Sanitary Design and Construction of Food Processing and Handling Facilities

Introduction

To ensure safe food and adequate sanitation programs, the facility and surroundings in which food processing and handling operations are conducted must be designed and constructed with sanitary design principles in mind. Many existing facilities do not have optimum sanitary design and construction. Certain adjustments and/or renovations, where feasible, may be necessary. While often discussed separately, sanitary construction and sanitary design are inter-related terminology.

The objectives of designing and constructing a sanitary food handling facility are to minimize harborages, eliminate the entrance of pests and other sources of contamination. To design and build in features that protect the food product from contamination should be the ultimate goal of planners and designers. The sanitary design features of a facility should be thoroughly evaluated on a periodic basis. Such evaluation should include the following:

• Premises, surroundings, and building site;
• Exterior building design and construction features;
• Interior building design and construction features; and
• Operational flow and facility layout.

Premises, Surroundings, and Building Site

The objectives regarding sanitary building site and exterior surroundings are to use every effort and means possible to minimize:

• harborages and infestations of vermin (e.g., rodents, insects, birds, other pests), mold and mildew, and microorganisms; and
• potential for contamination with environmental chemical pollutants.

The role of rodents, insects, birds, and other pests (e.g., frogs, reptiles) in spreading foodborne pathogens has been well documented. It is imperative that an adequate pest control management program is in place for food processing and handling facilities. While it is possible, with good practices and due diligence, to self manage pests, it is recommended that the services of a reputable pest management supplier be obtained. It is also a good plan to identify an employee that is assigned to work with the pest management supplier with regard to the location of bait stations, tracking trap and station activity, chemical storage, and the observation of proper pest control procedures. Proper
records and documentation of a pest control program is important to the success of an overall sanitation program. The topics discussed below regarding the location of traps and bait stations, maintenance of outside surroundings, and limitation of pest entry into buildings are all part of a successful pest management program.

**Location**

As with real estate, an important feature of a sanitary food facility is "location, location, location". Ideally, a facility should be located away from any contamination source (e.g., chemical plant, sewage treatment facility, salvage yard, livestock housing, cow pasture, or body of water). For many existing facilities, the location may not be in the control of the facility management as other industries may have moved in around the food facility. If, in the evaluation of the facility, it is found that sources of contamination are adjacent or near the building, special precautions are necessary to keep odors and contaminants from entering the yard or facility. When building a new facility, an inquiry should be made regarding the previous occupants and the type of operations previously conducted at that location.

**Site Condition, Preparation, and Maintenance**

When preparing a new site for construction, the site should be thoroughly cleaned of any potentially toxic materials and graded for appropriate drainage and prevention of standing or pooled water. Storm sewers should be designed and located to allow for adequate runoff. Where appropriate, paving should be used to minimize dust. In many cases, local, state, or provincial zoning rules may apply. These must be respected during the site selection and preparation phase.

Landscaping is another important consideration as shrubs, grass, and trees too close to the building can increase the chance of harborage of vermin. According to Graham, trees and shrubbery should be no closer than 30 feet from the building, and grass coverings should end 30 inches from the building walls (1991). Further, a gravel buffer should be established between the building and landscaping to discourage rodents. Under-laying the pea gravel with polyethylene film is also recommended.

Maintenance of the surroundings is also very important. Keeping the area uncluttered and free of refuse, and keeping the grass mowed and shrubs pruned on a regular basis will discourage insects and other vermin from taking up residence. The drainage system or landscape design must also be maintained appropriately to minimize standing water.

**Exterior Lighting**

A qualified lighting contractor should be consulted to evaluate adequacy and location of exterior lighting. While adequate lighting in external areas of a facility is important for an overall sanitary operation, it is also necessary for security protection. However, since outdoor lights may attract insects, the location of these fixtures is of critical importance for preventing insects from entering the facility. The location of fixtures, especially when
positioned over doorways, needs special attention. While high intensity, ultraviolet lights are often used for security purposes, these lights are especially attractive to insects. It is recommended that lighting be mounted on poles or standards, be at least 30 feet from buildings, and the light directed towards doorways and entrances (Graham, 1991). Lighting fixtures should be shielded with a non-breakable, transparent material.

**Driveways and Receiving Areas**

As the area used for receiving is the last line of defense in protecting the building, care should be taken to make sure that such areas are designed to minimize contamination and intrusion from pests. Driveways leading to receiving areas should be appropriately paved and constructed for adequate drainage. Asphalt driveways should be avoided, as this material may, in fact, attract rodents. Drains should be designed with catch baskets for debris, and hose stations should be provided to facilitate cleaning and maintenance. Bait stations and traps, where used, should be properly located.

**Exterior Building Design and Construction**

The primary objective of sanitary design in building construction is to design and construct a building that is cleanable. Other major considerations are to minimize contamination and adequately seal food processing and handling areas from sources of contamination.

Rather simple and inexpensive preventative measures can be built into building construction with regard to vermin proofing the building. For example, installing flanging to foundations below grade level will discourage rodents from burrowing under the floor slab. Further, avoiding any horizontal ledges or overhangs in construction will discourage roosting or nesting of birds. If ledges cannot be avoided, they should be sloped rather than flat or horizontal. Preventing the entry of rodents and insects into buildings can be accomplished by sealing all openings to the outside which are 1/4 inch or greater. The caulking and sealing of all joints has proven useful in preventing rodent entry. The vermin proofing aspects of the building needs to be regularly evaluated and maintained.

**Loading Docks, Platforms, and Receiving Rooms**

Receiving areas and rooms should be enclosed as much as is practicable. An improperly designed and constructed receiving room will provide an attractive harborage for birds, rodents, and insects. Enclosed receiving areas and rooms are less desirable to birds, rodents, and insects than a more open receiving area. Such areas must be critically evaluated to determine the adequacy of protection from contamination and entrance of pests. Loading docks and platforms should be designed to minimize entry of pests. Ideally, loading docks should be at least 3 feet above ground with the underside lined with a smooth, galvanized metal or similar material with a 12 inch over-hang to prevent rodents from climbing into the building. Properly installed rapid open/close doors or air curtains should be used to discourage entrance of insects and birds. Overhangs should be constructed to be free of roosting and nesting areas for birds.
Exterior Walls

Building materials used for exterior walls vary in their need for preventative maintenance with regard to re-caulking of joints. For example, a poured concrete wall, while being expensive, needs less maintenance than other materials because it does not have seams. A concrete block wall, if appropriately sealed, is also fairly maintenance free. Low-density concrete block (e.g., cinder block), commonly used in domestic building, should be avoided unless an adequate sealer is used to avoid moisture intrusion and penetration of mold and mildew. Concrete block walls should be sealed at the base and capped at the top. Corrugated metal siding is the least desirable material for wall construction in a food handling facility. If used, it is imperative that it be adequately caulked along the base and at the seams. Further, corrugated metal siding needs a good maintenance program to maintain an effective seal. The maintenance frequency is also affected by climate conditions.

Roofs

Roof construction and design should not be overlooked. The roof should be designed and built so it can be kept clean, especially where there is the possibility of product spillage or deposition on the roof. Food related dust (e.g., flour, powdered milk, or grain) can accumulate on the roof and is an invitation to birds and insects. Smooth membrane type roofs are often the most desirable type of roof for food processing facilities. Tar and gravel roofs are usually not recommended as they tend to attract dust and are very difficult to clean and maintain.

Openings into the Building

Any openings into buildings, including doors, windows, ventilation ducts, and other openings must be appropriately sealed and protected. Openings into the roof such as exhaust fans for air handling systems, ventilation ducts, and plumbing vent pipes must be sealed, and appropriately flashed and screened. Windows are discouraged in food processing operations as they present sanitation problems due to glass breakage and overall maintenance considerations. If used, windows should be designed to be flush with the inside wall and be permanently closed. Sills should be sloped away from the wall at not less than a 45 degree angle to prevent birds from nesting or dust from collecting.

Interior Building Design and Construction

The sanitary objectives for interior building design and construction are to:

- minimize potential harborages of pests and microorganisms;
- maximize cleanability; and
- maximize the protection of the food products from contamination.
As previously discussed, a new facility is easily built with sanitary design criteria in mind. Building designers can integrate sanitary objectives without adding a great deal of cost to a construction project. Existing facilities present a different set of challenges due to construction practices that are now considered obsolete, and cost considerations for updating these facilities. Having a facility designed and built to sanitary specifications does not guarantee a safe food product if the facility is not adequately cleaned and maintained on an appropriate schedule.

**Interior Walls**

A cleanable, sanitary wall is one that is

- hard, flat, and smooth;
- free of pits, cracks, checks, and crevices;
- impervious and non-absorbent;
- resistant to cleaning and sanitizing chemicals;
- corrosion resistant;
- durable, easily maintained, and wear resistant; and
- properly installed, sealed, and covered.

The wall should be installed and maintained to assure these properties are met from the floor to the ceiling. In addition, if used openings and windows are used they should be installed and sealed to maintain the floor to ceiling properties.

There are several acceptable surfaces and materials available for walls in food processing and handling areas. Some of these are described below:

**Seamless Poured Concrete** is often recommended, because of its lack of seams and associated maintenance requirements. However, such walls should be finished smooth and sealed. They can be improved by painting with a semi-gloss or gloss epoxy enamel. Specialized spray coatings for concrete walls using epoxies and fiber glass are the most recent innovations which have proven to be impervious, cleanable, and durable.

**Concrete Block** walls should be heavy density, non-porous blocks. Concrete block walls should be installed in a stack bond pattern (with reinforcement), rather than a running bond pattern (see Fig. 1), as there is less hold up of dust and moisture. As stated previously, the concrete blocks should be installed with a solid cap on the top course and without ledges or crevices. For additional durability and cleanability concrete block walls should be appropriately sealed and finished by painting with semi-gloss or gloss epoxy enamel paint covering.
Fiberglass Panels are a highly acceptable wall material and are commonly used in newly constructed facilities. These panels are available from several different suppliers. While most of the available panels are acceptable; gel coated, reinforced fiberglass panels are most recommended. This material, when properly installed and sealed at the seams, provides a continuous, hard, durable, and cleanable surface. However, if fiberglass board is improperly installed, improperly maintained, or becomes damaged, it can lose its desirable features. If the panels extend to the floor, they are vulnerable to damage from forklifts and related equipment. In high impact locations, a concrete curb may be recommended. To prevent creation of a ledge (which will collect dust) the top of the curb should be sloped at a 45 degree angle or greater or the curb constructed in a bull nose design.

Glazed Ceramic Tile, due to its durability and resistance to a wide range of chemicals, is the most highly recommended wall material in wet processing areas and is often used in dairy and beverage plants.

Wood (e.g., plywood, pressed wood), due to its porosity, is not recommended and should be avoided for interior walls in food facilities. Wood cannot be adequately sealed.

Metal panels (e.g., stainless steel, galvanized metal) are not usually recommended for walls in a food facility due to condensation problems. Plus, expansion and contraction of metal panels make maintenance of the seam seals very difficult. Due to problems with zinc flaking and potential product contamination, galvanized metal should be absolutely avoided.

Walls should be covered with a light colored paint and caulked, sealed or grouted appropriately at joints and junctions. Such coverings and sealants are used to enhance the impervious properties, cleanability, and ease of maintenance. However, if such coverings are not maintained, checks and flakes can form, decreasing the cleanability of the surface. Thus, a preventative maintenance program should be in place to keep walls in good repair.
**Junctures** between walls and ceilings, and between walls and floors should be rounded (or coved) with a radius of one inch or greater. Coving minimizes a right angle crevice, which is difficult to clean and maintain. An example of a wall to floor juncture is shown in Figure 2.

