, or reduce shelf life) and potentially cause consumer illnesses
- contamination of the next day's production
- insects and rodents to be attracted to your facility

CLEANING STEPS

After production is done for the day, cleaning should be done as follows:

1. **Manually** remove large particles/debris
2. **Pre-rinse** with water to remove large amounts of food particles/soil
3. **Wash** with detergent and mechanical action
4. **Post-rinse** with water to remove detergent and loosened food particles/soil
5. **Inspect**
6. **Sanitize** to kill any remaining microorganisms and prevent growth of microorganisms
7. **Verify** that cleaning was effective through visual inspection, ATP and micro swabs, etc. Record results.

SANITATION CHECKLIST	YES	NO	COMMENTS
Are sanitation procedures documented?			
Is the cleaning frequency adequately keeping the facility and equipment clean?			
Are employees trained on how to properly clean both food and non-food contact surfaces?			
Are employees cleaning at the appropriate frequency?			
Are employees using the cleaning and sanitizing chemicals as per the manufacturer's instructions, are they appropriate for a food facility?			
Is Personal Protective Equipment (PPE) provided and used?			
Are pre-operational inspections being performed and documented?			
Are sanitation activities being documented and corrective action taken when deviations occur?			



NON-FOOD AGENTS

WHAT ARE NON-FOOD AGENTS?

Any non-food chemicals such as water-treatment chemicals, boiler water-treatment chemicals, chemicals for cleaning and sanitizing, maintenance lubricants and grease, pest control chemicals, etc.

WHY DO YOU NEED TO CONTROL NON-FOOD AGENTS?

Non-food agents/chemicals purchased and brought into your facility can be a chemical source of contamination to your food. Non-food agents/chemicals being purchased for use in your facility must be approved for use in a food establishment. You must also be mindful of handling, storage, transport, and use of these agents. Non-food agents must only be used by trained personnel and in accordance with the manufacturer's instructions. Non-food agents/chemicals should be properly stored in a manner that does not pose a risk to food safety. For example, chemicals may be stored in a locked, well-ventilated, labelled and organized chemical storage closet or cabinet.

NON-FOOD AGENT CHECKLIST	YES	NO	COMMENTS
Are non-food agents documented, and are specification sheets maintained?			
Are non-food agents properly stored?			
Are non-food agents suitable for use?			
Are non-food agents handled and used by trained staff?			
Are non-food agents used according to their intended labelled use?			
Are non-food agents controlled and labelled?			
Are non-food agent concentrations verified and prevent risk of contamination?			

PEST CONTROL

WHY DO YOU NEED A PEST CONTROL PROGRAM?

Pests cause contamination of food products, raw materials, packaging, etc., with their droppings, urine and disease. They also can cause physical damage by chewing/gnawing on food and packaging.

COMMON PESTS IN THE FOOD INDUSTRY

- ✓ Flies, moths, wasps
- ✓ Rodents (mice, rats, minks, groundhogs)
- ✓ Insects (beetles, earwigs, cockroaches)
- ✓ Birds (seagulls)
- ✓ Other animals (pets and wildlife)

MAIN GOALS OF A PEST CONTROL PROGRAM

1. To prevent pests from getting into the facility
2. To prevent conditions that will allow them to live in the facility if they do get in

Most food processing establishments contract pest control to a licensed pest control operator. They can provide expert advice on placement, type, and number of pest control devices. Pest control can be carried out internally provided that the person responsible has knowledge of what is required and holds a current and appropriate pesticide applicator's license.

TIPS TO PREVENT PEST PROBLEMS

Pests need three things to live: food, water and harbourage. If you remove the food (through a good sanitation program) and harbourage areas, they will not be able to infest your facility.

Exterior Building and Property

- ✓ Do not store materials directly on the ground
- ✓ Ensure garbage is well sealed and removed regularly
- ✓ Eliminate vegetation and objects that provide food or harbourage for pests
- ✓ Ensure all vents and openings are screened
- ✓ Ensure all doors and windows are sealed and, where applicable, screened
- ✓ Keep all exterior doors closed when not in use
- ✓ Eliminate any standing water around the facility

Interior Facility

- ✓ Regularly clean, inspect, and seal cracks in floors, walls and ceilings. Mice can enter through a hole as small as a dime or as big as their head
- ✓ Keep floor drains clean and routinely inspect cover plates and catch basins
- ✓ Doors and windows should be close fitting to prevent pests from entering

Storage Areas

- ✓ Store products away from walls and off the floor to allow for inspection and cleaning
- ✓ Store all rejected, damaged and infested product that might attract pests away from raw materials and finished products, and dispose of it as soon as possible

Types of Traps

- **Bait Stations** – To be used outside only and serviced by licensed pesticide applicators
- **Mechanical** – Also called “tin cats”, typically with a glue board installed. Snap traps should not be used. These types of traps are usually baited with allergens (cheese or peanut butter) or with poison
- **Light or Pheromone** – Insects are attracted to the light or pheromone and get trapped on glue pads inside the trap (glue boards must be present). Bug zappers and fly sticky tape must not be used in a processing facility

Trap types and locations must be included on a facility map, with a corresponding identifier on the wall and the trap so that both the pest control provider and the operator know the number and location of devices. This helps if they accidentally get moved or damaged. It is recommended that pest control devices be placed on either side of the entries into the facility (tin cats inside), and outside bait stations be located at appropriate distances. If using fly lights, they must not be placed over or within close proximity of equipment, product, or packaging material.

PEST CONTROL CHECKLIST	YES	NO	COMMENTS
If contracted pest control is in place, is the person properly licenced, insured, trained, and providing well-documented monthly inspection reports, including bait usage?			
Are the appropriate means of pest control implemented properly and identified on a facility map, the trap and the wall?			
Are controls (i.e., traps, lights, bait stations) regularly monitored?			
Are the interior and exterior facility conditions maintained in a manner that prevents pests?			
Are storage areas kept clean and all items kept off the floor and away from the wall?			
Is there evidence of pests (i.e., droppings, nesting, fur, insects [dead or alive], rodents, birds, etc.)?			
If there are catches documented, are corrective actions completed to correct the issue? Is pest control monitoring increased?			
Are pets not permitted in the facility and storages?			



CONVEYANCES AND EQUIPMENT

DESIGN AND INSTALLATION

Equipment must be constructed and maintained properly so it does not become a risk to the product. In many cases, product directly contacts equipment, so it can become a significant risk to your process if not controlled. Equipment and the ability to be cleaned have been the cause of recalls and, unfortunately, loss of life. Some things to keep in mind for equipment design:

- ✓ Smooth, durable, non-corrosive, non-absorbent, non-toxic, impervious, cleanable, and compatible with your product type and current cleaning chemicals
- ✓ Made of material not affected by food products
- ✓ No rust, lead, or exposed wood
- ✓ Constructed and installed so that all areas are reachable for cleaning, sanitizing, inspection and maintenance
- ✓ No crevices, cracks, pits, angles, or ledges where food can get trapped and build up
- ✓ If conveyors are used, ensure there is no fraying material or missing links (Note: do not use piano hinges)
- ✓ No open ends and table legs should be sealed
- ✓ Seams are smooth and continuous, and no 'bubble gum' or spot welding
- ✓ Proper drainage and ventilation
- ✓ Wiring meets the Canadian Electrical Code (CSA)

Any new equipment should be assessed prior to purchasing to ensure these requirements are met. Equipment should be assessed by multiple personnel with different expertise, including but not limited to sanitation, maintenance and quality and food safety. It should also be verified that the equipment is functioning as intended by the manufacturer.

MAINTENANCE AND CALIBRATION

Once the equipment is installed, it needs to be put on a preventive maintenance schedule per the manufacturer's recommendations. The preventive maintenance schedule is part of the preventive maintenance program, which contains a list of equipment that may impact food safety. The frequency and procedures to perform each preventive maintenance task must be documented. When breakdowns occur, maintenance work must be controlled to ensure any product risks are minimized. The affected product must be assessed, and if compromised, it must be disposed of or reworked if possible. If the breakdown is going to be lengthy, the product must be controlled properly (i.e., placed back into cooler). Breakdowns should be documented so that preventive maintenance for that equipment can be adjusted.

Equipment that comes into contact with or that is located above exposed product requires regular maintenance and calibration. Maintenance and calibration are performed to prevent, eliminate, or reduce the likelihood of identified hazards. The maintenance and calibration of equipment should be documented to include the calibration method, procedure, frequency, schedule, records with results and corrective actions.

CONVEYANCES

Conveyances are defined as a means of transportation that may include but are not limited to trucks, trailers, forklifts, pallet jacks, trollies, etc. The condition of conveyances can pose a risk of food contamination if they are not maintained and part of a sanitation schedule.



CONVEYANCES AND EQUIPMENT CHECKLIST	YES	NO	COMMENTS
Is all equipment assessed for proper requirements before purchasing?			
Is all equipment constructed, designed, and installed to allow ease of inspection, cleaning and maintenance?			
Equipment and conveyances are smooth, durable, non-corrosive, non-absorbent, non-toxic, impervious, cleanable, and compatible with your product type?			
Is equipment free of crevices, angles, or ledges (i.e., dead spots) where food can get trapped and build up?			
Equipment and conveyances are included on a sanitation schedule?			
Is equipment properly stored?			
Is equipment free of rust, lead, or exposed wood?			
Are there any open ends or table legs that should be sealed?			
Are seams smooth and continuous with no 'bubble gum' or spot welding?			
Is all equipment verified that it is functioning as intended before use?			
Are all equipment and conveyances on the preventive maintenance schedule and regularly maintained and calibrated, where applicable?			



CONDITIONS RESPECTING THE ESTABLISHMENT

The premises, or environment at a food facility, can greatly impact the safety of the product. Premises include both the external and internal environment. The external environment can impact food safety as things like dust and pollutants can enter the facility via doorways, windows and air intakes. A poorly maintained exterior can attract pests to the premises and provide harbourage areas. Internal premises includes building structure, design and condition, equipment layout, product/employee flow, ventilation, temperature, lighting, water and sewage systems, all of which can pose risks to the product if not constructed properly and well maintained.

Acceptable building materials are included in the CFIA Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products. The CFIA no longer updates this database. If a building material is not on the list, it is your responsibility to request proof from the supplier that the material is suitable for use in a food processing facility.

A few basic premise considerations applicable to all operations include the following:

External Environment – External Surroundings

- Located away from or protected against potential sources of contamination (landfills, polluted areas, floodplains, etc.)
- Vegetation is controlled and not growing directly against the building
- No litter, old pallets, equipment, etc. outside against the building
- Adequate drainage near facility (i.e., no pooling water)

External Environment – Building Exterior

- No holes or cracks in walls, foundation and roof
- Air intakes are screened and filtered; windows are screened
- Doors are self-closing and close-fitting (i.e., no gaps or light visible when closed)

INTERNAL ENVIRONMENT – BUILDING INTERIOR

- Floors, walls, ceilings, windows, and doors are cleanable, constructed of appropriate materials and designed to allow maintenance, cleaning, and sanitizing activities
- Sewage and waste effluent systems do not pass directly over or through production
- Sewage and other effluent systems must not be interconnected (i.e., not connected to floor drains or sinks)
- Regulate the flow of employees from the entry point of the premises to the final product to prevent cross-contamination and secure access to the establishment
- Adequate lighting is provided, and lighting is shatterproof or protected from breakage
- Appropriate facilities and receptacles for waste and offal disposal are provided and maintained
- Ventilation provides sufficient air exchange to prevent accumulation of steam, condensation, and dust, to remove contaminated air and to maintain pressure in high-risk areas

Hygienic Flow and Separation

- Traffic flow (people, product, ingredients, packaging) must prevent cross-contamination between raw products and ready to eat products
- Traffic flow (people, product, ingredients, packaging) must prevent cross-contact of products containing allergens and non-allergenic products
- Designated areas for storage and labelling of processing aids and preservatives

Personnel Facilities

- An adequate number of handwash stations are provided at all production area entrances and throughout the production and storage areas
- A separate lunchroom area is provided for staff to prepare and eat food
- An area is provided for employees to change clothes and store personal items that is separate from the production and storage areas
- Personnel facilities are readily accessible, maintained, and adequately equipped with potable water for handwashing, soap, single-use paper towel, waste receptacle, sanitizer (if applicable) and handwashing signage

WATER, ICE, AND STEAM

Water, ice, and steam are used in food processing facilities as an ingredient, part of the process (chilling, rinsing), sanitation and personnel hygiene (handwashing). Therefore, water, ice and steam quality can greatly impact the safety of the product. A safe, adequate supply is critical. In addition to water and ice being potable, it is important to have an adequate volume, temperature and pressure depending on what the water is being used for. If processes require the use of ice or steam in direct contact with the product or equipment, it must be included in your premises' preventive controls and subject to the same requirements as water.

To ensure the safety of water, water sources must be tested. It is recommended that municipal water sources are tested for microbiology semi-annually whereas, water sources, such as dug wells, are tested monthly. Water results must meet the Guidelines for Canadian Drinking Water Quality (the Guidelines) for total coliforms and E. coli. The Guidelines state, for both: none detectable per 100 mL.

The quality of the water should also be assessed depending on the use. For example, detailed chemical analysis tests should be done for water used as a product ingredient regularly to ensure the water meets the Guidelines for chemical and physical parameters (i.e., mineral content). If water is not used as an ingredient, quality tests may be less frequent (annual) with quality observations (i.e., colour, turbidity, odour, etc.) conducted on a regular basis.

BASIC STEPS TO FOLLOW WHEN COLLECTING A WATER SAMPLE *

- ✓ Use a sterile container obtained from the lab. Do not open until ready to collect the sample
- ✓ Wash your hands and wear gloves when collecting the sample to prevent contamination
- ✓ Remove any screens, hoses, nozzles, etc.
- ✓ Clean the inside and outside of the tap opening with rubbing alcohol
- ✓ Open tap fully and allow the water to run for 3-5 minutes before collecting the sample
- ✓ Reduce flow when collecting the sample to prevent splashing
- ✓ Maintain sterility of the container when collecting a sample: hold the sample container at the base, remove the sample container cap with your free hand, taking care not to touch the edge, cap or allow water to flow over it into the container—do not lay it down! Do not touch inside of sample container or cap with your hand or the tap
- ✓ Fill sample bottle to the line, leaving a little air space in the container to allow for mixing.
- ✓ Take samples to the lab immediately. Place in a cooler with ice for transport. If delivery is delayed, store the sample in a fridge. A new sample will need to be collected (in a new container) if the stored sample cannot be delivered to the lab within 24 hours of collection.

* Follow the instructions as directed by your testing lab.

There are a number of actions to take when the test results do not meet the requirements. If the water is not used as an ingredient, or for handwashing, washing food equipment/utensils or used directly on the product, operations may continue using an alternate source of potable water, but all use of facility water should cease immediately. Facilities must have deviation/corrective actions in place and fill out a report. A series of testing must be completed to determine the source of contamination, and the municipality must be notified if the tests indicate the source of contamination is the municipal supply.

WATER TREATMENT

Water treatment may be required to make water potable. A common chemical water treatment is chlorination. There are special considerations when using chlorination to treat water, such as the concentration. Some physical water treatment methods include ultraviolet (UV), ozonation, activated carbon contractors, filters and reverse osmosis. Water treatment records must include the method of treatment, sample site, analytical results, date and the analyst. It is essential that backflow preventers are in place to prevent contamination of the water source.

ALLERGENS AND FOOD ADDITIVES

Allergens

Allergen management is a key part of preventing mistakes that can affect how your company/products are viewed. If a mistake is made, the following can be affected:

- Consumer perceptions, attitudes, and trust due to adverse media coverage
- Product, brand and franchise image
- Regulatory attitudes and trust

WHAT EXACTLY IS AN ALLERGEN?

An allergen is a specific protein in a food or food particle, most often eaten or inhaled, that causes an abnormal response by the immune system (antibodies are released such as immunoglobulin E [IgE] antibodies and chemicals such as histamine) in the body to the food and causes an allergic reaction. Allergic reactions can cause serious illness and death, and as such, allergens are considered chemical hazards.

MOST COMMON FOOD ALLERGENS AND PRIORITY ALLERGENS

Health Canada and the Canadian Food Inspection Agency have identified the most common food allergens and related sensitivities in Canada:

- Eggs
- Milk
- Mustard
- Peanuts
- Crustaceans and molluscs
- Fish
- Sesame seeds
- Soy
- Sulphites
- Tree Nuts
- Wheat and triticale

Note: Priority allergens differ by country. Be aware of the allergens and labelling requirements for any countries you are exporting to. For example, celery is considered an allergen in Europe but not in North America.

Potential sources of food allergens are:

- Unknown ingredients in raw material
- Mis-formulation and rework
- Improper clean-up/storage
- Cross-contact by dust, particles on equipment, utensils, bulk carriers and personnel
- Mislabelling (incorrect or old label being used, no allergen declaration on lubricants)

To control potential sources of food allergens:

- ✓ Good personal hygiene and personnel processing practices (i.e., wash hands, wear clean attire)
- ✓ Separate production rooms
- ✓ Separate production times (i.e., process non-allergen products first or on separate days)

- ✓ Separate lines/equipment/utensils
- ✓ Designated employees for different lines
- ✓ Pre-operational cleanup and inspection if allergen product produced mid-shift
- ✓ Check all incoming ingredients and labels
- ✓ Separate storage and shipping of allergenic ingredients and products
- ✓ Dispose of obsolete materials (i.e., labels, formula documents, ingredients, etc.) to ensure they're not mistakenly used
- ✓ Employee training
- ✓ Proper labelling

FOOD ADDITIVES, PROCESSING AIDS AND ADDED NUTRIENTS

Health Canada defines a food additive as any chemical substance that is added to food during preparation or storage and either becomes a part of the food or affects its characteristics for the purpose of achieving a particular technical effect. If food additives are used, ensure that the additive is on Health Canada's list of permitted food additives and approved for the commodity. Information regarding permitted food additives can be found on Health Canada's website.

Processing aids may be used as long as they do not result in an unsafe food product. It is the responsibility of the facility to prove it will not render a product unsafe. Vitamins, minerals, and amino acids can also be added if they are listed in Part D of the Food and Drug Regulations (FDR).

Operations must have controls in place to ensure that food additives, vitamins, minerals, and amino acids used are approved by the FDR and are added in levels approved for use by the FDR. Operations must be able to verify the level of the substance in the final product and develop documents for each different product describing the following:

- The name of the substance
- Level at which it is added
- Processing step at which it is added
- Procedures followed to add the substance to food

CONDITIONS RESPECTING THE ESTABLISHMENT CHECKLIST	YES	NO	COMMENTS
EXTERNAL SURROUNDINGS AND BUILDING EXTERIOR			
Is there a risk of contamination from neighbours?			
Are driveways paved or well-maintained to prevent excess dust and mud?			
Is all vegetation controlled and not growing against or next to the building?			
Is there pooling of water?			
Are there any old pallets, equipment or litter against the building?			
Is the building exterior maintained in good repair (i.e., no holes or cracks in walls, foundation and roof, windows/air filters are screened, pipes are sealed, etc.) to prevent entry of pests and contaminants?			
Is access secure? Doors are self-closing, close fitting and lockable?			
BUILDING INTERIOR			
Are floors, walls, ceilings, windows and doors cleanable, constructed of appropriate materials and maintained?			
Are wall, floor and ceiling junctions sealed and coved if possible?			
Are exposed pipes, ducts and beams located far enough away from walls/ceilings for cleaning access?			
Are stairs/catwalks constructed of the appropriate materials and do not pose a risk to products?			
Are windows made from shatterproof glass or protected from breakage?			
Is there pooling of water? Are floors sloped to allow for drainage?			
Are hoses hung up after use, and is the nozzle kept off the floor?			
HYGIENIC FLOW AND SEPARATION			
Are incompatible operations (allergens, ready to eat vs. raw) controlled by physical separation or other effective controls?			

CONDITIONS RESPECTING THE ESTABLISHMENT CHECKLIST	YES	NO	COMMENTS
ALLERGENS AND FOOD ADDITIVES			
Are incoming materials and their labels being inspected?			
Are the proper labels that reflect the current formula of your product being used?			
Are measures to avoid cross-contact between allergen and non-allergen products documented and being followed (i.e., separate production rooms, production times, line/equipment/utensils, storage, etc.)?			
Are obsolete materials being discarded?			
Are employees properly trained on allergen management?			
If your facility uses food additives, are they approved by Health Canada?			
If your facility uses a processing aid, can you prove that your product is safe?			
If your facility uses vitamins, minerals, or amino acids, are they approved and found in Part D of the Food and Drug Regulations?			
LIGHTING			
Is there adequate lighting for the intended activity to be conducted effectively?			
Is the lighting protected from breakage?			
VENTILATION			
Is there adequate ventilation (i.e., any signs of condensation)?			
Is the ventilation system designed to prevent contamination (air flows from clean to dirtiest areas)?			
Is the ventilation system clean and maintained?			
EMPLOYEE FACILITIES			
Are there an adequate number of handwashing stations provided?			
Do handwashing stations have an adequate supply of potable warm water, soap, paper towels, sanitizers, garbage, handwashing signs?			
Is there a separate lunch/break area for staff to prepare and eat food?			
Is there a separate washroom/changing area?			
Are there an adequate number of washrooms provided?			

CONDITIONS RESPECTING THE ESTABLISHMENT CHECKLIST	YES	NO	COMMENTS
WATER, ICE, AND STEAM			
Water, ice, and steam are safe for the intended use (seawater, drinking water, etc.)?			
Is there an adequate supply of potable water for processing, sanitation, personnel hygiene?			
Are water testing records maintained?			
Is there prevention of back-flow where required?			
Are water storage facilities designed, constructed, and maintained to prevent contamination and tampering of water supply?			
Is there no cross-contamination/connection between sanitary water and unsanitary water supplies?			
Are ice testing records maintained?			
Are steam verification records maintained?			
Is the water, ice, and steam equipment designed, installed, and maintained in a manner that will not become a risk to food safety?			
WASTE DISPOSAL			
Are there appropriate facilities for garbage and waste?			
Are waste storage areas and containers identified, secured and clean?			
Is waste disposal, including effluent lines designed and protected to not pose a risk of contamination?			
Are drainage and sewage systems adequate for the volume and type of effluent being produced during processing and cleaning?			

UNLOADING, LOADING AND STORAGE (INCLUDING PURCHASING)

Below are general best practices to follow to ensure incoming materials do not become a source of contamination and that outgoing product is not contaminated during shipping, storage and transportation.

PURCHASING

When purchasing ingredients and raw materials, ensure that they are from known, approved suppliers/sources and that required information, such as specifications, letters of guarantee and/or certificates of analysis, are on file. An approved supplier program (see page 31) is a great way to ensure that only those preapproved incoming ingredients, packaging or non-food agents/chemicals are received prior to coming in contact with or being introduced as a component of your product and do not pose a source of contamination. This includes purchasing food grade gases such as nitrogen, carbon dioxide and oxygen for modified atmosphere packaging.