![Figure 2. Coved Wall/Floor Juncture](image)

**Ceilings**

Ceilings in food handling facilities are often neglected from a sanitary design and construction perspective. Ceilings should meet the same objectives mentioned for walls. In addition, they need to be included in a preventative maintenance program. Improperly installed ceilings, ceilings that promote condensation, or poorly maintained ceilings (e.g., flaking paint) can actually increase the potential for overhead contamination of food products.

**Concrete** ceilings are often recommended due to durability and minimal maintenance requirements. The most recommended installation is the concrete slab with exposed double tee beam construction, which avoids ledges associated with I-Beam construction. Concrete ceilings should be ground smooth, appropriately finished, and caulked at the joints.

**Metal** ceilings are not recommended due to condensation maintenance problems. Joints in metal panel ceilings are very difficult to maintain. Corrugated or ribbed sheet metal ceilings are very difficult to clean and maintain, and have areas for harborage of insects and rodents.

**Wood ceilings**, due to their porosity, are impossible to clean and maintain and must be avoided.

**Dropped ceilings** are acceptable only if properly installed. False ceilings, which create a crawl space above the ceiling for utilities and services, should be avoided. The crawl space also becomes very attractive to insects and rodents, increasing the potential of product contamination. Because fiberglass panels can be glued in and sealed at the joints they are acceptable in dropped ceiling application. However, they are very difficult to maintain in a continuously sealed condition. Permanent dropped ceilings, which
essentially create a walk-on second floor above the processing area, are more desirable, especially those with a permanent smooth concrete ceiling. The additional floor is used to run utilities, air handling ducts, fans, and similar services. In dairy and beverage plants, clusters of air operated valve systems are used in automated process control systems for transporting liquids and cleaning solutions. Due to the complexity of such valve clusters, they can create dust collection points over processing areas. They are often conveniently located in this upper floor over a dropped ceiling and away from the processing area. Pipes, conduits, and similar accoutrements can be installed in vertical runs through the ceiling into the upper floor. However, the junctures of these pipings need to be properly sealed and the seals maintained in good repair.

**Insulation**

Insulation materials available do not meet the requirements for walls and ceilings in a food facility and are easily punctured or torn. Thus, insulation, where used, should be installed so that it is not exposed and is sealed off from food processing and handling areas. The type of insulation material used must also be considered. The insulation material should be:

- nontoxic;
- odorless;
- unattractive to pests; and
- non-contaminating.

With these criteria in mind, asbestos insulation is avoided. Fiberglass batting insulation should also be avoided as it attracts insects and rodents, and the fibers may become airborne causing a contamination hazard. Acceptable materials may include: Styrofoam panels, foam glass, and urethane. For special applications requiring insulation of equipment (e.g., steam piping), it is recommended that manufacturers supply documentation of acceptance of the material in food applications.

**Floors**

Due to heavy day to day exposure to a variety of chemicals and food products, the floor in a food processing and handling facility is the most difficult surface to maintain. Floors should be smooth, impervious, non-absorbent, corrosion resistant, cleanable and in good repair. For safety considerations, floors should not be so smooth that they cause employees to slip and fall. In addition to being constructed and sealed adequately, the floor should be installed to provide adequate slope for drainage and prevention of pooled water.

Today, highly acceptable materials are available for constructing and surfacing of floors in a food processing and handling facility. The most recommended are sealed concrete, epoxy sealed concrete, quarry tile, and glazed tile. Each of these materials would provide an acceptable floor surface if properly installed and maintained in good repair. Once the integrity of any of these surfaces becomes compromised, they can harbor
microorganisms, especially in wet areas. Unsealed concrete floors should be avoided as they are highly porous and break down with continued exposure to chemicals. Once cracks, crevices, spalls, or other damage occurs, a concrete floor is especially vulnerable to harboring microorganisms. Quarry tile or glazed tile floors require additional maintenance as grout lines can erode causing a multitude of problems. As mentioned for walls and ceilings, metal and wood must be avoided as a floor construction material.

**Drains**

Floor drains are a major source of microbial contamination in a food processing facility. Thus, they require special attention. Floor drains should be:

- of adequate number and size;
- appropriately located;
- designed and installed so that they are cleanable; and
- maintained in good repair.

Circular, catch basket drains are most often recommended provided that they are appropriately sealed and grouted to the floor, and are maintained in good repair. Trench drains, although used in many operations, can have problems. A trench drain should be constructed and installed to provide adequate slope or grade ensuring there is no standing water in the trench. The grouting and sealing of trench drains at the floor junctures is also more difficult to maintain than the seals of circular drains.

**Interior Lighting**

Adequate lighting is important for all operations conducted in a food facility. This is especially true in cleaning and sanitizing and related operations. Recommended lighting levels vary between regulatory officials and other sources. A general suggested range of lighting recommendations has been presented in Table 1.

<table>
<thead>
<tr>
<th>Area</th>
<th>Light Intensity (Foot Candles)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw material receiving</td>
<td>20 - 30</td>
</tr>
<tr>
<td>Ingredient warehouse</td>
<td>20 - 30</td>
</tr>
<tr>
<td>Bulk ingredient storage</td>
<td>30 - 40</td>
</tr>
<tr>
<td>Processing departments</td>
<td>55 - 65</td>
</tr>
<tr>
<td>Product inspection</td>
<td>110 - 130</td>
</tr>
<tr>
<td>Packaging</td>
<td>70 - 80</td>
</tr>
<tr>
<td>Finished product warehouse</td>
<td>20 - 30</td>
</tr>
<tr>
<td>Maintenance areas</td>
<td>70 - 80</td>
</tr>
<tr>
<td>Area</td>
<td>Light Intensity (Foot Candles)</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Administrative offices</td>
<td>60 - 90</td>
</tr>
<tr>
<td>Cafeteria</td>
<td>40 - 50</td>
</tr>
<tr>
<td>Locker rooms/restrooms</td>
<td>30 - 50</td>
</tr>
</tbody>
</table>

Light fixtures should be of the type approved for food facilities, and should be equipped with break resistant lenses or shatterproof shielding. The fixtures should be designed to be moisture resistant and cleanable.

**Heating, Ventilation, and Air Conditioning (HVAC) Systems**

Heating, ventilation, and air conditioning (HVAC) systems function to maintain the temperature and humidity of a facility. Day to day sanitary operations are dependent upon a properly functioning system for prevention of condensation as well as overall employee comfort. In addition, it is desirable to create positive air pressure differentials in critical or sensitive food handling rooms (e.g., packaging rooms). Because of these demands, the facility should have properly sized units and an adequate distribution system to do the job. Because HVAC systems have proven to be a source of contamination with pathogenic microorganisms (especially *Listeria monocytogenes*), certain sanitary construction, design, and installation features need to be considered. Systems should be constructed, designed, installed, cleaned, and maintained so that they are not a source of contamination. For example, the air supply should be located to not draw air from nearby sources of contamination (e.g., chemicals, bird droppings); adequate filters should be installed (and changed frequently); and duct work should be located outside of the processing areas. Finally, air handling systems should be designed to be cleanable. HVAC systems available today, that can be adequately cleaned, should be considered in new construction or renovation. However, many existing systems are not designed and constructed with cleanability in mind. Care should be used in using corrosive chemicals in cleaning these older systems.

**Handwashing sinks**

Handwashing sinks, lavatories, or stations should be:

- conveniently located near food operations;
- of sufficient number based on the size and function of the operation;
- constructed and installed to meet plumbing codes including appropriate backflow prevention and no submerged inlets;
- installed with faucets of sanitary design (preferably foot or electric eye operated);
- supplied with hot (not steam) and cold water in order to provide an adequate flow of water at 85° - 100° F;
- provided with an adequate supply of soap, single service towels, and a covered waste receptacle; and
• maintained, cleaned, and kept in good repair.

Employee Facilities, Locker Rooms, and Restrooms

Employees need suitable facilities where they can safely store their clothes and other personal items. Maintenance and construction recommendations for walls, ceilings, and floors of locker rooms, restrooms, and related facilities should meet the same criteria as those for other areas of the facility. Lockers should be sealed to the wall and should have sloped, rather than flat, tops to prevent accumulation of dust and debris. Employee facilities should not open directly into processing or other critical areas. Most food regulations require a two-door separation between locker rooms or restrooms and food processing areas or food handling areas.

Freezers, Refrigerators, and Coolers

Permanent freezing and refrigeration rooms should meet the same sanitary construction and design criteria as other rooms in the food facility. With the exception of the refrigeration units and drain trays discussed below, an appropriately constructed and designed freezing or refrigeration room should present minimal sanitation problems. However, when modular type units are installed in a facility, they can be a source of dust and debris accumulation and contamination concerns. These units must be installed with sufficient space between the unit and the wall (approximately 18 inches) to allow accessibility for cleaning. Because the units or boxes are of flat-top design they tend to collect dust and debris, unless they are caulked and sealed to the ceiling. If they are free standing units, sufficient clearance should also be allowed above the unit to provide access for cleaning.

Refrigeration units, due to coils, fins, and other dust collection points, can also be a source of contamination. These units should be designed and installed for adequate cleaning. A major contamination problem area is the condenser draining system. Drains, trays, and pans should be installed to prevent overhead contamination of stored food products, and should be flushed and cleaned daily. Drain lines exiting refrigeration rooms or boxes should be installed to drain into a floor drain, with an appropriate air gap, and should not drain directly into critical food processing and handling areas.

Overall "Protection from Contamination" Features of Interior Construction

In addition to having sanitary walls, ceilings, and floors, a sanitary food processing and handling facility must also have designed-in (integrated) features to protect the food products from contamination. Facilities should be periodically inspected and evaluated for potential contamination of product due to the facilities themselves. Utility and water supply lines, and other accoutrements hung or attached to the wall or ceiling must be appropriately caulked and sealed to the wall or mounted in such a way to allow cleaning behind and around. For example, it is recommended that a minimum of 1 inch clearance be allowed for cleaning around and behind items hung on walls (Graham, 2004). Further,
electrical boxes and related equipment should be water proof and of acceptable sanitary design. Exposed threads should be minimized on hangers used for piping and other equipment or other attachments, as they accumulate dirt and dust. If threads are used, they should be of sanitary design to be cleanable, rather than the standard threaded rod from the hardware store. Wherever appropriate, shielding should be provided over product conveyances and areas where food products are exposed. However, such shielding should be constructed of appropriate, cleanable material. Rather than horizontal or flat, the shielding should be gabled or sloped at a minimum of a 20 degree angle to prevent ledges that can collect dust and dirt.

**Operational Flow and Facility Layout**

**Operational Flow-through Pattern**

Ideally, a facility should be designed to provide a flow pattern for food products (as well as personnel and equipment) to prevent potential contact of the finished product with raw materials. Flow should be in one direction and follow a logical sequence from raw material handling to finished product storage as shown in Figure 3.

![Figure 3](image.png)

**Physical Separation**

As much as is practicable, there should be a physical separation between raw and finished products and minimal entry into critical areas. Such physical separation should be accomplished by installation of walls and doorways with anti-back tracking features, and by adjusting air handling systems to provide positive pressure in finished product rooms. As the best physical separation can be undermined by human error or improper personnel flow, there should be an operational and philosophic separation between raw and finished product. This can be accomplished by barring employees working with raw materials from entering finished product rooms, this includes maintenance and janitorial staff. It is recommended that standard operating procedures be developed and implemented regarding product flow.

In addition to providing procedures for personnel and equipment within the facility, the movement of equipment in and out of the facility by maintenance crews should also be considered. Color-coding is often used, with different colors identifying different areas of the facility. Color-coding can be applied to clothing (e.g., uniforms, frocks), cleaning
supplies (e.g., brushes, brooms, pails), containers (e.g., pails, lugs), gaskets, forklifts, and any other equipment. Separation can also be accomplished by the installation of sanitizer systems (e.g., foot baths, spray systems) inside entrance doors to critical areas. It is imperative that these sanitizer systems be maintained in good repair and working order and that they are used. Visitors, suppliers, laboratory personnel, truck drivers, inspectors, management, and all other individuals should be made aware of operating procedures with regard to separation between raw and finished products. Self-inspections by quality assurance personnel, regulatory inspections, or tours should be done in a counter product traffic direction starting with finished product rooms and ending in raw material handling areas.
Pest Management Standards
For Food Plants

For definition purposes,
“Action Threshold”: means level of pest activity or pest damage that triggers a pest management response.
“Company”: means the pest management firm.
“Contact”: means the food plant contact person.
“Devices”: are any equipment used to monitor or control pests including, but not limited to, insect monitors, rodent bait stations, insect light traps, pheromone traps, and rodent management stations.
“Employee”: means pest management firm employee.
“Good Manufacturing Practices”: means the FDA’s Current Good Manufacturing Practices in the United States, or equivalent outside of the U.S.
“Pest management product”: means any lure, bait, monitoring product, pesticide, or any other formulated material used in performance of pest management activities.
“Plant”: means a food manufacturing facility including associated warehousing and does not include restaurants or other food service facilities.
“Rodent bait station”: means any station used for placement of solid rodenticide bait.
“Rodent management station”: means any station used for monitoring or managing rodents. These include mechanical traps, rodent bait stations (see above), and other placed equipment for rodent management.
“Technician”: means the pest management firm employee providing service.
Section 1
Personnel

1.1 Employee Identification

Reasoning
This section sets forth minimum standards for company employee identification so that the plant has a clear understanding of which personnel are from the pest management firm to ensure that plant food safety and security are maintained.

Standard
All employees entering grounds of a food plant shall display photo identification to include: Employee name, Employee identification number (if issued by the company), Company name, Company phone number, Employee photo, Date of issue. The identification shall be displayed at all times while the employee is on site unless personnel practices set by the plant prohibit such badges. In addition, plants may require other identification such as visitor badges and the employee must comply at all times with the visitor/contractor policies of the plant.

1.2 Uniforms
Reasoning
Uniforms are an important part of the plant safety and standards program. Criteria set are designed to comply with the majority of food plant requirements for uniforms.

Standard
All employees who perform service work in food plants shall wear uniforms meeting the plant’s current requirements and at least the following criteria:
- Slip resistant sole shoes (safety toe if required by plant)
- Socks
- Long pants
- Shirt with sleeves (short or long) with company logo or company name
- Uniform closures shall be in compliance with plant requirements.
- A clean set of clothing shall be used in plants if the previous account visited has exposed the clothing to contaminants. These contaminants include but are not limited to chemical, microbiological, or allergens such as peanut products. More stringent requirements may be in place for individual plants in addition to these standards and service personnel must comply with those standards.

1.3 Security and Criminal Background Checks

Reasoning
Security is a major concern at all food plants. This section is designed to ensure that personnel in food plants have had proper background checks and that they comply with plant rules.

Standard
Any newly hired employee, including management, entering a food plant shall have a criminal background check performed covering the previous five years prior to the date of hire. The checks shall be part of the records of the company and shall include all states or provinces in which the employee has lived and/or worked during the previous five years. Resulting action as a result of the check will be at the discretion of the company management. Some food plants may have specific requirements and companies must comply with these requirements in addition to the above. Reminder: Companies must comply with government regulations related to obtaining background checks.

Plants may also have policies regarding when an employee is permitted onsite and/or escorted.

Companies should understand and comply with all plant policies and provide a written procedure to employees with a copy in the plant as to:
- Whether advanced notice must be given prior to arrival onsite
- Parking and vehicle use
- Substitute employees (technicians taking the place of previous technicians may have to be
  - on a roster provided to the plant) Sign in policies
- Hours of operation when employees may have access
• Visitor badge policies
• Escort policies
• Restricted areas
• Access to locked or restricted areas via an assigned key, card, FOB, access code etc.

1.4 Plant Personnel Practices

Reasoning
It is imperative that all employees entering a food plant property understand and comply with the plant personnel practices. Besides being required by law, compliance is important as a part of food safety and also plant personnel morale.

Standard
All employees entering a food plant property must have reviewed and signed off on the standards of the plant in terms of personnel practices as outlined by the plant. If a special set of standards is in place for plant contractors, then the employee must comply with the standards. If any questions or conflicts arise, the employee must notify their supervisor and the plant contact person.

A copy of the signed document shall be maintained in the plant files.

1.5 Vehicles

Reasoning
Plants have very specific requirements for vehicles both in terms of operations and in terms of security. This section sets the minimum for vehicle standards.

Standard
All vehicles used for service must:
• Be clearly marked with company name
• Be properly licensed
• Have a current inspection if required by the state or province.
• Have adequate insurance coverage for bodily injury, property damage and any other coverage that may be required by the plant.
• Be parked in properly assigned area
• Contain materials and equipment secured when unattended to restrict access.
• Drivers: A five year motor vehicle background check must be completed for all new company employees who will drive on plant property.

All drivers must have viewed the NPMA Safe Driving Video or participate in an insurance industry approved program annually and the company must retain safe driving training records as required by the insurance company.

In addition, the vehicle must include at least the following equipment:
• First aid kit
• Spill control to cover all products on the vehicle
• Service Kit (carrying kit for small quantities of products and equipment)
• Change of clothing and/or coveralls
1.6 Safety

Background
Safety is a vital part of any pest management program. The pest management company and the food plant both must maintain safe working environments. Beyond just minimal regulatory requirements, policies must be in place to ensure a safe work environment.

Standard
Each company must have a documented safety training of all employees working in food plants. Safety training should include but is not limited to:

- Plant specific safety training
- The company and plant specific respiratory protection program
- Pesticide safety including the proper understanding of all labels of products to be used in the food plant, proper use, and disposal of products and containers
- Proper storage of products and equipment
- Emergency response procedures in case of spills

Plants should have an inspection aisle of at least 18 inches along walls. Commonly, this area is painted white or another light color in order to contrast with droppings or insects. Traps may be placed along these areas. Due to concerns about allergens, no peanut butter or nut based attractants may be used inside a plant unless approved by plant contact.

2.6 Rodent Program-Monitoring

Adjustments to the program based upon observations may be made at any time. Use of “temporary” program changes are acceptable. All traps, bait stations, and other devices must be opened and inspected. Record of service verification or bar code shall be on the inside of the station requiring the station to be opened. Observations must be recorded as outlined in the Recordkeeping section. A master map of all rodent control devices used on the property must be maintained and kept current. Rodents must be disposed of offsite according to plant and company policy. Rodents, droppings, and any urine deposits or residue must be handled using protective equipment per company policy.

2.7 Insect Program

Inspection
A thorough inspection shall be conducted of the exterior of the building including raw material receiving, receiving docks, shipping docks, load levelers, waste disposal, entrances, roof areas, exterior storage such as silos, doors and windows, and ventilation intakes to investigate signs of infestation or possible signs of infestation by insects. A thorough inspection of the accessible components of the plant shall be conducted not less than monthly. The areas to be inspected include but are not
limited to floor/wall junctures, drop ceilings, equipment, processing areas, warehousing materials and racking, offices, locker rooms, mezzanines, raw material handling and processing, returned goods areas, sample areas, windows, ventilation, shop areas, packaging storage and equipment, laboratory areas, and cafeterias.

In the course of the inspection, maintenance issues such as, but not limited to, holes in walls, pipe chases, bulk feed lines, spilled food items, or open doors/windows shall be noted.

Recommendations shall be made to the plant to reduce chances of future infestation.

A summary of infestation observations, potential infestations and recommendations for pest prevention shall be documented and presented to the plant’s pest management contact.

Action Thresholds and Corrective Action
Corrective action will be taken, when appropriate, based on inspection, monitoring data and trend analysis in accordance with thresholds developed by the company in partnership with the plant.

Stored Product Insects
Determination of the source of stored product pests must be completed prior to action.

Sometimes, a certain lot of raw materials can be isolated as the source. If pests have spread into the plant, management measures must be performed.

Pheromones and pheromone traps may be used as part of the monitoring and management processes.

Non-Stored Product Insects and Occasional Invaders
Determination of source and entry point, real or potential, is necessary in developing a control/management program. Commonly, mechanical alterations on the exterior will be necessary such as filtering incoming air, sealing cracks, repairing door gaskets or self closing doors, etc.

Pesticide/ Product Use
In the event it is necessary to apply a pesticide product to help manage insects the product shall be appropriately labeled for the intended use and site. These products may be residual, non-residual or non-regulated/exempt products.

An approved pest management product list should be developed by the company and approved by the authorized plant contact person.

Space treatment may be used to reduce adult populations. This may also include the use of
insect growth regulators (IGRs).
General applications may be used only if the use of the product will not contaminate the food product. After coordination with the plant contact fumigation may be considered as part of the management plan. These standards do not address fumigation specifically.
Insect bait stations may be used in areas not prone to heavy traffic or water accumulation.
Treatment of electrical panels and boxes must be done with extreme care per the label and liquids should not be used.
All pesticide products must be used according to label instructions.
Insect Light Traps and Other Flying Insect Traps
Insect light traps (ILTs) may be installed to monitor and manage certain flying insects and to be used as part of the decision making process for adjusting the program for certain insects (e.g. Indian meal moths, fruit flies, etc.). Placement must be according to manufacturer’s instructions and in compliance with any regulatory policies and guidelines. In absence of instructions, ILTs should be placed in such a manner that will maximize insect capture without: interfering with plant operations
• being visible from the exterior
• being likely to attract insects to open food
• Any ILT must be recorded on the site layout or map, and ILTs must have the same recordkeeping as other types of devices. Findings and seasonal requirements will dictate frequency of inspection as determined by the company. Insect traps must be monitored based upon the contract. Weekly monitoring is suggested for most cases, unless the traps are in an area or at a time of year when there is no activity (e.g. unheated warehouse or in cold winter climates).
2.12 Compliance with Plant Food Allergen Control Program

Background
Many consumers have acute reactions to food allergens. “Big Eight” allergens include: cow’s milk, eggs, peanuts, tree nuts, soybean products, wheat, fish, and crustacean shellfish. Consequently, food plants must declare if there is a possibility of any of these products entering the food either as an ingredient or an incidental additive. Plant policies and third party auditor standards may require formal food allergen control programs and these might affect pest management practices.

Standard
The pest management company must comply with any plant food allergen control program as it relates to pest management practices.

2.13 Quality Assurance
At least once per year, prior to the anniversary of the date on which the company began pest management services at the food plant, a supervisor, quality assurance staff person, or a manager from the pest management company shall review the entire program onsite. The QA audit shall include a review of the program, records, pest activity trends and frequency of
service, as well as the monthly inspections to make sure that all documentation is in order. In addition, labels and Safety Data Sheets must be reviewed to make sure that all products used have current information. Safety Data Sheets and labels of pest management products used at that facility must be filed either in hard copy or via electronic records. Results of the quality assurance audit must be filed in the plant, with a copy in the pest management company office.