UNLOADING (RECEIVING)

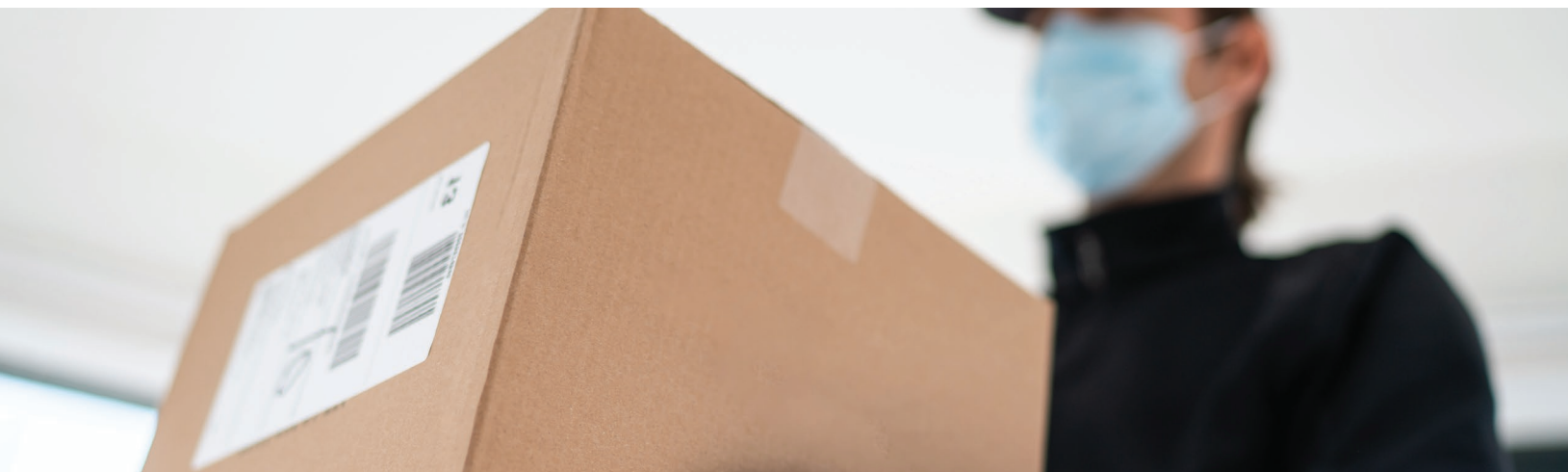
When unloading incoming materials, inspect the incoming trailer or vehicle for any sources of contamination. Inspect for cleanliness, good physical conditions and any incompatible products (i.e., non-food chemicals, animals, materials with a strong odour). Combined loads are common for small shipments. However, other materials on the vehicle must be compatible. Also, be sure if the purchase is temperature-sensitive, that the temperature of the transport vehicle was maintained at an appropriate temperature. Check the temperature of the product and check for any evidence of contamination, spoilage, damage, foreign material, or off-odours. Also, check best before or expiry dates on incoming materials to ensure that the components' shelf-life has not been exceeded or that they are not expired or expiring soon after receipt. Ensure unloading occurs in a timely manner and in an appropriate area (i.e., not in a parking lot) which avoids holding material at temperatures (or other conditions, i.e., rain) that may cause deterioration. Ensure that packaging materials are clean, intact and do not pose a source of contamination.

LOADING (SHIPPING)

Product to be loaded should remain at proper storage temperatures until ready to load and should be neatly stacked and securely wrapped. Material should not be placed directly on the transport vehicle floor. Temperature requirements must be maintained during shipping. Check the trailer for temperature, cleanliness and physical conditions before loading. For both unloading and loading, the vehicle must meet certain requirements such as cleanliness, physical conditions, temperature, and it should not be carrying any hazardous or incompatible materials. Loading and unloading should be done in a manner to avoid contamination of the product.

STORAGE

Raw materials, ingredients, packaging and finished product should be protected from cross-contamination and damage during storage. They must be stored off the floor and away from the walls to allow for proper cleaning, inspection and pest control. Practice FIFO (first in, first out) stock rotation to ensure older product, product close to its shelf-life or expiry, is used first. Conveyances and equipment must be stored in clean locations away from employee traffic and food production areas. Be sure to monitor the temperature in storage areas to keep product safe and in good quality. Note that non-food chemicals must be transported, received and stored separately. They must be stored in a clean, correctly labelled container in a well-ventilated area where there is no possibility of cross-contamination with the food product. Access to these chemicals should be limited; they should only be handled by authorized personnel and those who have received proper training.



UNLOADING, LOADING AND STORAGE (INCLUDING PURCHASING) CHECKLIST	YES	NO	COMMENTS
Are ingredients and raw materials purchased from an approved supplier/source?			
Are incoming ingredients and raw materials inspected upon receiving?			
Are the carriers inspected for cleanliness, good physical condition, temperature and any incompatible product/hazardous material upon receiving and before shipping?			
Are incoming ingredients, raw materials and product loaded and unloaded to avoid contamination and damage (i.e., using appropriate equipment, a good seal between the carrier and establishment, appropriate area)?			
Is all product to be shipped neatly stacked, securely wrapped and not placed directly on the trailer floor?			
Are raw materials, ingredients, packaging and finished product stored off the floor and away from walls?			
Are 'first in, first out' stock rotations followed?			
Are best before or expiry dates monitored upon receipt and during storage to ensure products are used prior to expiry date?			
Are raw materials, ingredients, packaging and finished product stored at the correct temperature and is the temperature monitored?			
Are equipment and conveyances stored to avoid contamination?			
Are non-food chemicals transported, received and stored separately? Are they stored in a clean, correctly labelled container in a well-ventilated area with restricted access?			
Are holding procedures for returned or suspect product/material documented and implemented?			
Are all held items properly identified and adequately segregated?			

COMPETENCY

TRAINING

Employees must be properly trained on food hazards, food hygiene, clean/sanitary conditions and general hygienic practices. Employees must also complete technical training such as how to use equipment and monitoring devices and properly monitor critical control points. Training is ongoing, and employees must be evaluated to verify the effectiveness of the training. Training must also be documented. Even visitors and contractors require training if entering the processing and storage areas.

COMPETENCY AND TRAINING CHECKLIST	YES	NO	COMMENTS
Is there a written training program?			
Are training records maintained and readily available?			
Are employees trained to carry out the tasks that they are responsible for?			
Is training effectiveness monitored, verified and documented?			
Is training conducted in a language all staff understand?			
Is visitor and contractor training documented?			

HYGIENE

Employees, visitors and contractors can be a source of contamination and must be properly trained on food hazards, food hygiene, clean/sanitary conditions and general hygienic practices to prevent the risk of contamination or spread of diseases. Sources of contamination include, but are not limited to, employee and visitor practices/behaviour, clothing, footwear and protective coverings, personal cleanliness, communicable disease, illness, symptoms and lesions. All employees, visitors and contractors must follow the company's hygiene policy.

BASIC PERSONNEL HYGIENE

A few basic hygiene rules for safe food production include:

- ✓ Showering/bathing daily and wearing clean clothes/smocks

- ✓ Clean, short fingernails (i.e., no fingernail polish or artificial nails)
- ✓ No jewelry in production areas (medical jewelry may be worn, and some places allow plain wedding bands)
- ✓ No smoking, chewing gum, eating, drinking, or spitting in the processing or storage areas
- ✓ Wear hair and beard nets and suitable clothes/gloves/footwear
- ✓ No personal items in the production area
- ✓ No loose objects in the production area (i.e., pens, paper clips, pins, buttons, etc.)

HANDWASHING

Handwashing is the single most important thing that people can do to prevent contamination of food. Employees need to know when and also how to wash their hands. Hands need to be washed at the following times:

- ✓ At the start of the shift
- ✓ After breaks
- ✓ After smoking, eating, or drinking
- ✓ Each time the employee enters the production area
- ✓ After handling anything dirty and going back to handle product (i.e., picking something up off the floor, tools, garbage, pallets, etc.)
- ✓ After using the washroom
- ✓ After coughing or sneezing
- ✓ After touching face, adjusting hair net/beard net, or using a tissue

Proper handwashing procedures can be found under the Quality and Food Safety tab of the Perennia website www.perennia.ca.

If your handwash station is not hands-free, please make sure to get the paper towel ready to turn off the taps before you begin.



"Handwashing is the single most important means of preventing the spread of infection"

– CENTERS FOR DISEASE CONTROL AND PREVENTION

EMPLOYEE ILLNESS AND INJURY

Employees must cover any cuts or wounds with a secure, waterproof covering that can be easily detected if it comes off (i.e., metal detectable or bright coloured). If an employee is injured on the job, ensure that any product that came in contact with blood or bodily fluids is disposed of and that the area is cleaned and sanitized thoroughly before production resumes. These incidents should be documented. Employees displaying any symptoms of an infectious disease or illness should refrain from coming to work and only return 48 hours after their last symptom has subsided as their disease could be transmitted to others through the product. If you are unsure if an employee's illness is a risk to your product or employees, contact your local Public Health Office. They can advise you and even provide education sessions to your company and employees. Employees are expected and should be trained to sneeze and cough into their elbow or turn their head into their shoulder, stepping away from the production line to avoid contaminating the product and/or equipment.

PERSONNEL PROCESSING PRACTICES

In addition to personal hygiene practices, personnel processing or good manufacturing practices need to be in place for all food production facilities. This would include such things as having facility access through the main entrance and all additional doors locked with restricted access. Employees must be trained in proper traffic flow and product flow around the facility in order to prevent cross-contamination or cross-contact. There must be procedures in place for any visitors or contractors to follow to avoid introducing sources of contamination into the facility. Food contact and floor contact items must be kept separate. Handwashing sinks should not be used to clean food equipment and vice versa. Equipment sinks should not be used to empty mop buckets or have floor contact items cleaned in them. Doors must be kept closed at all times, including cooler and freezer doors. Waste bins must be kept clean and in good condition and emptied whenever full. Employees must be properly trained on how to manage incidents such as glass breakage, product that falls on the floor or is exposed to condensation or blood/bodily fluid incidents. Product spills must be cleaned up regularly to prevent contamination and/or infestation. Product packaging should only be used for the product, not for things such as equipment parts, temporary stands, tools, or garbage.



Hands should be scrubbed for 20 seconds or the time it takes to sing "Happy Birthday" to yourself twice!

HYGIENE CHECKLIST	YES	NO	COMMENTS
Have hygiene and good manufacturing practices been documented for the facility?			
Are employees trained on the facilities hygiene practices prior to starting employment and at least annually?			
Are employees wearing clean protective clothing, hair coverings, gloves and footwear?			
Are employees following proper hygiene practices (i.e., no smoking, eating, drinking, spitting, wearing jewelry or having personal items in the production area)?			
Are employees handling food properly to avoid cross-contamination (i.e., correct use of utensils and equipment)?			
Do employees have proper hand hygiene (i.e., clean, short fingernails; cuts or wounds covered with metal detectable or bright coloured coverings)?			
Are employees washing their hands frequently and at the appropriate times?			
Are employees using the correct technique to wash their hands?			
Are employees in good health with no signs or symptoms of any illness/disease?			
Are employees trained on how to prevent cross-contamination (i.e., procedures for glass breakage, product that falls on the floor or is exposed to condensation, visitors and contractors present during production and blood/bodily fluids protocol)?			
Are employees trained on and following good manufacturing practices (i.e., proper traffic flow, restricted access, etc.)?			

INVESTIGATION, NOTIFICATION, COMPLAINTS AND RECALL

RECALLS – ARE YOU PREPARED?

By CFIA definition, a recall is when a product is removed from sale, or a correction is issued in regard to a product on the market. The issue could pose a risk to health or could be that the product is non-compliant with CFIA legislation.

There are two types of recalls and three levels of recalls.

Voluntary Recall – a recall that is initiated and carried out by the recalling firm without a ministerial order

Mandatory Recall – a recall as per Section 19 of the Canadian Food Inspection Agency Act

Class I Recall	A situation in which there is a reasonable probability that the use of, or exposure to, a non-compliant product will have serious adverse health consequences, possibly even fatal.	A public alert IS issued
Class II Recall	A situation in which the use of or exposure to a non-compliant product may have temporary adverse health consequences or where the probability of serious adverse health consequences is remote.	A public alert MAY BE issued
Class III Recall	A situation in which the use of or exposure to a non-compliant product is not likely to have adverse health consequences.	A public alert IS NOT usually issued

Other types of product removal include:

Product Withdrawal – a firm's removal from further sale or use or correction of a marketed product that does not violate legislation administered by the CFIA. This does not constitute a product recall.

Stock Recovery – a firm's removal or correction of a violated product that has not been marketed or that has not left the direct control of the firm. It is not considered to be a recall.

Regardless of the size or number of products produced, every food business needs to have a recall plan and be prepared to use it.

CFIA has outlined steps to conducting a recall.