2.14 Annual Training
At least once per year, the pest management company shall offer to conduct an educational program for plant personnel. Date, content, and list of those who attend must be kept in the plant pest management records. The following staff should be encouraged to participate:
Management
• Supervisory staff
• Security
• Mechanics
• Production lead staff
• Warehousing staff
• Quality Assurance staff
• Plant contact
• HACCP committee, if applicable
• Others determined by the plant management

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SECTION
While the plant ultimately makes the decision as to who may attend, the content
may include,
but is not limited to:
Review of the pest management program
•
Vulnerable areas
•
Practices which may reduce pest pressures
•
Review of audits and monthly reports
•
How to record a pest sighting
•
Review of FDA, state, provincial, local, and third party audits and inspections as
related to
•
pest management.
How plant personnel should interact with pest management tools and devices
•

2.14 Annual Review
A review of the entire pest management plan should be performed on an annual
basis and
adjustments made as necessary.
The annual review shall include, but is not limited to:
Thorough inspection of the exterior property
•
Thorough inspection of the interior of the plant
•
A summary of pest infestations and conditions conducive to infestation
•
An analysis of pest trend data

Results of the Quality Assurance audit

Section 3
Communications

3.1 Reporting
All records and documents may be retained electronically. All documents in the pest management filing system must be available to the plant within a reasonable time as determined by the plant. The plant has the option of requesting copies of all documents produced including service tickets for their files. The pest management company must keep a backup copy of all documents at the pest management company office. The pest management company shall not surrender any copies of materials to any official without the express written permission of the plant contact or their substitute. If there is a regulatory audit of the pest management such as the state department of agriculture or other pesticide enforcement agency, the pest management company may surrender documents to the agency if required. While paper backup information may be permitted, official documentation and reporting listed in these standards shall be retained in the following manner:

Reporting shall provide access to all service data

Record recovery shall be available on demand with the ability to be sorted by product used,

area, pest, date, time, and shift.

Trends shall be determined at the interval of service.

Data onsite may be gathered by handheld electronic devices or manually or a combination of
these methods
An analysis of pest trends should be used to modify the pest management
program if necessary.
All inspection reports such as, but not limited to the NPMA 38, may be available
online
Standard Section: Recordkeeping and Contracts—Title: Contracts—Standard
Number: 4.1
Prior to completing any work in a food plant, a signed contract must be in place
unless
specifically waived by the food plant and must include:
Name of Plant
•
Plant contact person
•
Frequency of visits
•
Description of services
•
Term of contract
•
Fee
•
Equipment storage and product storage specifications
•
Scope of emergency calls
•
Products which may be used
•
Service records to be issued to the plant
•
Requirement to notify plant of any new products used
•

SECTION 3: COMMUNICATION

SECTION 4
Recordkeeping & Contracts

4.1 Contracts
Prior to completing any work in a food plant, a signed contract must be in place unless specifically waived by the food plant and must include:
Name of Plant
• Plant contact person
• Frequency of visits
• Description of services
• Term of contract
• Fee
• Equipment storage and product storage specifications
• Scope of emergency calls
• Products which may be used
• Service records to be issued to the plant
• Requirement to notify plant of any new products used

4.2 Labels and Safety Data Sheets
A copy of all EPA, PMRA (Canadian Pest Management Regulatory Authority), or other country product labels and Safety Data Sheets for pest management products used at the plant shall be maintained in the plant by the pest management company. Only labels and Safety Data Sheets for products which may be used at the plant should be included in the “active” file. This may also be filed electronically or web-based depending on plant policy and government regulations. A label and Safety Data Sheets shall be added for any new products used.
4.3 Pest Sighting Log
Each pest management company shall provide a Pest Sighting Log to be maintained in a plant office which may be the pest management area. The log can include dates, times, locations, type of pest, action taken, and name of reporting employee. The log must be reviewed by the technician at each visit and data may be included in adjusting the pest management program as necessary. At the periodic training by the pest management company, the use of the log should be discussed.

4.4 Licenses and Certificates
Credentials to be maintained at the plant with the pest management records must include:
Copy of the certification or registration document, if issued in the plant jurisdiction, for each
• person who will perform pest management services in the plant
Copy of the pest management company license to operate issued by the state or provincial
• lead pesticide enforcement agency if issued by the state or province in the jurisdiction.
Copy of the insurance certificate
• Copy of proof of successful completion of verifiable food plant pest management training
• and exam for each technician servicing the plant.
(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following: (i) Using ingredients free of contamination. (ii) Employing adequate heat processes where applicable. (iii) Using adequate time and temperature controls. (iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them. (v) Cooling to an adequate temperature during manufacturing. (vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including: (i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing. (ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers. (iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter. (iv) Providing physical protection from contamination, particularly airborne contamination. (v) Using sanitary handling procedures.
(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices: (i) Monitoring the aw of food. (ii) Controlling the soluble solids-water ratio in finished food. (iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the aw of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices: (i) Monitoring the pH of raw materials, food in process, and finished food. (ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.


§ 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]

Subpart G—Defect Action Levels
§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.
(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or
the requirements in this part that food manufacturers, distributors, and holders shall observe
current good manufacturing practice. Evidence indicating that such a violation exists causes
the food to be adulterated within the meaning of the act, even though the
amounts of natural
or unavoidable defects are lower than the currently established defect action
levels. The
manufacturer, distributor, and holder of food shall at all times utilize quality
control operations
that reduce natural or unavoidable defects to the lowest level currently feasible.
(d) The mixing of a food containing defects above the current defect action level
with another
lot of food is not permitted and renders the final food adulterated within the
meaning of the act,
regardless of the defect level of the final food.
(e) A compilation of the current defect action levels for natural or unavoidable
defects in food
for human use that present no health hazard may be obtained upon request from the Center for
Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration,
5100 Paint Branch
Pkwy., College Park, MD 20740.
56035, Nov. 6, 2001]
The Do’s and Don’ts of Food Plant Personal Hygiene Practices

By Tammi Frederick

Good personal hygiene policies and practices are the foundation for successful food safety and quality assurance in all food manufacturing facilities. Plant personnel are among the most significant reservoirs and vectors of microorganisms, chemical residues and foreign materials in the food facility, and as such, can be a source of unwanted contamination to products. Comprehensive personal hygiene programs, coupled with a top-down philosophy supporting sound sanitary practices as part of the corporate structure, are key to implementing best practices for compliance with Good Manufacturing Practices (GMPs), Sanitation Standard Operating Procedures (SSOPs) and related sanitation and food safety audits. The top-down approach ensures that personal hygiene policies and procedures are implemented by all personnel—management, visitors, production, sanitation and maintenance staff—at each company and in each facility, reducing the risk of product contamination and the likelihood that such product will reach the consumer.

Addressing all the potential personal hygiene trouble spots can be challenging, however, because the routes, or vectors, of contamination are varied and complex. In any given food plant there is a wide range of activities and movement that can result in the transfer of microorganisms, chemical adulterants or foreign objects from plant personnel to the food product. The transfer of contaminants can occur through a direct route, such as bacteria transferred from the body, skin, mouth, hands or hair to the product, or indirectly via their personal equipment, such as clothing, footwear, utensils and other tools used in their daily tasks. Everyone in the food production environment must understand that anything that travels through or is mobile in the facility is a potential source of contamination and must be tracked and controlled. Certainly, people are the biggest “movers” in the plant and therefore a source of cross-contamination when moving from one processing area to another, followed by the tools and equipment they carry and use, which includes everything from sanitation foamer carts and hoses, to forklifts and pallet jacks, to pens and tape.

From a food safety and quality assurance view, improving our ability to identify and
control these vectors of contamination, however wide-ranging, is critical to our efforts to produce safe and wholesome foods for our customers. The good news is that many best practices in personal hygiene are well-established in the food industry. Staying on top of some of the more common personal hygiene practice “do’s and don’ts” is also a good idea, especially in preparation for an audit or inspection of your facility.

**Getting Personal with People**

There is little debate that people are a primary source of potential contamination in the plant, especially with regard to microorganisms and foreign materials. A good way to reduce the incidence of people-related contamination is to institute a system of designated and dedicated personnel: those who are non-product handlers and those who are product handlers. In this system, people who are designated as food handlers never, under any circumstance, pick up items from the floor or from other non-product contact surfaces. Designated non-product handlers are dedicated to tasks such as picking up items from the floor and other surfaces, and can handle squeegees, hoses, pallets and other production tools, but can never, under any circumstances, touch or handle food product. Providing employees with different colored hats or aprons to distinguish product handlers from non-product handlers makes this policy easier to implement and enforce than trying to track and monitor each individual to ensure that they go and wash their hands after they pick something up off the floor. Color-coded clothing makes it very obvious to all employees who is and isn’t allowed to touch product, and leaves no grey area for interpretation if one witnesses a designated product handler picking up something off the floor. It is simply a huge violation.

Three important areas of focus when setting personal hygiene policies to prevent contamination by people of food product are protective outer clothing, footwear and hand washing.

**Protective outer clothing.** Food processors must provide employees with the ability to create a barrier between themselves and the product. These items typically include company-provided coats/smocks, plastic aprons or plastic sleeves, hairnets and snoods, and gloves, when appropriate. Essentially, protective clothing provided by the company should never be worn outside of the plant premises, should always be worn in the plant production areas and should be regularly changed.

*DO provide appropriate clothing to prevent product contamination. Factory clothing should be hygienically designed to prevent foreign bodies from shedding directly (i.e., lint, buttons) or indirectly (i.e., outside pockets from which objects can fall out into product). Whenever possible, smocks should not have outside pockets. Many aprons, gloves and smocks used in food production are constructed and designed to prevent microbial cross-contamination of the product from the employee.*

*DO control the laundering of protective clothing to ensure the sanitary condition of the material. Laundering has to be controlled by the company in order to achieve a greater level of confidence that these items have been cleaned and sanitized adequately before being worn in an area where it may come into contact with your finished product.*
• DON’T allow jewelry in the production area, period. In the era of tongue rings and body piercings, it is good to have a completely restrictive policy to prevent foreign material inclusions from personnel to the line. In addition, a pre-shift check of the condition of clothing or footwear for frayed edges or loose items, such as buttons or snaps, can help control inadvertent foreign material contamination of product during the shift.

Footwear. Again, the goal is to have an effective barrier against microbial contamination from humans and/or equipment that travels through food-contact areas. Footwear can be a vehicle for the transfer of pathogens from production areas deemed as high risk to low-risk areas, a fact that requires either that footwear is dedicated exclusively to either low risk or high risk areas, or that these items are decontaminated between areas to prevent cross-contamination. Foamers are the most commonly used footwear decontamination method in the industry because they offer the advantage of sanitizing other vectors like pallet jacks, forklifts and carts at the same time. Foot dips/baths and bootwashers also are common.

• DON’T create a bacteria bath. In facilities or areas in which foot dips are utilized, it is essential that they are monitored to make sure that a “bacteria bath” has not been created. Foot dips need to be monitored not only for adequate concentration but also for appropriate volume of sanitizing solution. Often, by the end of the first break in a given shift, there is so much organic material built up in the container that there is no longer any sanitizer effectiveness. In fact, the foot dip is a pool of bacteria that everyone walks through. Thus, routine monitoring of the volume and concentration and regularly changing the dip solution is best.

• DO require that nonporous footwear is worn, especially in the production areas. Footwear should be constructed of material that is cleanable. It should not be made of leather or cloth that will get and stay wet, which is uncomfortable for the wearer and may result in the employee avoiding the necessary foamers and foot dips so they don’t have to be wet all day.

• DO require that footwear remain and be cleaned at the facility. Ideally, you should have a policy that employees leave their footwear at the facility in order to mitigate contaminants carried into the plant from home. Also, it is important to provide appropriate cleaning resources such as cleaners and brushes for all employees at end of the production shift, as well as appropriate storage conditions.

Hand hygiene. The bottom line is that all personnel in the food manufacturing environment must regularly and adequately wash their hands to prevent microbial contamination of foods and food-contact surfaces. It needs to be stressed that this applies to everyone that enters the production facility. At bare minimum, everyone prior to going to work or coming into a production environment should have to stop and wash with soap and water, and when appropriate sanitize, their hands. Hand washing policies should require employees to wash after any type of activity that could contaminate the hands
with pathogens, including using the restroom, blowing the nose or touching body parts, handling raw food, waste or nonfood-contact surfaces such as light switches or pipes, and working a shift. Employees also should wash before entering food handling areas, changing clothing and putting on gloves.

- **DO** provide appropriate hand washing resources for the number and placement of your employees. If 200 employees are going back to the line at the same time after break, there has to be enough hand washing stations to accommodate that flux of employees. If hand washing stations are not placed in convenient locations, employees may skip washing. In some operations and in some production areas, employees need access to hand washing stations more frequently than just at start-up and at break, so the key is keeping the units accessible and well-stocked so that employees will use them. If personnel have to travel to find a sink, it isn’t going to happen.

- **DO** institute some type of hand washing verification method. Random use of hand swabs or plates are very effective to verify hand cleanliness. It doesn’t require a large number of employees to get the word out that random checks are going to be conducted, and pulling random personnel and doing a hand swab helps keep everybody honest. Training is an important part of instilling good hand washing practices. Hand swab and plate verification are effective training tools because people often are amazed when they see what is still growing on their hands after a rudimentary wash.

**Getting Personal: Equipment**

Plant personnel use a variety of tools and equipment throughout the production environment that also should be addressed in the company’s personal hygiene policies. These include tools and equipment used in production, maintenance and sanitation activities.

**Production Tools and Equipment.** From a GMP standpoint, we have to make sure that hand tools and utensils such as knives and scissors that are used by personnel in food production activities do not become a source of product contamination. Examples include microbiological cross-contamination (i.e., the employee uses a knife in a raw materials area but before cleaning and sanitizing the utensil, sets the knife on a surface on the finished product side); chemical residue contamination (i.e., the employee uses scissors to open a plastic bag of allergen-containing ingredient and then uses the same scissors to open a container of non-allergen-containing ingredient); and foreign material contamination (i.e., the employee’s thermometer falls out of ill-designed smock pocket into product). Again, anything that moves within the plant has to be controlled, including tool carts, scale carts, ladders, pallet jacks, forklifts, foamer carts, cleaning chemical and sanitizer containers, and hoses.

- **DO** ensure that employees have the appropriate resources to do their job—and that the company maintains control of those resources. The ideal situation is that all tools are company-owned, are all turned in at the end of every production shift and then are distributed back to employees clean and inspected prior to resuming their work shift. You do not want 2,000 employees bringing tools from home to accomplish their jobs and
thereby raise the possibility of outside contaminants entering the plant.

• **DO** make sure that production tools are cleanable and maintained in good condition. For example, scratches or cracks in the handle of a food-contact knife creates a great niche for microbial growth and contamination. Eventually, the microorganisms are going to slough out onto your product. Tools should be constructed from materials that are rugged and as “microbe” free as possible. It is a good idea to put one person in charge of making sure that tools are well-maintained so that they can be replaced when they are worn or are in poor condition. A system should be in place for how tools are cleaned, at what frequency, and how they are stored and where. This is more easily accomplished if the tools are owned by the company and not by the employees.

• **DO** control the number of tools and supplies that are taken out to production areas. This is a good idea for everything from ink pens and tape rolls, to sample bags, safety goggles and thermometers. For example, it is recommended that employees use one-piece ink pens made of metal, rather than plastic cap-and-pen types, both to reduce the chance that a pen cap falls into product and to ensure that the metal detector will let us know that there is a problem if the entire pen falls in. If we can control and minimize the amount of supplies and the number of people who are taking those types of supplies into the production areas, we are better able to achieve accountability if a tool or supply item gets dropped or lost and can put corrective action wheels in motion quickly.

**Maintenance tools and equipment.** In general, maintenance staff is one of the most critical groups to the success of overall control in any GMP or personal hygiene plan. These personnel are highly mobile within the plant, moving from clean to dirty and/or raw to ready-to-eat areas of the plant as maintenance tasks dictate. Therefore, segregation of maintenance personnel and their tools and equipment is recommended to prevent contamination. Ideally, mechanics are dedicated by department, their tools and equipment are dedicated by department, and they have a cleaner and sanitizer available to them for use prior to working on any food-contact surface.

• **DO** provide good cleaning and sanitizing resources to maintenance personnel. Cleaning and sanitizing of tools is critical. The biggest challenge is that, nine times out of 10, maintenance personnel own their own tools and do not want to dip those tools in quaternary ammonia or chlorine for fear that these treatments will corrode them. Try to find cleaners and sanitizers that are less harsh on these tools but that still provide an adequate barrier and cleaning mechanism.

• **DO** ensure that maintenance personnel are knowledgeable about sanitation and personal hygiene practices. Look at the maintenance crew’s practices and procedures during preoperational activities, from what outer garment they wear to the sanitary condition of their tools, as well as equipment tear-down and set-up activities following third shift. We must ensure all personnel are taking the appropriate precautions so when handling the cleaned and sanitized equipment, we are not being a source of contamination to that area and/or equipment.
Maintenance also should be held accountable for equipment parts and tools following any work they perform in production areas, primarily from a foreign material prevention standpoint.

**Sanitation tools and equipment.** The company must give its core group of sanitarians the resources to do their job properly. This means ensuring that their equipment is being maintained in a condition that can be cleaned and in sanitary condition. This includes rain suits, hoses, brushes and foamer carts, for example, all of which can be vectors for microbial contamination. Typical plant flows start on the raw side and then move to the ready-to-eat side. Sanitarians follow that flow, and as such, any of that critical sanitation equipment should be designated and dedicated by side or department to avoid potential cross-contamination.

- **DO** designate or dedicate sanitation personnel, tools and equipment. Color-coding of sanitation tools is a tremendous tool because it works in all languages and makes these tools easily distinguishable from other production tools for better accountability. Sanitation tools and equipment should be designated and dedicated by three categories: food contact, non-food contact and drain. In other words, the facility should have a minimum of three different types of sanitation activity brushes so designated and dedicated to each of the three described functions for each area of the facility.

- **DON’T** allow food-contact surface equipment to be placed on the floor during sanitation disassembly/reassembly operations. During disassembly and prior to reassembly, many plants will place equipment parts on the floor, essentially “storing them until they are needed for reassembly. Even if a sanitizer spray is used at some point during the equipment cleaning and sanitizing process and before reassembly, food-contact surface equipment that makes contact with the floor is very risky. Facilities should provide sanitarians and maintenance staff with dedicated racks or carts on which to store parts as equipment is being disassembled, cleaned and sanitized, and readied for reassembly prior to the start of production.

- **DO** provide a control plan for cleaning and storage of sanitation department rain suits, footwear and tools. Again, we have to give our sanitarians the resources for proper cleaning and storage of their equipment so that they can be maintained, cleaned and stored in a sanitary environment.

**Training for Success**
Training is essential to educate employees and reinforce good personal hygiene practices. There are many training aids available to food processors in the form of on-line or print manuals, posters and signage, and videos for use in new hire orientations and employee refresher courses. Also, many food companies today are using digital cameras to take “do’s and don’ts” pictures in their facilities and incorporating these images into multimedia presentations and training manuals. This is a very effective and inexpensive training tool that captures visually the actual environment in which employees work, creating high recognition and retention of what constitutes “good” versus “bad” practices. Regardless of what training tools or formats you opt to use, it is essential that the top-
down approach apply to personal hygiene education activities—and that these efforts are ongoing—in order to ensure a high level of contamination prevention and control in the food processing environment.

• **DO** plan an immediate refresher on personal hygiene policies and practices following new hire orientation. When new hires attend their first orientation, they are typically bombarded with a lot of important information in a relatively short period of time. These new employees might be introduced to a slew of important company policies and protocols ranging from Occupational Safety and Health Agency (OSHA) requirements, to insurance and benefits information, to food safety and personal hygiene rules, all within a six-hour orientation and their total comprehension is likely not great. Providing a follow-up refresher session on personal hygiene policies two weeks after the orientation—even just 30 or 40 minutes to refresh and reiterate policies and protocols on hand washing, outer clothing, sources of cross-contamination, etc.—helps raise employee comprehension. At this point, employees have been in the plant for two weeks and have some experience to better understand how these practices have an impact on food safety.

• **DO** incorporate personal hygiene practices as a topic of discussion in other venues. For example, most facilities that comply with OSHA requirements conduct monthly safety meetings for all employees. Using five or 10 minutes of that meeting to cover a hot button GMP or personal hygiene topic is very effective in keeping everyone focused and aware. Similarly, an annual refresher that covers the company’s entire policy and protocols for product protection is a good idea.

• **DO** employ visual aids to create continual employee awareness of personal hygiene best practices. The best way to accomplish this is to place signs on bulletin boards in hallways, break rooms and other high-traffic areas that reiterate personal hygiene messages such as showing the sequence steps of good hand washing procedures or images that show how easily jewelry, tape and pens can get into the finished product. Posters that feature drawings, simple “yes/no” symbols and pictures help to overcome language barriers.

Ultimately, all employees want to be part of the food safety team; they want to do the right thing. If we give them the resources to do the job properly in terms of personal hygiene practices and sanitation best practices, they will practice what is preached and potential sources of contamination will be significantly reduced.

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Dairy Establishment Inspection Manual – Chapter 10 Prerequisite Programs
1.10.01 - Premises Program

Building and surroundings are designed, constructed and maintained in a manner to prevent conditions which may result in contamination of food.

This documented program as well as its effective implementation will help control operational conditions within an establishment, allowing for environmental conditions that are favourable to the production of safe food. It serves as a prerequisite program or universal-type Critical Control Point (CCP) for a Hazard Analysis Critical Control Point (HACCP) based program.

1.10.01.01 General

Dairy establishments and importers must have a documented program in place to monitor and control all elements in this section, and maintain the appropriate records.

The premises include all elements in the building and building surroundings: building design and construction, product flow, sanitary facilities, water quality, drainage, the outside property, roadways and waste disposal.

Adherence to the criteria is verified by examining the establishment's written program that outlines the procedures that will be undertaken to ensure satisfactory conditions are maintained. The program must specify:

- areas to be inspected (what is done),
- tasks to be performed (how it is done),
- person responsible (who does it),
- inspection frequencies (how often or when it is done),
- records to be kept,
- parameters of acceptability/unacceptability (tolerances),
- results of monitoring,
- verification procedures (both on-site and record review) and
- action to be taken for deviant situations.

The monitoring and verification procedures clearly define the preventative measures taken to prevent the re-occurrence of deviations. The person responsible for verifying the program must be different from the person performing the task. This program must also be updated as required when changes occur.
The actual monitoring of the adequacy of this program will be done by inspecting and assessing tasks 1.10.01.02 to 1.10.01.11.

1.10.01.02 Plant Blueprints and Process Flow

Up-to-date blueprints are a requirement for the registration and licensing of a dairy establishment. The operator must notify the Canadian Food Inspection Agency (CFIA) and responsible provincial authority of any proposed major modification to the registered establishment and submit detailed plans and specifications of the modification. Major modifications that would require the submission of plans and specifications include changes to the boundaries of the registered premises, building additions, changes to the product flow and/or employee traffic flow in the establishment, changes to the air flow, changes to the critical process equipment, changes to the activities and/or products being produced in the establishment.