1. Assemble a recall management team
2. Notify CFIA, immediately
3. Identify all products to be recalled
4. Detain and segregate products to be recalled
5. Prepare a press release (dependent on recall class level)
6. Prepare the distribution list (where the product went)
7. Prepare and distribute the notice of recall
8. Verify the effectiveness of the recall (i.e., how much of the total amount of the recalled product produced was recovered)
9. Control the recalled product (i.e., quarantine)
10. Decide what to do with the returned product (i.e., rework or destroy)
11. Identify and correct the cause of the recall
12. Methods to assess the effectiveness of the establishments recall procedure (i.e., procedures for testing the recall plan such as a mock recall procedure)

PRODUCT TRACEABILITY - YOU HAVE A RECALL PLAN, BUT CAN YOU REALLY FIND ALL YOUR PRODUCT?

Product traceability is not only about your own finished product. The food contact components that are used to produce or package the product must be able to be traced as well.

Product traceability will allow a company to limit the scope of the recall and quickly and accurately remove affected products from the market. Your company must be able to trace raw ingredients, rework, packaging materials and finished products.

The best practice is to link all raw ingredients to the supplier and all raw ingredient lot codes to the finished product lot codes. Do not forget to trace reworked products or product samples that were sent for sales, testing or taken for staff or personal use. Code finished products by lot and record the amount of each lot of each finished product produced. Include all brand names and sizes.

DISTRIBUTION RECORDS

Distribution records will be helpful in determining how much of each product went where, allowing quick and accurate recall of the product. Distribution records should be product and lot code specific and include the following:

- Name and address of the account
- Type of account (i.e., manufacturer, distributor, retailer)
- Who to contact at the account and their contact information
- Product name and lot code they received
- Amount of product shipped to that account

PRACTICE, PRACTICE, PRACTICE

Testing the recall plan is just as important as having one. Since recalls can happen to anyone at any time in any industry, you have to be prepared at all times. A practice or mock recall is a means to test the recall plan and see that it continues to be effective in tracing all materials coming in and all products going out within a reasonable amount of time, along with the recall process. It's also a good time to test the communication plan to see if all the contact lists are up to date.

Mock recalls are typically completed at least once per year; customers may require them to be done twice per year. Your finished product must be traceable to the customer (one step forward) and must also show traceability through to the ingredient/primary input supplier (one step back). To do this, the date of receipt of raw materials, food contact packaging, materials or other processing inputs will need to be recorded.

Once the mock recall is completed and recorded, take the time to determine if your recall plan was effective. Is there room for improvement? The gaps identified are critical in strengthening the traceability program and recall plan. Make corrections as soon as possible to be ready for a potential recall. These documents must be kept for two years.

SFCR REQUIREMENTS (CONSUMER PROTECTION)

Must prepare and keep documents (records) that:

- Identify your food
 - » Common name
 - » Lot codes or other identifier (including how to interpret the lot codes)
- Trace the food you provide to someone else, one step forward:
 - » Name and address of the person
 - » Date you provided it
- Trace the food (ingredients) another person provided you, one step back:
 - » Name of the food
 - » Name and address of the person who provided you with the food
 - » Date on which it was provided to you

LABELLING REQUIREMENTS FOR TRACEABILITY

Product labels must include:

- Common name
- Lot code or other unique identifier
- Name and principal place of business of the person by or for whom the food was manufactured

COMPLAINTS

Complaints can vary from quality issues to food safety concerns or even legality issues (misrepresentation). A documented customer/consumer complaint program enables a food business to quickly assess and investigate the complaint to determine severity. Complaints related to food safety, pests and product misrepresentation must be investigated to determine the root cause and corrective actions. Complaint files allow a business to track the number and type of complaints and, therefore, can be used as a form of continuous improvement. Complaints must be assessed, investigated and resolved in a timely manner. Should processes or procedures require changes based on the results of the assessment and investigation, ensure that changes are made and appropriate personnel are notified.

CUSTOMER/CONSUMER COMPLAINT RECORDS

Complaint records should include the following:

- Date and time complaint was received
- Contact details (name, address, phone number, email, number of complaints)
- Communication format (phone, in person, email)
- Complaint description
- Store location/place of purchase and date of purchase
- Delivery information
- Product(s) involved (name, format, quantity, dates/codes)
- Was product safety compromised?
- Was CFIA contacted/notified by the customer/consumer?
- Did the product cause injury or illness?
- Can a sample be recovered?
- Describe how the product was stored, handled and used by the client after delivery
- Investigation (who and results)
- Corrective Action
- Follow up with customer (date, name, communication format, comments)

INVESTIGATION, NOTIFICATION, COMPLAINTS AND RECALL CHECKLIST	YES	NO	COMMENTS
Is there a documented recall plan in place, with step-by-step instructions of what to do in a recall situation?			
Is there a cross-functional recall team in place whose members understand their designated role and responsibilities?			
Is there complete and accurate recall team, CFIA and customer contact information?			
Are products and all components used to produce or package the products traceable (lot-code specific)?			
Is there a written traceability program documented (including ingredients and packaging)? Has it been tested?			
Are production and distribution records complete and accurate?			
Are measures in place to assess the effectiveness of your recall procedure? Has a mock recall been completed?			
Are product labels compliant with SFCR requirements?			
Are lot codes established, are they permanent, unable to be altered, smudged, or removed easily?			
Has reworked product been accounted for in the inventory?			
Have staff sales, personal use, sales samples, products sampled and sent for testing/analysis been accounted for in the inventory?			
Is there a documented customer/consumer complaint program in place?			
Are customer/consumer complaint forms completed, filed and readily available?			
Are customer/consumer complaints assessed, investigated and resolved within a timely manner?			
Are changes required to processes or procedure communicated to appropriate personnel?			

**CREATING YOUR
PREVENTIVE
CONTROL PLAN/
FOOD SAFETY
PLAN/HACCP
PLAN**



HACCP BASICS

The acronym HACCP stands for Hazard Analysis Critical Control Point.

HACCP is a systematic, scientific approach to identifying and controlling food safety hazards during the production/ manufacture of food and related products.

The intent of documenting a HACCP plan is to take a proactive approach to identify and control the food safety hazards associated with the production of products that are not already controlled by prerequisite programs.

MANAGEMENT COMMITMENT

In order for a HACCP-based quality and food safety system to be effectively implemented, you need support from management/owners. Without their support, it is very difficult to implement positive change. A quality and food safety system changes and grows with your company and must be reviewed regularly in order to keep it current and effective. As your facility, procedures, process, employees, and products change, so will your program. When a HACCP Coordinator regularly reviews their prerequisite program and HACCP plan, it is crucial to communicate with employees and management. This provides an opportunity to educate employees and management and also learn more about the process to ensure they have things properly documented. By asking questions about the process, getting their coworkers' input, and evaluating the effectiveness of the records and standard operating procedures (SOPs) for those using them, they are positively changing attitudes and behaviours, which over time will help shape the company's culture and create awareness.



PREVENTIVE CONTROL PLAN

The Preventive Control Plan will be documented through a hazard analysis process. For each different product/process type at your facility, there needs to be a Preventive Control Plan. Hazards will be identified for incoming materials and ingredients, cross-contamination points and process steps. Appropriate controls for each will be implemented to reduce the risk or eliminate the hazard. Those control measures need to be monitored to ensure they effectively control the hazard. The control measures can include your prerequisite programs or critical control point(s). If one of those control measures fails, then corrective actions need to be taken and a corrective action/deviation report documented. The root cause of the incident needs to be determined and addressed to prevent reoccurrence.

There are 12 steps when implementing a HACCP Plan. These steps can be divided into the five preliminary steps and the seven basic principles of HACCP.

FIVE PRELIMINARY STEPS

1. Assemble a HACCP team
2. Describe the product
3. Identify its intended use
4. Construct a process flow diagram and a plant schematic
5. On-site verification of #4 above

SEVEN BASIC PRINCIPLES OF HACCP

6. List all potential hazards associated with each step, conduct a hazard analysis and identify control measures
7. Determine critical control point(s) (CCPs)
8. Establish validated critical limits
9. Establish a system to monitor control of the critical control points
10. Establish corrective actions to be taken when monitoring indicates a deviation of the critical limit at a critical control point
11. Validate the HACCP plan and then establish verification procedures to confirm the HACCP system is working as intended
12. Establish record keeping

When implementing a HACCP plan, the first step is deciding who should be on the HACCP team for each HACCP Plan. Secondly, determine how many HACCP Plans

are needed. In other words, how many different products/processes? For example, a seafood processor that produces fresh fish fillets, live shellfish and smoked salmon will have three HACCP plans.

A **HACCP team** can consist of senior management and production employees from various disciplines, such as:

- CEO, Owner, Operator
- Quality Assurance, HACCP Coordinator, PCP Manager
- Receiver/Shipper
- Production Supervisor/Manager
- Sanitation
- Maintenance
- Purchasing and/or Sales
- Product Development

A smaller company may only have two or three people that fill these roles. The person that deals with product safety and quality will have the proper food safety training and will be the one that leads the HACCP team. A cross-functional team is important because food safety and quality is everyone's responsibility, and one person cannot successfully do it on their own.

The rest of the HACCP steps will correspond with forms and are discussed in further detail in the following section.

THE FORMS

A HACCP plan generally consists of 11 forms that are best completed in the following order:

- Form 1: Product Description
- Form 2: List of Product Ingredients and Incoming Materials
- Form 3: Process Flow Diagram
- Form 4: Facility Schematic
- Form 5: Biological Hazard Identification*
- Form 6: Chemical Hazard Identification*
- Form 7: Physical Hazard Identification*
- Form 8: CCP Determination and Other Control Measures (Decision Tree)*
- Form 9: Hazards Not Controlled by the Facility
- Form 10: Critical Control Point(s) (CCP)
- Form 11: Process Controls (PC)

*Forms 5 to 8 can be combined into a Hazard Identification and CCP Determination form.

Each form is in place to help guide the team through the hazard analysis process in order to eliminate or decrease the food safety risk in the products.

Form 1's basic purpose is to record the products produced, their specific requirements and special characteristics that need to be considered when completing a HACCP plan. Form 1 should include the product name, important product characteristics, how the product will be used, packaging used, shelf-life of the product, where it will be sold, important labelling instructions and special distribution controls. With regard to the intended use of the product, be very clear in the documentation and on the labels as to the intended final use of the product; for example, 'keep frozen' or 'cook prior to consumption' statements. Consumers have suffered from foodborne illnesses as a result of pathogenic bacteria being found in shellfish (i.e., recall due to *E. coli* found in oysters). Consumers have also become sick by eating seafood due to undeclared allergens (i.e., recall due to sulphites found in shrimp).

The purpose of **Form 2** is to help identify all ingredients, processing aids, other inputs and packaging materials used to produce the products that were recorded in Form 1.

Form 3 is documented to show the process steps for the products listed in Form 1. The process flow diagram gives you a snapshot of the process and helps determine what potential hazards could be present at each step in the process. It is important to include everything (inputs and outputs), including rework, store sales and waste where applicable. Each step in the process will be numbered, and a hazard category will be assigned to each (Biological, Chemical, and/or Physical). This information will be used in the hazard analysis in forms 5-8.

The purpose of **Form 4** is to document the facility and how ingredients, product, rework, allergens, chemicals, personnel and waste move through it. This form is for all products that are made in the facility. It is important to include all processes in order to identify any cross-contamination or cross-contact points. Examples of cross-contamination or cross-contact are waste with finished product or raw ingredients, chemicals with product, people with product and allergens with non-allergens. Draw a picture of the facility as if you were looking down onto it, and make sure all equipment and rooms are included and labelled. To show the movement of ingredients, product, rework, allergens, chemicals, personnel and waste, use different colours or different types of lines. Where the different lines cross are the potential cross-contamination points. The cross-contamination points identified here will be inputted into forms 5-8. Pest control trap numbers (bait stations, tin cats and fly traps) can be included on this schematic, or you can create a separate map as part of the pest control program.

Forms 5, 6, 7 and 8 can be combined to make it easier to complete the hazard analysis. This is the form that pulls the information gathered in forms 1-4 together and then looks at the process and hazards in detail. This form(s) asks five questions to help guide you through the hazard analysis process and determine if the hazards identified are controlled under the documented preventive controls/prerequisite programs or will need to be controlled as a process control (PC) or a critical control point (CCP). Note that you cannot have a PC without a CCP, but you may have a CCP without a PC.