Blueprints and/or process flow diagrams provide a documentation of the structures in a plant as well as product flow. Refer to Chapter 3.0 Registration (Section 3.5) for list of blueprints required. Blueprints or plant schematics should cover:

1. Equipment types and location,
2. Product piping (raw and finished), Clean In Place (CIP), water and other lines that may affect the safety of the product, an up-to-date schematic of floor drains and traps. If the original schematics are not available, new schematics must be created; and
3. Product flow, i.e. raw materials, packaging, finished product, raw cheese production versus pasteurized cheese production, etc.

Cross connections and cross contamination have been factors in the outbreak of milkborne illnesses in the past. Adequate segregation of incompatible products and activities must be provided by physical means (e.g. separate areas/rooms) or other effective means where cross contamination may result. Examples of incompatible products and activities would include raw milk/pasteurized milk products, raw milk cheese production/pasteurized cheese production. If an establishment produces both pasteurized products and unpasteurized products such as heat treated or raw milk cheeses, pasteurized products must be processed first followed by the raw product or these could be processed on different days. It is also critical that the establishment is designed to avoid contamination between raw product and any product undergoing or having completed maturation or ripening.

All new registrations must have separate rooms for incompatible products. Existing registered establishments must make every effort to separate incompatible products. If a plant is undergoing renovations in the facility then segregation by physical means should also be considered at this time. The type of product being produced would also have to be considered, for example, open cheese vats versus fluid milk plants where product is contained mostly within pipelines. Measures to control cross-contamination risks may include personnel practices (changing clothes, use of foot baths), operational segregation
and/or making construction modifications to the plant, with the corrective action dependent upon the type of products and processing equipment used in the plant.

Buildings and facilities must be designed to facilitate hygienic operations by means of a regulated flow in the process from the arrival of the raw material at the premises to the finished product. Living quarters/areas where animals are kept must be separated (complete segregation/separation with no common hallway or entrance way) and not open directly into food handling, processing and packaging areas.

Plant management must ensure that equipment and/or pipelines are not installed in a manner that will jeopardize the integrity of the processing or CIP systems, resulting in cross-connections or processing problems. Plant management must thoroughly review and approve all proposed installations. Minor changes such as pumps or pipelines must also be reviewed and approved. Colour coding of the pipelines on the schematic and use of the envelope method may help to identify cross-connections.

A cross-connection is a direct connection allowing one material to contaminate another. There needs to be a complete segregation of incompatible products such as raw materials and pasteurized or sterilized food products, cleaning products and food products and waste materials or utility materials and food products.

Segregation of incompatible products must be accomplished by the use of separate pipelines and vessels and establishing effective physical breaks at connection points by at least one of the following arrangements: physical disconnecting of pipelines, double block and bleed valve arrangements, double seat valves, aseptic barriers, or other equally effective systems. The installation of segregating valves does not constitute a physical break and is not acceptable, except that a properly designed block and bleed valve arrangement or properly designed aseptic barrier may be used to separate cleaning solutions from food products during CIP or mini-washes.

Plant management and the inspector must follow-up on areas where there appears to be a potential cross-connection. Even if the plant does not have a schematic piping diagram for the plant, an assessment for cross-connections must be made.

Schematics for processing systems will be evaluated under the appropriate task, e.g. for High temperature Short Time (HTST), 1.11.01, Aseptic Packaging and Processing System (APPS), 1.14.01 and Higher Heat Shorter Time/ Extended Shelf Life (HHST/ESL), 1.17.01.

1.10.01.03 Building Exterior

The building exterior is designed, constructed and maintained to prevent entry of contaminants and pests. Prevention of pest entry and harbourages is an important factor for the exterior structure. The building must not be built in close proximity to any environmental contaminants and industrial activities that are likely to contaminate dairy
products within the establishment. Roadways must be maintained to minimize environmental hazards. The surrounding property must be adequately drained.

When evaluating the roof and exterior structure, the elements within this task may contribute to contamination of the plant environment in 3 ways:

1. provide entry points for pests,
2. contribute to air borne contamination,
3. permit leakage of water into plant.

Airborne contamination and leakage of water are the two most important factors with regards to the inspection of the establishment roof. Flat roofs are permissible; however, there must be no accumulation of water. For powder plants, if the air intake supply originates on the roof, and the dryer exhaust stack exits on the roof, powder build-up must be minimized; the roof must be washable.

An establishment with driveway, parking lots and surroundings that are clean and well maintained can give a first impression of good sanitation. When evaluating this task, consider the potential for contamination of the plant interior from:

1. Dust and soil migrating to the plant interior.
2. Pests gaining entry to the plant; surrounding trees and shrubs provide food and harbourage for pests.
3. Storage of equipment, supplies, etc.

**1.10.01.04 Building Interior**

This task covers all floors, walls, ceilings, stairs and elevators, utility lines and electrical boxes in the establishment. As well, all windows, doors and openings (plastic curtains, hoseport, can inlet and outlet), loading facilities, lighting and ventilation are included.

**The building interior is assessed separately for every room in the establishment (exception is item (D) Loading Facilities which is only assessed once).** For example, the floors, walls, ceilings, lighting, ventilation, drainage will be rated together for each room in the establishment.

The interior of the plant must be designed to minimize contamination of food, to facilitate sanitary operation and to provide for easy and effective cleaning. To achieve these objectives, attention must be paid to the structural design of the establishment. Facilities must be adequate for maximum production volume.

The interior structures are unlikely to have direct contact with the food produced in the plant. However, accumulations of dust and dirt and condensation may become sources of contamination. It is necessary then to design, construct, finish and maintain these structures in a manner that prevents such conditions. Floors, walls and ceilings are to be constructed of materials that are suitable for the production conditions in the area and are
listed in the Reference Listing of Accepted Construction Materials, Packaging Materials, and Non-Food Chemical Products published by CFIA or the manufacturer has a letter of no objection from Health Canada and will not result in the contamination of the environment or food. The reference listing can be consulted for further information.

Older establishments with floors, walls and ceilings which are well maintained and meet the regulatory requirement of a hard finish that is suitable for cleaning, smooth and impervious are not required to renovate or upgrade construction materials to those listed in the Reference Listing of Accepted Constructed Materials, Packaging Materials and Non-Food Chemical Products. As renovations and repairs to the facility are made it is expected that all new construction materials and coatings will be on the list.

Interior structures that do not meet the design criteria outlined on the facing page may be assessed as satisfactory provided that management has an effective program to monitor and clean them. For example ceilings with exposed steel joints and H-beams are not satisfactory in areas where the product is exposed to the atmosphere, except if a program is in place that affirms their good condition through regular cleaning, dusting and inspecting. If no program is in place then modifications or renovations may be required. Another exception to the design criteria outlined on the facing page would be for dry storage areas where less stringent requirements would be acceptable. Existing walls in dry storage areas which exhibit signs of deterioration due to moisture indicate that the construction materials may not be acceptable for that area, and/or ventilation may be inadequate. In these cases even if there is no contamination risk, the materials must be replaced with an approved material that is smooth, hard, and impervious to moisture in order to better facilitate cleaning and withstand working conditions.

A) Floors in processing and receiving areas must be sufficiently sloped to drain to trapped outlets (i.e. ¼ inch per foot or 2%) to enable rapid drainage of liquids. Pooling of liquids must be avoided because they provide a good medium for microbiological growth.

B) Utility lines include all lines for water, steam, electricity, coolants, air and vacuum. The contamination potential of utility lines must be carefully assessed. Colour coding of these lines is recommended to aid in their identification.

C) Where there is a likelihood of breakage of glass windows that could result in the contamination of food, the windows must be constructed of alternative materials or be adequately protected. Where applicable, doors are kept closed and are well sealed to minimize contamination risks (e.g. receiving rooms, boiler rooms, etc.).

D) In the evaluation of the loading area, 2 aspects are important: product integrity and pest control. It is important that the products be protected from exposure to extreme temperature that would have an adverse effect on product integrity. Products can be protected by the use of air curtains, strips of plastic or similar set-ups.
E) The lighting in an establishment must be bright enough for safe food handling and thorough cleaning. Lighting must be appropriate such that the intended production or inspection activity can be effectively conducted; lighting should not alter the food colour. Inspection areas are defined as any point where the food product or container is visually inspected, e.g. Empty container evaluation, product sorting and grading, product evaluation areas in the lab. An establishment must have adequate supplementary lighting (e.g. flashlights) for the inspection of the interiors of bulk tankers or storage tanks. Bulbs and fixtures must be protected to prevent contamination should breakage occur in areas where dairy products and incoming materials are located. All bulbs and fixtures must be clean. Light intensity is to be measured with a light meter at a distance of 75 cm from the floor.

F) This task will also assess if there is a need for ventilation and if the ventilation is adequate. Ventilation assessed in this sub-item is for individual ventilation and heating units within a specific room. The heating, ventilation and air conditioning (HVAC) system will be evaluated under task 1.10.01.10.

The air quality within the room must be examined. Three conditions may apply:

1. The room may receive air from a central HVAC system,
2. The room may have its own independent HVAC system,
3. The ambient air may be the air supply for the room.

In situations (i) & (ii), the installation of an HVAC system or exhaust fans may be required if inferior air quality is evident or there is exposed product. Some rooms require specialized treatment of air. In rooms used for starter manufacture, it may be necessary to maintain the room under positive pressure to eliminate the possibility of airborne contamination.

Ventilation systems are designed and constructed so that air does not flow from contaminated areas to clean areas. Adequate ventilation must be provided to prevent unacceptable accumulations of steam, condensation or dust and to remove contaminated air. Inadequate ventilation may lead to the presence of odours, condensation or mould growth. Direct air movement onto product, product contact surfaces or filling and packaging areas must be avoided (airborne contamination has been suspected as a vehicle allowing pathogens to enter the product).

G) Drains must be trapped and be of adequate size, number and location to prevent the pooling of milk, water or other processing wastes and not pose a contamination risk to dairy products.

Trapped floor drains are essential to prevent possible off odours and contamination of plant air. Drains must be individually trapped; central trapping systems without individual traps are unacceptable because contamination and odours could originate from sewer pipes located between untrapped drains. Bell type traps which are well maintained
and in good condition are acceptable. Other acceptable types of traps include U or P types. All new drain construction must have U or P type traps.

Because of the potential to harbour microorganisms, floor drains should be located so that they are readily accessible for cleaning, sanitizing, and inspection. Ideally, floor drains should not be located under or near filling and packaging equipment.

Floors and drains should be constructed and maintained to ensure proper drainage. Brushes used for cleaning floor drains must not be used for any other purpose. Floor drains must be frequently cleaned and periodically flushed with a sanitizing solution. Floor drain covers and baskets should be cleaned and sanitized after each production run. Under no circumstances should high pressure hoses be used to clean drains.

Establishments must be designed and constructed so that there is no cross-connection between the sewage system and any other waste effluent system in the establishment. Effluent or sewage lines must not pass directly over or through production areas unless they do not pose a contamination risk (e.g. properly protected).

In the event that there are cross connections between plant waste and human waste, within the facility, this task must be scored as non-satisfactory. Establishments must have an action plan in place to mitigate the risk of contamination of the product if a problem with the drainage system occurs. The action plan must also include the provision that if an actual problem does occur, that production will not re-start until the drainage system is fixed. Establishments are to be reminded that meeting regulatory requirements is a condition of registration. Establishments operating with drainage problems can be denied registration renewal. It is expected that all new registrations meet the regulatory requirements prior to registration.

The above statements also apply to establishments seeking Food Safety Enhancement Program - Hazard Analysis Critical Control Point (FSEP-HACPP) recognition. Requirements for FSEP-HACPP recognition should be no stricter than what we require in non-FSEP-HACPP establishments. Establishments can be FSEP-HACPP recognized as long as acceptable short and long term action plans are in place.

1.10.01.05 Waste Disposal

Other agencies (e.g. environmental agencies) usually have jurisdiction over sewage disposal. Our concern is that the dairy products are not exposed to contamination risks from the sewage disposal methods.

A) Sewage must be disposed of in a sanitary manner. It is imperative that it not become a source of contamination to the plant environment. Of particular importance is the prevention of odours and pests. For example, open sewage near the plant must not be allowed.
B) Garbage disposal evaluates the handling of wastes from within the plant during operations and the waste collection facilities outside the plant.

It is important that waste be properly disposed of to prevent it from becoming:

1. an attraction to pests, and
2. a contribution to airborne bacterial contamination.

Within the plant there must be a sufficient number of garbage containers so that they are accessible to all employees. Plastic bags are permissible but if contamination is a great risk then covered containers are required. These containers must be clearly identified, leak proof, emptied regularly, and cleaned and sanitized prior to use.

If there is a garbage storage room in the plant it must be emptied daily. If odours are a problem then a ventilation system must be installed. The surface of the walls and floors must be cleanable. To facilitate cleaning, the room should be located near a spray hose and also have a nearby drain.

Waste disposal facilities that are located outside of the plant must not attract pests. They must have covers and be kept closed and in good condition. If compactors and bulk garbage units are used, they should be located on a concrete, curbed and drained ramp to facilitate the clean-up of spills. Washing facilities must be nearby.

Combustible wastes should not be burned in the plant vicinity in order to avoid airborne contamination by ash and odours.

C) Whey, if used as a food, can be further processed into products such as lactose, whey powder, whey protein concentrate, etc. and the handling of it as a food will be evaluated under the appropriate processing equipment. This task covers whey when considered as a waste product. Disposal should be by an approved method and must not pollute the environment nor implicate on the sanitary conditions within and outside the establishment.

1.10.01.06 Sanitary Facilities

Careful and frequent hand washing is required in food handling situations to reduce contamination. If a hand washing facility is difficult to find or operate it will not be used. Hand washing facilities in production areas must be of the remote-control type (foot, knee activated or timed). The location, number and the condition of the hand washing facilities is extremely important to the maintenance of good hygienic practices. Evaluations of adequate number and accessibility of handwash stations will be made by the inspector observing the work habits if the employees. These facilities must be provided with liquid or other type of soap dispensers, paper towels in suitable dispensers, and properly constructed and easily maintained receptacles for used towels. In areas where the product is handled directly, hand washing and sanitizing facilities must be
provided in a convenient location with trapped waste pipes to drains. It is not acceptable to use equipment and sanitizing facilities as hand dip stations.

Portable facilities and facilities with drainage piping not connected to a drain are not acceptable.

Washrooms must have hot and cold potable running water, soap dispensers, soap, sanitary hand drying equipment or supplies and a cleanable waste receptacle. Washrooms, lunchrooms and change rooms must be provided with appropriate floor drainage, good ventilation and be well maintained in a manner to prevent contamination. Specific attention is required to ensure that pest harbourage and dirt/dust accumulations do not occur. Double doors must separate employee facilities from the processing rooms; these doors are to be self-closing.

1.10.01.07 Essential Signs

Essential signs are required to enforce management policies. No smoking and unauthorized personnel signs are to be posted at outside and inside entrances to the plant and all receiving, processing and storage areas. Hand washing signs are to be posted in washrooms and in all product handling areas. Hazardous material signs are required in areas where cleaners, pesticides, etc. are kept.

The adherence to these management policies is assessed under task 1.10.04.02 - Flow and Practices and task 1.10.04.03 - Hygiene & Health.

1.10.01.08 Non-Processing Areas

This task includes equipment cleaning and sanitizing facilities (e.g. Clean Out of Place - COP) as well as boiler and compressor rooms, retail operations, mechanical shops, etc.

Because there is no exposed product in these areas it is not essential to meet the same sanitary requirements as the food processing areas of the plant. The location of the non-processing area must not pose a risk of contamination to food processing and handling areas. Proper maintenance is required to ensure a sanitary environment.

1.10.01.09 Water/Steam Quality & Supply

This task assesses the quality of the water and steam emanating from the plant's lines and hoses for use in various processing applications. There must be a safe, sanitary and adequate supply of water for use in a dairy establishment at all times. The water supply source must meet the requirements of Health Canada's Guidelines for Canadian Drinking Water Quality. A summary of Guidelines for Drinking Water Quality in Canada can be found on Health Canada's website. These guidelines cover microbiological, chemical (e.g. agricultural, heavy metals), physical and radiological contaminants.
The document titled, Canadian Guidelines for Food Processing during Adverse Water Events is also available on Health Canada's website. These guidelines pertain to the safe use of water in the processing of foods during adverse water events. The document is a good reference to assist the industry in minimizing economic impacts of adverse water events.

Typical contaminants that industry should be fully aware of include:

- **Bacterial pathogens** - Salmonella, Shigella, Campylobacter, Yersinia, Aeromonas and various strains of *Escherichia coli* (*E. coli*).
- **Viral pathogens** - Norwalk virus, hepatitis virus and other human enteric viruses.
- **Protozoan parasites** - *Entamoeba histolytica*, *Giardia lamblia*, *Cryptosporidium parvum* and *Cyclospora*.
- **Chemical contaminants that could result from environmental contamination or from a chemical spill, incorrect use of pesticides or cross contamination of the water supply with sewage or industrial waste.**
- **Cyanobacteria** or blue-green algae or pond scum which form in shallow, warm, slow-moving or still water that produce and release cyanobacterial toxins.

**A) General**

i. **Documented Program:**

Dairy establishments must have a complete written and fully documented program in place to ensure they are continuously using safe/potable water in the preparation and processing of food. It must monitor for microbiological, chemical (e.g. agricultural) and physical (e.g. heavy metals) contaminants. This program covers all aspects related to water (e.g. water source, in-plant water, reuse water, steam) used in the establishment.

ii. **Boil Water Advisory or Water Safety Alert/Drinking Water Avoidance Advisories:**

A boil water advisory or a water safety alert may be issued by the local public health unit or other responsible authority, as a result of unacceptable microbiological quality, significant deterioration in the microbiological quality of the source water, significant increase in turbidity (cloudiness) of the source water, chemical contamination, inadequate filtration and/or disinfection during treatment, re-contamination during distribution or as a precautionary measure when there is a concern that microbiological contamination may exist.

Drinking water avoidance advisories may be issued when there is concern about water safety that is not related to microbiological contamination. Examples may include chemical spill into a water source, the inability of existing treatment processes to treat a particular contaminant, cross connection or back flow of a contaminant into the distribution system. Drinking water avoidance advisories are issued when contaminants (e.g. nitrate, copper, cyanobacterial toxins, ethylene glycol) are present at levels
considered sufficient to cause acute health effects. These are issued only when there is convincing evidence of a significant public health risk.

Dairy establishments must have an action plan in the event of a boil water advisory/water safety alert/drinking water avoidance advisories. The action plan may include, but is not limited to disinfection, pasteurization of plant water, alternate water source, plant closure. Plant management must also include in the action plan an investigation into the safety of the product produced prior to the advisory.

iii. Communication Strategy:

It is recommended that dairy establishments, where possible, establish a communication strategy with the appropriate municipal, provincial or territorial water authorities for the timely exchange of information in the event of a boil water/water safety alert. It is recognized that there are differences in how this information is communicated, depending on the jurisdiction in which an establishment is located and as such will affect the degree to which an establishment can develop this strategy. Nevertheless it is the responsibility of the plant management to ensure they are continuously using safe/potable water.

B) Water Testing

1) Microbiological Testing:

The microbiological quality of water is determined by testing for the presence of indicator bacteria, such as coliform bacteria. Water must meet Provincial requirements, if these differ and are more stringent than Health Canada's Guidelines for Canadian Drinking Water Quality amended December 2010.

A 100 mL water sample is required for each test, and acceptable test methodology must be used. In Canada three methods are currently used to detect coliform organisms in water (presence-absence (P-A), membrane filter (MF) and multiple tube fermentation (MTF). The methods are described in detail in the most current version of the Standard Methods for the Examination of Water and Wastewater. Refer to Appendix 19 – 12D of Chapter 19 for more information on methods of analysis and procedures for sampling. The water can be analyzed at provincial or municipal public health laboratories, provincially recognized private laboratories or at the establishment's in-house laboratory, but it is critical for accurate results that the water sample size, sampling procedures and acceptable test methodology are followed.

Water is considered microbiologically safe if the maximum acceptable concentration (MAC) for total coliform and \( E. \ coli \) is non-detectable per 100 mL water sample. When using MF or MTF methods results reported as <1 CFU/100mL (for MF method) and <1.8 CFU/100 mL (for MTF method) are considered as meeting these standards,

\( E. \ coli \) is the only coliform bacteria that is considered faecal-specific. Therefore, the presence of \( E. \ coli \) indicates faecal contamination of the water and the possible presence
of enteric pathogens, and a boil water advisory should be issued by the local public health
unit or responsible agency.

The presence of total coliforms, in the absence of *E. coli* does not necessarily require the
issuance of a boil water advisory but corrective actions need to be taken. The operator
must re-sample and test any sites that are positive for coliforms.

If *E. coli* is confirmed, immediate re-sampling of the positive site is required, the
appropriate agencies should be notified, and if applicable, a boil water advisory should be
issued by the local public health unit or responsible agency and corrective actions taken.
An evaluation of any product will also have to occur

Refer to Appendix 19 - 12D for more information on corrective action and follow-up
procedures for unsatisfactory results. The corrective action and follow-up will vary
depending on whether the contamination was found in the source water sample or the in-
plant water samples or if the source water is municipal water or private well water.

i. Source Water:
The water entering the establishment meets the requirements of the official government
body having jurisdiction. The quality of the water supply must be analyzed at least once
per year to confirm its microbiological quality. If the source of the water is a private well
then the manufacturer is responsible to have the water analyzed. If the source of the water
is from the municipality and the analysis is carried out by the municipality, then the
manufacturer can obtain the analysis from the municipal agency. In either case the record
of the analyses must be on file at the establishment.

ii. In Plant Water:
The quality of product contact water must be tested once per month. Such analyses will
determine if the plant's water lines and filters are sanitary and effective. Product contact
water is defined as ingredient water, water used for flushing product, and water used for
washing and sanitizing purposes. A record of the analyses must be maintained by the
plant. Suitable sites for sampling include a drinking water tap and a point of use, such as
a hose. Sampling sites should be representative of different areas throughout the plant,
although not necessarily the same points at each occasion. Over time, the sample sites
should cover all applicable areas of the plant.

2) Chemical Testing:

Chemical analysis of the source water must be provided by the operator prior to
establishment registration. The range of chemical analysis will depend on local
conditions, such as geological formation, seepage from soil treated with fertilizers,
pesticides or local exposure to industrial pollution. To establish the range of tests and
when to test, Provincial Environmental authorities should be consulted. The guidelines
for chemical parameters can be found on the Health Canada website. Health Canada
recommends chemical testing the source twice a year.
If the source of the water is a private well the analysis must be undertaken by the manufacturer. Subsequent testing, once an establishment is registered may be required if there is any change to the well or piping system of a private well. If the source of the water is the municipality and the chemical analysis is carried out by the municipality, the manufacturer can obtain a copy of the analysis from the municipal agency. In either case the record of analyses must be on file at the establishment.

C) Operation

i. Water Filtration
Water used as a food ingredient or for flushing product must be filtered to remove hazardous extraneous material to a particle size of 2mm. Water used for CIP purposes must be free of rust, excessive scale and other foreign material. This may be done by filtering it.