To assist with Hazard Analysis, CFIA has an online tool called the Reference Database for Hazard Identification (RDHI). It can be found on their website; the link is provided below (last modified 2020-09-16). CFIA periodically updates the online tool. However, if you produce an innovative item, it may not be listed in this reference tool.

<http://active.inspection.gc.ca/rdhi-bdrid/english/rdhi-bdrid/introe.aspx?i=1>

Sometimes hazards are beyond the control of the facility. In those instances, **Form 9** comes into play. On this form, you record the hazard, what part of the process this affects (before or after receipt) and how the outside source will control it. For example, if purchasing and/or further processing farmed Atlantic salmon, it is the aquaculturist who is responsible for administering and following the withdrawal period for therapeutants, not the processor.

If it is determined that critical control points (CCPs) are required to control a hazard, then **Form 10** is used to describe the details of the CCP, who will monitor it, when and how it will be monitored, any critical limits that need to be adhered to and what records and standard operating procedures (SOPs) are used. Other details that need to be considered are how to verify that the hazard is being controlled properly and what happens if the critical limit(s) are not met.

The process controls (PC) that were determined through the hazard analysis are recorded on **Form 11**. Much like **Form 10**, you document the details and refer to the CCP that the process control is linked to.

Generally, it takes most operations 18 months to implement prerequisite programs (75% of operations can do it in 12-14 months and implement a HACCP Plan in 4 to 6 months). Rushing a program often results in incidents that could have been avoided or identified. Verify the system is effective. Is the final product completely safe, or was something missed? Keeping track of the HACCP records is critical. Records will demonstrate the application of the HACCP plan. Records should be simple and non-redundant. Feedback from employees on their usability will be beneficial as employees will be more likely to fill them out if they are easy to use. Records must be legible and filled out at the actual time the check was performed. They

must be signed by the person who monitors the task and by the person who verifies that the record is complete and the task was performed properly. Records must be kept for at least two years or for the duration of the product's shelf life plus one year unless otherwise requested.

DOCUMENT CONTROL CHECKLIST

Documentation of your quality and food safety system is essential. Documents are an important tool for training existing and new employees as well as ensuring procedures are followed consistently by all. Documents demonstrate the effective implementation of your quality and food safety management program and allow for continuous improvement. They are most often a condition of registration, licensing or certification and are evidence of due diligence on your company's behalf. Creating a basic template for documents such as procedures and work instructions will allow you to keep records organized, up-to-date, legible, accurate and readily accessible. Note that it is important to use appropriate languages in your documents. Use the following checklist to ensure the policies, procedures and records contain all requirements.

POLICIES/PROCEDURES	
Header/Top of Page	<input type="checkbox"/> Company Name <input type="checkbox"/> Title of Document <input type="checkbox"/> Date Created/Revision Date <input type="checkbox"/> Supersedes Date <input type="checkbox"/> Author/Approved By
Body of Document	<input type="checkbox"/> Scope/Purpose <input type="checkbox"/> Responsibility (name and/or position) <input type="checkbox"/> Frequency <input type="checkbox"/> Work Instructions/Procedure/Policy (i.e., what and how, keep it simple, clear and easy to follow) <input type="checkbox"/> Revisions/Changes Highlighted (for easy reference) <input type="checkbox"/> Monitoring <input type="checkbox"/> Verification <input type="checkbox"/> Corrective Action/Deviation <input type="checkbox"/> Any Supporting Documents
Bottom of Document	<input type="checkbox"/> Page Number (i.e., Page 1 of X) <input type="checkbox"/> Change Log (can be in a separate document)

RECORDS

Header/Top of Page	<input type="checkbox"/> Company Name <input type="checkbox"/> Title of Document <input type="checkbox"/> Date Created/Revision Date <input type="checkbox"/> Supersedes Date <input type="checkbox"/> Author/Approved By
Body of Document	<input type="checkbox"/> Specification/critical limits that need to be followed <input type="checkbox"/> Brief outline of procedure (can be a checklist and/or a brief summary of the task) <input type="checkbox"/> Space to record information (keep it simple and record only information that will be used) <input type="checkbox"/> Corrective Action (a space for any issues or corrective actions taken during production) <input type="checkbox"/> Monitor's signature/initials and date and time of checks <input type="checkbox"/> Verifier's signature/initials and date
Bottom of Page	<input type="checkbox"/> Page Number (i.e., Page 1 of X)

DOCUMENT MANAGEMENT

Ensure that policies, procedures and records are:	<input type="checkbox"/> Kept for at least two years or for the duration of the product's shelf life plus one year unless otherwise requested <input type="checkbox"/> Secure and readily accessible to authorized personnel only (electronic or hard copy) <input type="checkbox"/> Core documents backed up in case of loss due to water, fire, theft, computer security breach, etc. <input type="checkbox"/> Controlled so that only authorized personnel make updates/changes <input type="checkbox"/> Outdated copies are collected and destroyed <input type="checkbox"/> Records are legible and completed in permanent ink. No liquid paper, ditto marks, scratch outs <input type="checkbox"/> Records are recorded by the monitor (person doing the work) in real-time and initialed and dated <input type="checkbox"/> Mistakes have a strike-through and are initialed by the monitor <input type="checkbox"/> Records are reviewed in a timely manner (daily, weekly, monthly, etc. dependent on the record) and initialed and dated by the verifier (trained person that did not do the work being recorded)
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APPROVED SUPPLIER PROGRAM



As the global food supply chain becomes more complex, establishing an approved supplier program becomes more important. An approved supplier program is one control measure to ensure that all incoming raw materials, ingredients, packaging materials and processing aids are safe for use and will not pose a risk of contamination to your product. In addition to the inputs already mentioned, approved supplier programs should also consider equipment and chemicals used in the facility that may come in contact with the food contact surfaces, such as those for cleaning, sanitizing, pest control or maintenance. They should also include service providers that impact product safety, such as those for pest control, laundry services, cleaning, maintenance, transport and distribution, storage, lab testing, catering services or waste management. Contracts or formal agreements with service

providers must clearly define expectations regarding product safety.

To develop an approved supplier program, begin by compiling a list of all suppliers of raw materials, ingredients, packaging materials, processing aids, equipment, chemicals and service providers. Each supplier and service provider should be subject to a risk assessment. The risk assessment should take into consideration different criteria regarding the product and the supplier. In the risk assessment below, each supplier will be scored against each criterion, and the overall risk will be calculated. Once the overall risk is calculated, the second table will be used to determine if the supplier is approved, conditionally approved, or unapproved.

RISK ASSESSMENT

Criteria	Risk Rating				Justification
	1 No Risk	2 Low Risk	3 Moderate Risk	4 High Risk	
A. Product Risk (inherent characteristics such as microbiological risk, allergen risk, pH, water activity, shelf-life, storage recommendations, susceptibility to fraud, etc.)			x		Product is groundfish, which has a neutral pH, high water activity, short shelf-life, and storage requirements to control inherent microbiological risks. It is also an allergen (fish) and susceptible to food fraud (species substitution).
B. Supplier History of Performance (history of non-conformances, complaints, recalls, food fraud incidents, etc.)	x				Supplier does not have any history of non-conformances, complaints, recalls, or food fraud incidents.
C. Length of Relationship with Supplier (trusted, long-time supplier or new)				x	Supplier is a new supplier.
D. Country of Origin (level of food safety regulations/enforcement)	x				Supplier is local supplier in Nova Scotia, Canada, where the level of food safety regulations and enforcement is high.
E. Specifications (availability of specifications, Safety Data Sheets, etc.)	x				Supplier has supplied current specifications for the product.
F. Food Safety Program (proof of annual third-party certification and audit results)	x				Supplier has provided proof of SQF Edition 9 certification and their most recent certificate.
G. Regulatory Compliance (licence or approval from the applicable federal/provincial regulatory agencies)	x				Supplier meets all Safe Food for Canadian Regulations and Nova Scotia Fish Inspection Regulations.
Overall Risk = A + B + C + D + E + F + G = 12					

Approval Category	Total Rating
Approved	7-14
Conditionally Approved (Additional Controls Required)	14-21
Unapproved	21-28

In this example, the overall risk is 12, and as such, the supplier was approved without the need to implement additional controls. Depending on the level of risk, you may need to have additional controls in place. This can include a third-party audited food safety program, product testing, supplier audits, etc. Obtaining evidence of these controls from the supplier is most often in the form of documents, records, etc. Examples of this include:

- A copy of their food safety plan (i.e., HACCP/PCP).
- A copy of their third-party food safety program certification (this can also be found and verified through online directories) or an SFC licence.
- Certificate of Analysis (COA) or Certificate of Conformity (COC)/Letter of Guarantee (LOG) or Letter of Analysis (LOA) outlining the results as well as the accredited lab and methods used.
- A copy of their second-party or third-party audit or inspection results.

In addition to the risk assessment, the approved supplier program should include the frequency, responsibility and method for monitoring and reviewing approved suppliers. This may be completed by the person responsible for the food safety and quality management system and involve an annual review of the risk assessment, specifications, food safety certification status or a supplier audit. The program

should also outline the procedure to follow when materials arrive from an unapproved supplier, such as conducting a risk assessment or product testing. A complete approved supplier program should include a register with the following information: the supplier's name, address, contact information, the item supplied, if current specifications are on file, the date the supplier was approved and who approved them.

A questionnaire is the easiest method of obtaining information about their quality and food safety management program for approving suppliers. The questionnaire should address the supplier's product safety, traceability, HACCP and Good Manufacturing Practices (GMPs). Below is an example of a supplier questionnaire that can be used to collect information used to evaluate supplier approval. Keep in mind that you may need to request additional information from the supplier depending on what item they supply. For example, if you are receiving aquaculture fish, you will need to ensure the harvester is following best aquaculture practices.

APPROVED SUPPLIER QUESTIONNAIRE EXAMPLE

SECTION 1. SUPPLIER INFORMATION		
Company name		
Company address		
Contact person, name and title		
Mailing address		
Email address		
Phone number		
Fax number		
Raw material, ingredients, packaging, processing aids, equipment, chemical or service supplied to (Company Name)		
SECTION 2. FOOD SAFETY PROGRAM		
Does your company have a food safety program in place? Circle one.	YES	NO
If yes, please indicate the food safety program and attach your latest audit certificate.		
Is the food safety program GFSI recognized? Circle one.	YES	NO
Are you inspected or certified by a provincial, federal, 2 nd or 3 rd party? Provide details.	YES	NO
Is your facility approved by the appropriate authority (i.e., CFIA, FDA, Provincial, etc.)? Provide details.	YES	NO
Do you have an Allergen Control Program? If yes, please complete the attached Allergen Checklist for each product supplied.	YES	NO

SECTION 3. COMPLETE THIS SECTION ONLY IF NOT GFSI-CERTIFIED		
Do you have an employee hygiene policy/GMPs, etc., in place? Circle one. If yes, please attach a copy of your policy.	YES	NO
Do you have a Pest Control Program in place? Circle one.	YES	NO
	Name of pest control provider	
	Frequency of service	
Please indicate the source of water for your facility (i.e., well, municipal, seawater).		
Do you conduct routine water testing? Circle one.	YES	NO
	Frequency of testing	
Do you have a documented Sanitation Program in place? Please provide details on sanitation at your facility. Circle one.	YES	NO
	Details	
Please describe your Recall and Traceability Program.		
Can you supply current specifications, certifications, etc. for items provided? Circle one.	YES	NO
Do you have a HACCP/PCP Plan? Circle one.	YES	NO
SECTION 4. PRODUCT TESTING/CERTIFICATES OF ANALYSIS		
Are your products tested before being shipped to customers? Circle one.	YES	NO
Is a Certificate of Analysis provided for each lot/batch of production? Circle one.	YES	NO
SECTION 5. SERVICE PROVIDERS		
Are you a service provider? Circle one.	YES	NO

ALLERGEN CHECKLIST FOR SUPPLIERS AND MANUFACTURERS

(Based on CFIA's Allergen Checklist for Food Suppliers or Manufacturers)

Please complete the following table for each product supplied. The first column describes the product component. The second indicates the allergens that may be found in the product, from addition or cross-contact. The third indicates the allergens present in other products that are run on the same equipment but at a different time. The fourth column indicates if any allergens are present in your plant.

Please fill in each cell of the table with a YES or NO and, when applicable, include the name of the ingredient. Do not leave any empty cells.

COMPONENT	PRESENT IN THE PRODUCT	PRESENT IN OTHER PRODUCTS MANUFACTURED ON THE SAME LINE	PRESENT IN THE SAME MANUFACTURING PLANT
Peanut or its derivatives, i.e., peanut pieces, oil, butter, flour, mandelona nuts (an almond flavoured peanut product), etc. Peanut may also be known as ground nut.			
Tree nuts, i.e., almonds, Brazil nuts, cashews, hazelnuts (filberts), macadamia nuts, pecans, pine nuts (pinyon, pinon), pistachios and walnuts or their derivatives, i.e., nut butters and oils, etc.			
Sesame or its derivatives, i.e., paste and oil, etc.			
Milk or its derivatives, i.e., milk caseinate, whey and yogurt powder, etc.			
Eggs or their derivatives, i.e., frozen yolk, egg white powder and egg protein isolates.			
Fish or its derivatives, i.e., fish protein and extracts, etc.			
Crustaceans (including crab, crayfish, lobster, prawn and shrimp) and Shellfish (including snails, clams, mussels, oysters, cockle and scallops) or their derivatives, i.e., extracts, etc.			
Soy or its derivatives, i.e., lecithin, oil, tofu and protein isolates, etc.			
Wheat/Gluten or its derivatives (triticale), i.e., flour, starches, brans, etc.			
Sulphites, i.e., sulphur dioxide and sodium metabisulphites, etc.			
Mustard or its derivatives			
Others (as considered necessary)			

Do you have procedures to avoid cross-contact of the product with the allergens not present in the product but noted in the third or fourth columns? YES NO

Please attach a finished product label to this form for each product. If for any reason there are any modifications in this product, you are responsible for updating your records, including labels and specifications, and for notifying us immediately.

Approved Supplier Programs must be reviewed annually at a minimum, including a review of the appropriate documentation required (i.e., specifications, certificates, etc.). Programs may need to be updated throughout the year as suppliers change or as new ingredients, equipment or services are required.

INCOMING AND FINISHED PRODUCT SPECIFICATIONS



INCOMING AND FINISHED PRODUCT SPECIFICATIONS

Specifications are information sheets that describe a product and outline important characteristics and attributes. These sheets ensure the production of a consistent, safe and high-quality product. Specifications are developed for incoming raw materials such as ingredients, additives and processing aids that may have an impact on the finished product. They are also developed for packaging that comes in direct contact with the product, chemicals and finished products.

When developing and approving specification sheets, it is important to ensure that all specifications meet the relevant regulatory and customer requirements. Below are examples of what should be included on specifications sheets for raw materials, packaging, chemicals and finished products.

Raw Materials

When sourcing raw materials, it is important to ensure they are from an approved supplier and that the supplier provides current and complete specifications with all relevant information. Raw material specifications may include, but are not limited to:

- Components or composition including the presence of allergens
- Organoleptic information
- Shelf-life
- Shipping and storage conditions
- Handling instructions
- Allergen information
- Properties that impact safety and quality such as pH or water activity
- Microbiological, chemical and physical limits

Packaging & Chemicals

When sourcing packaging material that will be in direct contact with the product, it is important to ensure that any chemical components of the packaging will not migrate and pose a source of chemical contamination to the product. It is also important to consider the suitability of the packaging material for the product. Packaging specifications may include, but are not limited to:

- Details on chemical migration
- Material components or composition
- Physical dimensions
- Performance specifications
- Storage conditions
- Labelling

Packaging that comes in direct contact with the product must be accompanied by a certificate verifying that it meets regulatory requirements and/or approval criteria. This may be in the form of a letter of guarantee, certificate of analysis/conformance or a certificate or letter from the appropriate regulatory agency.

Hazardous chemicals such as those used for cleaning and sanitation or maintenance must also have specifications on file, such as technical data sheets and safety data sheets. These sheets must outline:

- Components including the presence of allergens
- Usage and handling instructions such as the concentration and temperature for use, duration of application, method (i.e., foaming, manual scrubbing, etc.) and if rinsing is required
- What material the chemical can be used on
- Health, safety and environmental considerations such as storage and disposal requirements and personal protective equipment (PPE) required



Finished Product

Finished product specifications must be developed and approved by the manufacturing company and meet all relevant regulatory and customer requirements. Finished product specifications may include, are not limited to:

- Product name
- Size/content/weight
- Composition and ingredients, including the presence of allergens
- Manufacturing methods
- Shelf-life
- Quality attributes (acceptable vs. nonacceptable)
- Microbiological, chemical and physical limits
- Labelling and packaging, including traceability coding and country of origin
- Claims
- Storage and transportation requirements
- Handling instructions
- Product size used for shelf space, if applicable and requested by customer

Services Providers

Companies must also consider the contracted service providers that impact product safety, such as sanitation, maintenance, pest control, storage, or transportation. A written agreement detailing the service description and any relevant training, certificates, insurances, or permits should be on file for each service provider.

REVIEWING SPECIFICATIONS

As specifications help make decisions regarding product safety and quality, it is important to ensure they are current. Specifications should be reviewed frequently enough to ensure they are current, and they must also be reviewed when there is a change in product, supplier, or regulatory or customer requirements. It is critical for suppliers to notify their customers when there is a change in product specifications.



ENVIRONMENTAL MONITORING PROGRAM



An Environmental Monitoring Program (EMP) is a program that uses different indicator tests to monitor the presence or absence of pathogens, food spoilage organisms or allergens in the plant environment. Different indicator tests include ATP swabbing, total plate count (swabbing, settle plates), pathogen testing (swabbing, rapid testing), allergen testing, air sampling (food spoilage organisms), or rinse water testing (indicator organisms). The EMP is used to verify the effectiveness of pathogen control measures in the facility, such as the cleaning and sanitation program, allergen control program, or pest control program.

The EMP considers all areas of the production area and facility. These areas are classified into zones:

ZONE	DEFINITION
Zone 1	Direct food contact surfaces post lethal processing, i.e., skinners, knives, cutting boards, food contact conveyors, hoppers, food contact utensils, etc.
Zone 2	Non-food contact surfaces adjacent to food and food contact surfaces, i.e., production equipment, non-food contact conveyors, utility tables, control panels, aprons, etc.
Zone 3	Non-food contact surfaces located in or near the production area, i.e., floors, walls, drains, doors, hoses, carts, etc.
Zone 4	Non-food contact surfaces located remotely outside of the production areas, i.e., cafeteria, warehouse areas, maintenance areas, locker room, office areas, etc.

By considering all areas, all daily activities that have the potential to introduce environmental contaminants into the production area and finished product are considered, which enables identification and resolution of any issues.

IMPLEMENTING AN ENVIRONMENTAL MONITORING PROGRAM

- Hazard Identification** – complete an onsite review of the facility, creating a list of sample sites for each area and the Zone the site would be included in. If there is uncertainty on which Zone a site falls under, complete a risk analysis taking into account the risk level of the Zone (Zone 1 – High, Zone 2 and 3 – Medium, Zone 4 – Low) and the cleanability of the site/area (Easy to clean – Low, Harder to clean – Medium, Difficult to clean – High) to help determine which Zone the site falls under. A visual risk matrix can be developed to assist with this.
- Determine the type of sampling and testing to be completed** – take into consideration the target organisms or allergen for the site/area to be sampled. Determine which type of sampling will indicate whether or not the site/area is satisfactory or a risk.
- Set a frequency for sampling and testing** – frequency of sampling is essential to be adequate to manage risk to the consumer/customer. This may or may not be set by regulatory or third parties. Include reasons and supporting documentation for frequencies set.
- Record keeping** – keep a record of all environmental monitoring results, actions taken, etc. Ensure results are communicated as appropriate, evaluated as satisfactory or unsatisfactory and monitored.
- Perform a trend analysis for results on a regular basis** – this will assist in visually identifying increases in indicators that an issue is arising, trends for certain areas/fillers/zones, seasonal trends, etc.
- Corrective Actions** – implement a corrective action plan for non-conforming test results (i.e., complete root cause analysis, include immediate and preventative measures).

THINGS TO CONSIDER

Complete a baseline assessment to learn the current environmental status of the facility. This will also assist with setting limits for pass/fail sampling completed during routine production and assist in determining the frequency in which sampling should take place (i.e., if the baseline assessment indicates control or satisfactory results, sampling could take place on a monthly frequency, if the baseline assessment indicates unsatisfactory results the sampling should be completed on a more frequent basis along with a corrective action plan).

It is essential to re-evaluate the Environmental Monitoring Program annually or when there are:

- Product failures (i.e., product with positive results)
- Failures to identify and address significant issues (i.e., results identifying positive results which the site program did not, re-occurring and unresolved positive results)
- Changes in production and sanitation conditions, process flow, new equipment
- Changes in regulatory or third-party requirements
- New developments in scientific information
- Consistently negative results (consider whether the correct parts of the facility are being tested, is the testing being completed correctly? Is the appropriate test being performed?)

Rotate sample site schedules at a minimum annually to ensure the environmental conditions are captured throughout different seasons (i.e., summer, winter, high and low production volumes, etc.) to help identify and manage any risks that may go unidentified.

It is important to implement an effective Environmental Monitoring Program to be proactive, to monitor and control pathogens, food spoilage organisms, allergens and sanitation deficiencies. What is unknown could have a negative impact on the food safety of the finished product and the health of consumers.

FOOD DEFENSE PLAN



Food defense is the effort to protect the food supply against intentional adulteration that is intended to cause harm to public health. A food defense plan is a written program that identifies possible threats within the supply chain, manufacturing process and facility. It establishes mitigation strategies to reduce or eliminate these threats.

In recent years, food safety regulations such as the Food Safety Modernization Act in the U.S. and GFSI-benchmarked schemes such as SQF and BRCGS have introduced the requirement for sites to develop a food defense plan. There is no standardized format for the food defense plan. However, the following key elements should be included:

1. Designated food defense team and senior management person
2. Threat assessment
3. Mitigation strategies
4. Product protection plan
5. Annual challenge exercise and review

The following information provides guidance on each element and helps sites successfully develop and implement a food defense plan to meet regulatory and third-party certification requirements.

1. Food Defense Team

The food defense team will depend on the size of the operation. Ideally, the team should be cross-functional and include personnel from different departments such as production, sanitation, maintenance, transport, IT, etc., to better identify possible threats. A senior management person must also be responsible for and involved in food defense.

2. Threat Assessment

A threat assessment evaluates each step, point or procedure in the operation to identify points with a risk of intentional adulteration that could cause wide-scale public health harm. Different methods can be used to conduct a threat assessment. One method developed and described by the Food and Drug Administration is the Key Activity Type (KAT) method. This method is based on four activities that have been ranked by the FDA as the most vulnerable, regardless of food commodity, to intentional adulteration intended to cause wide-scale public health harm. The KAT method is an appropriate method for conducting threat assessments because it takes into consideration an inside attacker and the three required elements of a threat assessment:

2. The degree of physical access to the product
3. The ability of an attacker to successfully contaminate the product

Each process step is assessed to determine if the activity fits within one or more of the KATs. Process steps that fit within one or more of the KATs are actionable steps and require mitigation strategies to minimize or prevent intentional adulteration. The four KATs are:

1. **Bulk Liquid Receiving and Loading** – Includes opening inbound/outbound transport vehicles, opening vent hatches or other access points, attaching any pumping equipment or hoses and unloading/loading the bulk liquid. This is a KAT because it involves a large volume of product, physical access to the product, and the contaminant can easily go undetected as it mixes within the liquid.
2. **Liquid Storage and Handling** – Includes bulk or non-bulk liquids in storage or handling tanks, silos, totes, or any containers where the tamper-evident seal is broken. This is a KAT because the contaminant can easily go undetected as it mixes within the liquid.
3. **Secondary Ingredient Handling** – Includes any point, step, or procedure where dry or liquid secondary ingredients are manipulated by human contact prior to or during the addition to the product flow. This includes opening ingredients, preparing ingredients such as measuring, weighing, premixing, adding ingredients, or reworking product. It also includes the storage of partially used, open containers of secondary ingredients where the tamper-evident packaging has been broken. This is a KAT because it involves a potentially large volume of product being contaminated, and the ingredient is easily accessible by employees.
4. **Mixing and Similar Activities** – Includes mixing, homogenizing, grinding and coating. Equipment associated with these activities includes mixers, blenders, homogenizers, mills, grinders and other similar equipment. This is a KAT because the contaminant can be easily mixed into the product and go undetected, and it may potentially contaminate a large volume of product.

3. Mitigation Strategies

Mitigation strategies are procedures established to minimize or prevent intentional adulteration at each KAT. For each mitigation strategy, monitoring procedures must be defined, including what will be monitored, how it will be monitored, how often it will be monitored and who is responsible for monitoring. Monitoring procedures are

1. The potential public health impact (i.e., severity and scale) if a contaminant (biological, chemical, or physical) was introduced

recorded, and corrective and preventive actions must be established in the event of a deviation. The mitigation strategies will be specific to the facility and the KAT identified. Some examples of mitigation strategies may include:

- ✓ Security cameras and proper CCTV signage
- ✓ Adequate lighting surrounding the premises, especially around entrances and shipping/receiving areas
- ✓ Controlled access to the facility and off-site storage (i.e., key fob system, security fencing)
- ✓ Protection of chemicals, packaging, ingredients, and air, gas and water supplies
- ✓ Protection of sensitive data systems and the data (i.e., labels, specifications, formulations)
- ✓ Control visitors (including contractors) through a visitor policy and sign in sheet

- ✓ Inspect vehicles to ensure vehicles are locked, and seals are intact and match shipping records, and if there is any evidence of tampering
- ✓ Securely storing raw materials and finished product and maintain an inventory
- ✓ Use tamper-evident packaging
- ✓ Development and implementation of an approved supplier program
- ✓ Raw material and final product testing
- ✓ Employee integrity screening
- ✓ Employee training on food defense
- ✓ Providing employees with a method to anonymously report suspicious behaviour, etc.

Below is an example of one way to document a food defense plan:

PROCESS STEP	KAT (1, 2, 3, 4) & EXPLANATION	MITIGATION STRATEGY & EXPLANATION	MONITORING PROCEDURE	DEVIATION PROCEDURE	VERIFICATION PROCEDURE	ASSOCIATED RECORDS
Brining	3 – Secondary ingredient handling. Contaminants could be added when employee is mixing the brine solution.	Brine solution is mixed by trained authorized personnel only and salt is stored in a tamper-evident or sealed container. The employee responsible for preparing the brine solution records how much salt was used and signs their name.	Who: Production Manager Frequency: Daily How: Inspect salt container and storage area. Observe employee mixing the brine solution.	If the salt container appears to be tampered with (i.e., seal is broke), Production Manager must report to the Food Safety Manager immediately and initiate the Product Hold procedure. Corrective Action Record to be completed.	Who: Food Safety Manager Frequency: Weekly How: Verify Brine Mixing Record and Daily Inspection Record to ensure they are completed.	Brine Mixing Record Daily Inspection Record Corrective Action Record

4. Product Protection

A plan must be established to protect customers from potentially contaminated products in the event of a food defense crisis. When there is any uncertainty regarding product safety, the product must be placed on hold and segregated. Decisions on release must be made by authorized personnel. Any incident involving a recall will be handled as outlined in the site's recall program.

5. Annual Challenge Exercise and Review

The food defense plan is monitored regularly through facility inspections; however, an annual food defense challenge exercise must be completed and documented. An example of a challenge exercise may involve having an outside visitor attempt to enter the facility without following proper protocol to determine how employees react to an unfamiliar person or situation. The record of the challenge exercise should include the date and time, who was involved, the situation, how the employee(s) reacted, a summary and any corrective and preventive actions. The food defense plan must be reviewed annually to ensure it is up to date.

FOOD FRAUD



Food fraud refers to the intentional misrepresentation of food, food ingredients, food packaging and/or labels for economic gain. While it may not intend to harm consumers, food fraud activities can pose serious health risks to consumers if unidentified allergens or hazardous materials are added to the food product. Seafood is among the most targeted foods for fraud. The most common types of food fraud include:

- **Dilution:** Diluting a product by mixing in other ingredients and not declaring it on the label. For example, mixing oils extracted from two fish species and not declaring the common name of both species in the list of ingredients.
- **Substitution:** Replacing a product with something of a different character or quality, usually of lesser value. For example, selling skate wings as scallops or selling pollock as cod or haddock.
- **Mislabelling:** Making false claims or misleading statements on labels to make the product appear to be something it is not. This includes providing false product information regarding common name, net quantity, expiration dates, nutritional value, grades, country of origin, composition, quality, health benefits, or method of production. For example, labelling imported lobster from the U.S. as a Product of Canada or labelling farmed salmon as wild.
- **Unapproved enhancement:** Using illegal, unapproved and/or undeclared substances to improve a product.

- **Concealment:** Hiding the low quality (i.e., disease or defect) of a product.
- **Counterfeit:** Intellectual Property Rights infringement.
- **Grey Market Production, Theft or Diversion:** Legitimate product or product destined for disposal is stolen and sold/distributed outside of intended markets.

HOW TO PROTECT PRODUCTS AGAINST FOOD FRAUD?

One approach to protect products against food fraud is conducting a food fraud vulnerability assessment. This risk assessment evaluates the vulnerability of raw materials, ingredients, packaging and input materials to food fraud. It takes into consideration the risk associated with each material based on several factors as well as current mitigation strategies in place that reduce that risk. It also considers the overall impact a food fraud event would have on a business. By assigning scores and calculating the overall risk, a company can determine which items are at high risk of food fraud and if further mitigation strategies may need to be implemented. Below are the steps to follow to complete a vulnerability assessment.

Step 1. Determine the risk (A) associated with each raw material or input material

First, the company must determine the risk associated with each raw material or input material. Several factors should be considered and scored accordingly. For this example, consider a company processing frozen haddock.

RISK FACTOR	SCORING SYSTEM	SCORE	JUSTIFICATION
Nature of the Raw Material – Does the physical form of the food or food ingredient make it easy to adulterate? Liquids and powders are easier to dilute or substitute than solids.	1 – Solid (difficult to adulterate) 3 – Powder (easier to adulterate)	1	Haddock is a solid food that is more difficult to adulterate by dilution but could be substituted.
History of Adulteration – Is the food or food ingredient a frequent target of food fraud?	1 – Rare 4 – Frequent	4	Fish is a frequent target of food fraud, particularly substitution or mislabelling.
Length and Complexity of the Supply Chain – Is the supply chain short and simple or long and complex, allowing for more opportunities for adulteration?	1 – Short, simple supply chain 4 – Long, complex supply chain – more opportunities for adulteration	1	Haddock is received from local fisherman. Supply chain is short and simple, with little opportunity for adulteration.
Likelihood of Detection – What is the likelihood of detecting the adulterant in the material? This will require knowledge of common adulterants and depend on the testing methods used and the frequency.	1 – Highly detectable 3 – Low detection rate	3	Final product is not tested for any adulterants or species identification.
Geographic Origin – Is the material originating from an area where food fraud reports are rare or common?	1 – Reports are rare 3 – Reports are common	2	Reports of fish fraud in Nova Scotia are rare; however, there has been one report of mislabelling in the past year. However, experienced personnel may be able to properly identify the species visually.
Economic Factors – Is there an economic motive to adulterate?	1 – No incentive (cheap commodity) 4 – High incentive (high-value commodity)	4	There is incentive to mislabel or substitute other fish species such as pollock as cod or haddock for economic gain.
Ease of Access to the Raw Material	1 – Limited access 4 – Readily accessible	1	Haddock is securely stored during transport and at the facility.
Total Score:		16	

Based on the assessment, the total risk score (A) for haddock is 16.

Step 2. Determine the mitigation strategies currently in place and assign a score (B)

A company may have mitigation strategies currently in place. Each mitigation factor should be given a score. Note that depending on the number of mitigation strategies in place, the scoring system may need to be adjusted.

MITIGATION STRATEGIES	SCORING SYSTEM	SCORE	JUSTIFICATION
Approved Supplier Program – The company has an approved supplier program in place outlining how suppliers are evaluated, approved and monitored.	0 – No approval system 2 – Comprehensive approval system (suppliers are required to have a food safety program or GFSI certification, provide audit results, undergo supplier audit, etc.)	2	Approved Supplier Program is developed, and haddock is received from an approved supplier.
Raw Material Acceptance Specifications/Criteria and Supporting Documentation	0 – No specifications/criteria developed or certificates required 2 – Specifications/criteria developed and supporting documentation (i.e., certificates of analysis, letters of guarantee, etc.) required	2	Specifications are on file for haddock and haddock is inspected upon receipt for acceptance.
Raw Material and Final Product Testing	0 – No testing 2 – Routine testing completed	0	No routine testing of raw material or final product conducted.
Total Score:		4	

Based on the risk assessment, the mitigation score (B) is 4.

Step 3. Determine the impact on business (C)

Next, the company must determine the impact on the business if the final frozen haddock product was found to be adulterated. Depending on the adulterating substance used, it could result in a catastrophic impact resulting in consumer illness or injury. However, as seafood is most often a target of mislabelling or substitution, it would most likely be a major impact (3) on the business and result in a consumer complaint, product recall and/or brand damage.

IMPACT ON BUSINESS (MULTIPLIER)	CATASTROPHIC – 4 (CONSUMER FATALITY, CLOSURE OF COMPANY)
	MAJOR – 3 (PRODUCT RECALL, BRAND DAMAGE)
	MODERATE – 2 (INGREDIENT FREQUENTLY USED, VERY LOW PRODUCT VOLUMES)
	INSIGNIFICANT – 1 (INGREDIENT RARELY USED, VERY LOW PRODUCT VOLUMES)

Step 4. Determine the overall risk rating

Considering the Risk Factors (A), Mitigation Strategies (B) and the Impact on Business (C), an overall risk rating is assigned and determined as low, medium, high, or extremely high. Where a raw material is identified as having a medium risk or higher, further mitigation strategies must be implemented to reduce the risk, such as additional assurance from the supplier or product testing. Keep in mind that product testing will require knowledge of common adulterants for the product and depend on the availability of the appropriate testing methods. Based on the assessment completed, haddock is at high risk for food adulteration (substitution), and as such, the company could conduct random sampling to verify the species or request that the supplier provide proof of species identification.

IMPACT ON BUSINESS (C)	OVERALL RATING (A-B = 16-4 = 12)					
		21-25	16-20	11-15	6-10	1-5
	CATASTROPHIC – 4	EXTREMELY HIGH				
	MAJOR – 3		HIGH			
	MODERATE – 2			MEDIUM		
	INSIGNIFICANT – 1				LOW	
RAW MATERIAL RISK RATING						

Raw material, ingredient, packaging or food	Supplier	Supplier Location	Risk Score (A)	Mitigation Score (B)	Impact Score (C)	Risk Level*	Additional Mitigation Required? (Y/N)	Mitigation Measure
Haddock	XYZ Seafoods	Nova Scotia, Canada	16	4	Major (3)	High	Y	Further proof from supplier of species identification

Steps 1-4 are to be followed for each different raw material or input material. If materials are similar, they may be grouped together. However, care must be taken to ensure that the risks are the same for each material. For example, if the materials are sourced from a different country, supply chain or harvester, different risks may be introduced.

CONTINUOUS IMPROVEMENT PLAN



CONTINUOUS IMPROVEMENT PLAN

Continuous improvement is an ongoing effort to improve products and/or processes. There are always opportunities for improvement in any quality and food safety system. Developing a continuous improvement plan is a requirement of Global Food Safety Initiative (GFSI) benchmarked schemes and a way for senior site management to demonstrate their commitment to the quality and food safety system and culture. One tool used to outline the process of continuous improvement is the DMAIC model: Define, Measure, Analyze, Improve and Control.

DEFINE

Continuous improvement begins by defining a problem or area of improvement in a process and/or product. Consider the following scenario: a company processing groundfish conducts daily inspections to determine if employees are following the company's Employee Hygiene and Good Manufacturing Practices (GMP) Policy. The Production Supervisor completes these inspections, and any deviations observed, such as an employee not wearing their hairnet or not washing their hands after returning from break, are recorded. The Production Supervisor has noticed an increase in deviations in the last few months, which has driven the company to prioritize employee hygiene and GMPs as an area of improvement.

One tool that can help to identify and define the problem is root cause analysis. In the scenario given, the company conducted a root cause analysis and found that the frequency of training employees on the Employee Hygiene and GMP Policy (annually and upon hire) is too infrequent, and employees tend to forget.

Once the area of improvement is identified, and the problem is defined, the next phase is to measure.

MEASURE

Measuring continuous improvement can be accomplished by establishing Key Performance Indicators (KPIs). KPIs are defined as quantifiable measures used to evaluate an organization's success, employee behaviour, etc., in meeting objectives for performance. KPIs must be SMART:

- **Specific** – clear and directly related to the site's continuous improvement goals
- **Measurable** – enables the site to assess progress towards continuous improvement goals
- **Achievable** – targets must be challenging but realistic with sufficient resources available
- **Relevant** – targets aim to improve product quality and safety or processes
- **Time-bound** – a target timeline must be established, i.e., long-term or short-term. The timeline must allow the site to review progress and, if necessary, redefine the problem and solutions.

Below are some common examples of KPIs for quality and food safety. It is best to focus on one or two KPIs when beginning.

- Customer complaints
- Internal and external audit/inspection results (i.e., score, number and type of non-conformances)
- CCP deviation incidents
- Non-conforming product incidents
- Product recall or withdrawal incidents
- Number of product rejects and returns
- Amount of rework and waste
- Final product testing results



- Environmental monitoring results
- Pre-operational inspection results
- Pest control inspection findings
- Meeting finished product specifications
- Water quality results
- Sensory evaluation results
- Shelf-life study results
- Label compliance
- Employee training completion (i.e., employees have received adequate training and annual refresher training and effectiveness checks are completed)
- Record keeping completion (i.e., records are filled in correctly and verified in a timely manner)
- Corrective/preventative action completion
- Non-conformance completion and closure

The measurement of current performance is critical since it serves as the reference point for improvement and as a visual for recognizing progress and the completion of tasks. During the measure phase, data is collected to identify and monitor defects in the product or process.

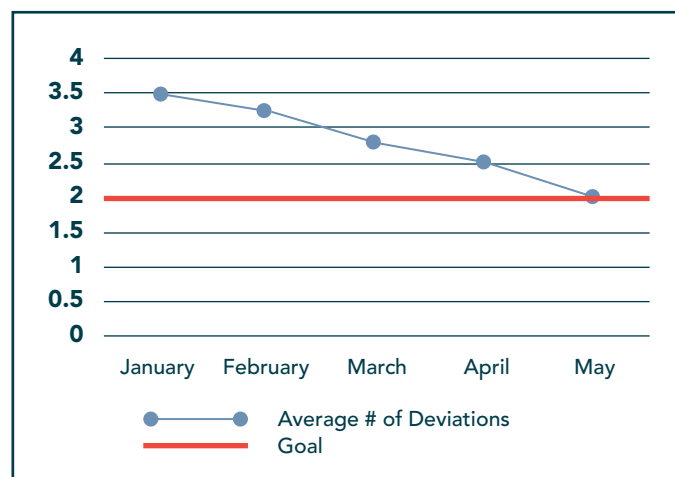
Using the scenario described above, the company's KPI to measure employee adherence to the hygiene GMP policy will be the average number of deviations found during the employee hygiene and GMP inspections per month. The company has determined the current average to be 3.5 deviations/month and aims to decrease the average to ≤ 2 within five months. To complete this, the number of deviations will be recorded on the Daily GMP Inspection Record, and at the end of each month, the average number of deviations will be calculated.

Once the KPIs have been identified and measured, the next phase is to analyze the data.

ANALYZE

The data can be analyzed using statistics, charts, or graphs to view the data objectively and to observe trends. This visualization will allow the site to compare the results with the baseline and the targeted goal. In the scenario given, the Food Safety Manager will calculate the average deviations per month and plot the results on a line graph:

Month	Week	# of Deviations	Average # of Deviations/ Month
January	1	3	3.5
	2	4	
	3	4	
	4	3	
February	5	2	3.25
	6	2	
	7	3	
	8	6	
March	9	3	2.8
	10	4	
	11	2	
	12	3	
	13	2	
April	14	2	2.5
	15	3	
	16	2	
	17	3	
May	18	3	2
	19	2	
	20	2	
	21	1	



IMPROVE AND CONTROL

Once conclusions are drawn based on the data, changes can be made to improve the process. In the given scenario, to increase awareness and understanding of the Employee Hygiene and GMP Policy, the policy will be reviewed during toolbox talks before production, and it will also be posted in all staff amenities. The Production Supervisor will be responsible for completing the toolbox talks and following up with employees who are not following the Employee Hygiene and GMP Policy.

Once the solution is implemented, it is critical to continue monitoring performance to determine the effectiveness of the solution in achieving improvement. If not, the site may need to redefine the problem or KPI, reanalyze the data or determine a new solution. In this scenario, if the company

did not see a decrease in deviations, the root cause may not have been identified correctly and would need to be redefined, or a new solution such as changing the training style to one that is more effective for the employees may need to be implemented. Once a company achieves one of their current continuous improvement goals and the problem is under control, they can now focus on another area of improvement using the DMAIC model process.

Continuous improvement and KPIs must be discussed and reviewed by senior management at an appropriate frequency or at a minimum quarterly. All discussions must be communicated to all levels of staff and management. The continuous improvement log shown below is a convenient method for summarizing the company's improvement goals and efforts.

Date Initiated	KPI	Action to Be Taken	Responsibility	Target Date	Completed Date
January 1, 2021	Average number of deviations related to Employee Hygiene and GMP per month	Increase awareness of the Employee Hygiene and GMP Policy practices by reviewing them during the daily toolbox talk before production and posting the Employee Hygiene and GMP Policy in all staff amenities. The number of deviations for each will be recorded, and the monthly average will be calculated and trended.	Production Supervisor Food Safety Manager	June 1, 2021	June 1, 2021

RESPONDING TO A NON-COMPLIANCE - 8 STEPS TO A SUCCESSFUL DEVIATION RESOLUTION

- 1. Identify the Problem.** Look at the whole picture; investigate when, where, what, who, why and how. Determine if product was affected and if food safety has been compromised.
- 2. Avoid Assigning Blame.** Your first priority is to get the situation under control; identifying the root cause and any disciplinary actions (i.e., addressing behaviours, coaching, etc.), if necessary, can be focused on later.
- 3. Conduct an Investigation.** Inspect the area, product, packaging, personnel practices, and equipment that may be contributing to the problem. Interview employees, review records and consumer complaints, write down all details, dates, times, lot codes, findings, etc. Save emails and other correspondence in case you need to go back and reference these.
- 4. Implement.** Implement any immediate corrective actions to prevent reoccurrence and to ensure the situation is fully under control. Further solutions and corrective measures may need to be applied after conducting a root cause analysis.
- 5. Segregate the Product.** This is where your traceability exercise practices will be useful. Crunch the numbers to make sure all input and output numbers match. Any discrepancies need to be investigated. If you determine that the incident is serious and that product has left your control, this is when your Recall Plan will be initiated.
- 6. Root Cause Analysis.** Regardless of which method you use (i.e., fishbone, 5 why, is/is not), make sure you do not do this step on your own. A root cause analysis always works best when using a cross-functional team that can see the issue from all sides. This will ensure you have covered all aspects and are implementing the proper corrective and preventative actions to address the root cause. Consider whether or not this non-compliance can occur elsewhere within the system.
- 7. Assign and Communicate the Permanent/ Preventative Corrective Action.** Actions to be taken to correct and bring the process/issue back into control and prevent reoccurrence. This can only happen after a thorough root cause analysis is completed. This may involve improving procedures, equipment modifications or other lines/processes. Communication is key to preventing the issue from occurring again and for the team, including employees on the floor, to understand the corrective actions that have been put in place.
- 8. Conduct an Effectiveness Check.** Review corrective and preventative actions taken to determine whether they were effective. This will ensure that the issue has been fully addressed and that corrections continue to be effective.

EXAMPLE OF A CORRECTIVE ACTION PLAN

Report # (YYYY - #): 2021-08		
SECTION A: DEVIATION DESCRIPTION		
Date Reported: August 10, 2021		Reported By: Remi Morris (Production Supervisor)
Deviation Description: Metal detection test wands were not detected at the routine verification check completed by the line operator after break at 11:05 AM.		
Check one of the following options:		
Was Product Involved? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Was Product Safety Compromised? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
If Yes, describe: Yes, product from 9:05 the last good check until 11:05 when the problem was detected and recheck was completed.		
Quantity and Dates Affected: 2 pallets, 70 cases – Production Date: August 10, 2021, between 9:05 AM and 11:05 AM.		
Product Affected was Held: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	Date Held: August 10, 2021	Date Released: August 11, 2021
If product wasn't held, explain why:		
Product Disposition: Check which applies and explain. <input type="checkbox"/> Product was re-worked: <input type="checkbox"/> Product was destroyed: <input checked="" type="checkbox"/> Product was put back into stock: Product was passed through the metal detector after regular set-up the next day and passed.		
Completed By: Remi Morris (Production Supervisor)		Date: August 11, 2021
SECTION B: CORRECTIVE ACTION DESCRIPTION (IMMEDIATE CORRECTIVE ACTION)		
Correction (Immediate Corrective Action) Taken: The production line was stopped, product was placed on hold since the last successful metal detector verification check (9:05 AM), and the daily initial set-up was completed on the metal detector. Once the metal detector set-up was successful, the remainder of the product was put through.		
Assigned To: Lola Laffin (Line Operator)		Completion Date: August 10, 2021
Is Preventative Action Required? If Yes, complete remaining sections <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		
SECTION C: PREVENTATIVE ACTION		
Description of Root Cause (Determined using 5 Whys or Fishbone Diagram):		
Why did the metal detector not detect the test wands during the 11:05 AM verification check? The metal detector was not set to the correct setting.		
Why was the metal detector not on the correct setting? During break, the metal detector was unplugged and plugged back in immediately by an employee.		
Why was the metal detector unplugged? The employee was trying to unplug the automatic taping machine to move it to a different production line.		
Why did the employee not put the metal detector on the correct setting? The employee did not know the settings would be affected when unplugged and plugged back in.		
Why did the employee not know the settings would be affected? The Metal Detection SOP used to train the employee does not outline this or to notify the Production Supervisor if power is interrupted.		
Why does the Metal Detection SOP not outline this? This incident never occurred before.		
Preventative Action Taken to Prevent Reoccurrence: Update the Metal Detection SOP to state that if the metal detector is unplugged and plugged back in or any power interruption, the employee must notify the Production Supervisor. This update was communicated to all employees and recorded on a training record. The metal detector and automatic taping machine cords were labelled to prevent accidentally unplugging the metal detector.		
Target Completion Date: August 11, 2021		
Assigned To: Mr. Browning (Quality Control Technician)		Completion Date: August 11, 2021
SECTION D: FOLLOW UP		
Effectiveness Check: Were the corrections and/or corrective actions taken effective at preventing reoccurrence? Check one and provide details. <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO		Employees were interviewed by the Production Supervisor to ensure they were aware of the update to the Metal Detection SOP. Training records were verified by the Quality Control Manager
If yes, deviation is considered closed. If no, further corrective action must be taken.		
Completed By: Remi Morris (Production Supervisor)		Date: August 13, 2021
Verified By: Chloe MacDonald (Quality Control Manager)		Date: August 14, 2021

RESOURCES



Our Quality and Food Safety Team have created a variety of resources which can be found on our website at www.perennia.ca. We offer coaching, assessments and online or public training courses covering a variety of topics. We also have a monthly newsletter which you can sign up for at <https://us4.list-manage.com/subscribe?u=642ec925a6b70139cd668d4b0&id=0e9b713521>. Most recently, we have added a resources page, which includes Perennia's publications and fact sheets, recommended resources, and videos. If you have any questions, please do not hesitate to contact one of our Quality and Food Safety Team members. We are here to help.

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