Water could be filtered at the supply end or it could be filtered by a central filtration system. Wherever the location of the filter, it is important that all pipelines downstream from the filter are made of a material that does not contribute the addition of extraneous material to the water e.g. corrosion free (not rusting, not flaking).

ii. Design
Water that is used solely for fire protection, boilers or auxiliary services (e.g. cooling of compressor heads) does not have to meet the same criteria for potability. However, it is mandatory that there be no possibility of cross connections between the potable and non-potable systems, i.e. must be a closed system. A cross-connection, in the context of potable water, means any actual or potential connection between a potable water system and any source of pollution or contamination (Note: Bypass arrangements, jumper connections, removable sections, swivel or changeover devices, or any other temporary or permanent connecting arrangements through which backflow can occur are considered cross-connections.)

When water is used for cooling in the heat exchanger it must be potable.

Non-potable water may be used in an evaporator for condensing providing there are no restrictions (such as pumps) on the condensation line. Colour coding of non potable water lines is recommended.

Plant management must ensure that equipment and/or pipelines are designed and installed in a manner that will not jeopardize the safety of potable water used in dairy establishments. Therefore, plant management must ensure adherence to the requirements outlined under Appendix 19 - 12C with regard to the potential and actual risks associated with backflow as well as the use of appropriate backflow prevention devices.

Throughout the course of the in-depth inspection, particular attention must be paid to areas and processes in the establishment that have the potential to pose risks of backflow. These areas and processes include, but are not limited to:
- CIP and COP systems
- Water used for flushing product or chemical
- Raw receiving, rinsing tankers, silos
- Reclaimed water (cow water) from evaporators or membrane filters
- Boiler rooms and boiler water feed
- Cooling towers, plate heat exchangers using potable water, chilled water tanks and glycol supply systems
- Process water used for reconstitution or water for brining, etc.
- Fire protection water systems
- Other equipment using potable water such as fillers, homogenizers, separators

Devices used for prevention of backflow as per Section 6.0, Appendix 19 - 12C, require periodic testing at an appropriate frequency determined by the establishment or as per manufacturer's recommendations to verify that they are operational.

Where it is necessary to store water, storage facilities are designed, constructed and maintained to prevent contamination, e.g. covered, properly constructed of material(s) that will not contaminate the water and should allow for periodic cleaning and sanitizing. For example, these could be approved materials from the Canadian Water and Wastewater Association (CWWA) or materials for such use as per manufacturer's guidelines. Without proper design, operation, and maintenance of these facilities, stored water may easily become stagnant and subject to loss of chlorine residual, as well as bacterial re-growth, contaminant entry, and a host of other water quality problems.

iii. Water Treatment

If the source of the water poses a contamination risk it may be necessary to treat the water. The water treatment method used will depend on the reason for treating the water, e.g. microbiological, protozoan, viruses, chemical. Some water treatment devices are described in Appendix 19 - 12A.

Water treatment chemicals, where used, are listed in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products published by CFIA or the manufacturer has a letter of no objection from Health Canada.

The method of disinfection chosen by the operator must result in water that does not present a microbiological or chemical risk. Chlorine may be used as a disinfectant for well water supplies. The dose is dependant on the water flow rate, pH, temperature and chemical composition. Automatic dosing can be done by the use of a metering device. Where automatic chlorinators are used, it is essential that the establishment establish procedures to ensure water potability. Two controls which are fundamental when using automatic chlorinators are as follows:

1. A metering device for adding chlorine in the correct concentration, relative to the water flow rate, designed to readily indicate malfunction and
2. Such systems must be monitored and controlled twice daily. Tests shall be made to determine available chlorine level at a specific point, remotely located from the chlorine application site, but before distribution to the plant system. The establishment should have the appropriate test kit on hand (titration method) to determine available chlorine.

An automatic analyzer equipped with a recorder and an alarm, to ensure water potability, desired concentration and to prevent contamination may be utilized as an alternative to the above testing.

Where water is in direct contact with finished product, as is the case with washing cheese curds or when water is added unintentionally when flushing product post-pasteurization it is recommended that the operator considers installing an in-plant disinfection system for food application for those areas of the establishment. This water disinfection system should be handled like a critical control point including measurable tolerances for acceptability/unacceptability, monitoring and verification procedures and an action plan in the event of a failure to the system.

D) Water Reuse

Reuse water is water that has been recovered from a processing step, including from the food components, and that after subsequent reconditioning treatment(s), as necessary, is intended to be re(used) in the same, prior, or subsequent food processing operation.

The type of reconditioning to reduce or eliminate microbiological, chemical and physical contaminants will depend on the intended use of the water. Reuse water should not jeopardize the safety or suitability of the product. The source of the water and/or the prior collection and the intended reuse of the water dictate the degree of reconditioning and frequency of monitoring that is necessary. Reuse water intended for incorporation into a food product, used for flushing product or for washing and sanitizing purposes must meet the microbiological and chemical specifications for potable water.

The two types of reuse water identified for use in a dairy establishment are as follows:

i. Re-circulated water:
Re-circulated water is defined as water re-used in a closed loop for the same processing operation. Re-circulated water must be treated, monitored and maintained as appropriate for the intended purpose. Re-circulated water must have a separate distribution system which is clearly identified.

ii. Reclaimed water:
Reclaimed water is defined as water that was originally a constituent of a food, has been removed from a food by a process step, and that is intended to be subsequently re-used in a food processing operation. Condensed water from milk evaporators and water reclaimed from milk and milk products, also referred to as cow water, may be re-used within the establishment, thereby conserving water resources. Where water is reclaimed it
is important to ensure the water is safe and suitable for its intended purpose. This water may be treated and must be monitored and maintained as appropriate for the intended use within the establishment. Refer to Appendix 19 - 12B for specific requirements on this task.

E. Steam Supply

The operation of the boiler and the quality of the steam it produces are evaluated here. Within an establishment steam is used for cleaning, sanitizing and as part of the manufacturing processes. If it has direct contact with the product and product contact surfaces it must be **culinary type steam**.

i. Water/Steam:
The water from which the steam is generated may be a food ingredient and thus must meet all the regulatory requirements for potable water. Of particular risk are the corrosion inhibitors and water conditioning compounds that are used in the boiler.

Control of boiler operations, in particular the boiler feed water treatment, must be under the supervision of trained personnel or a firm specializing in industrial water conditioning. Boiler feed water must be tested regularly and the chemical treatment controlled to prevent contamination.

If the steam/hot water is in direct contact with product **and/or** the steam/hot water is used to sanitize product contact surfaces and is not followed by a potable water rinse then boiler treatment chemicals used must be listed in the Reference Listing of Accepted Construction Materials, Packaging Materials, and Non-Food Chemical Products published by CFIA or the manufacturer has a letter of no objection from Health Canada. In this case it is important that the operator of a dairy plant read the label of all water additives and consult with the manufacturer to assure that the water additives do not contain the following chemicals:

- 2-Amino-2-methyl-1-propanol
- Cyclohexylamine
- Diethylaminoethanol
- Morpholine
- Octadecylamine
- N,N-Bis (2-hydroxyethyl) Alkyl( C 12-C 18) amine derived from coconut oil
- Trisodium nitrilotriacetate

The prohibition of boiler water additives that contain amines is to eliminate the risk of forming nitrosamines in the dairy products.

ii. Culinary Steam
Culinary steam must meet certain standards because it is used in direct contact with milk and dairy products. Refer to Appendix 19 - 1 for further information on this task.
Direct steam injection that requires culinary steam is used in the following processes and products:

- Manufacture of ricotta and cottage type cheeses.
- Preheating of milk for production of evaporated milk, sweetened condensed milk and non-fat dry milk.
- Vacreation and pasteurization of milk and creams.
- Heating of water used in production of for example, butter oil and mozzarella cheese.
- Process cheese cooking.
- APPS processing.

It is recommended to periodically analyze steam condensate samples. Carry over of boiler water additives can result in the production of off flavours. Samples should be secured from the line between the final steam-separating equipment and the point of the introduction of steam into the product.

F. Water and Steam Hose Equipment

Poorly maintained hoses may contribute to the contamination of the water supply. Inspecting the condition of the hose equipment (nozzles, ends and exterior) is done to determine if it is maintained in a sanitary manner and is in good repair. Hoses are stored off the floor.

G. Records

The manufacturer has written records available to demonstrate the adequacy of the microbiological and chemical safety of the water and steam supply. The records include municipal and/or establishment's own water testing records for microbiological and chemical testing; water potability testing (water source, sample sites (including date and time sample taken), analytical results, analyst, date); water treatment records (method of treatment, sample site (including date and time sample taken), analytical results, analyst, date); water reuse records (for re-circulated and reclaimed water). The records specify the person who is responsible, analyses and results, parameters of acceptability/unacceptability (tolerances), frequency and results of monitoring and verification, satisfactory follow-up for out of specification findings and is updated as required.

1.10.01.010 HVAC (heating, ventilation, air conditioning) System Unit

This task assesses the HVAC system unit only. Individual ventilation units are evaluated separately under task 1.10.01.04 - Building Interior, in specific rooms.

Since air from the HVAC system unit is supplied to various parts of the establishment by ducts, it is important that this air supply not be a source of contamination. Pathogenic organisms can enter the product via a contaminated air source.
This unit is usually located on the roof or in a special room. Temperature is controlled by placing heating and/or cooling elements within the ducts. Filters are used to remove extraneous matter.

HVAC systems must be cleanable and maintained clean. Special attention to the condensate drip pans and drain line is required to minimize potential growth of pathogens. Air intakes should not be located near unfavourable activities (e.g. feed mills, livestock operations).

1.10.01.011 Glass Breakage Policy

This task will cover the policy required if an establishment handles glass containers or has glass or glass substitutes (e.g. plexi-glass) present in manufacturing areas, e.g. glass windows, UV lights, glass doors, in-line pH meters etc. The use of glass in processing areas should be discouraged. Where glass does exist it is recommended to be of the shatterproof type, where applicable. The receipt, acceptance and storage of glass is rated under task 1.10.02.03 Incoming Material.

The plant must have a documented glass breakage policy if it meets the above mentioned conditions, to assess if it will control the risk of glass contamination should breakage occur. Some guidelines that could be included in this policy are:

1. The line or processing area must immediately shut down.
2. Broken glass containers and/or loose glass fragments must be removed from the area.
3. Clean-up procedures are to be outlined (they must not spread the contamination).
4. The line (filler, capper) and/or area must be inspected to ensure that clean-up was adequate.
5. The breakage and the type (thermal shock, impact etc.) must be recorded.
6. Excessive breakage is to be investigated.

The records must be examined to determine if breakage did occur and if it was well handled and documented. The date, time and location of glass breakage, the type of breakage (e.g. thermal shock/impact), the extent of potential contamination (filler bowl, capper, hopper) and the results of the investigation must be recorded.

### Premises Program Summary Table

<table>
<thead>
<tr>
<th>Task</th>
<th>Inspection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Documented Program</td>
<td></td>
</tr>
<tr>
<td>1.10.01.01 General (HS=3)</td>
<td>Covers the outside property, roadways, drainage, building design and construction, product flow, sanitary facilities and water quality</td>
</tr>
<tr>
<td></td>
<td>Specifies the procedures to ensure maintenance of satisfactory conditions</td>
</tr>
</tbody>
</table>
• Specifies areas to be inspected, tasks to be performed, person responsible, inspection frequencies
• Specifies preventative measures to prevent the re-occurrence of deviations
• Specifies parameters of acceptability/tolerances
• Updated as required

(B) Records

A representative sampling of the plant's historical records must be assessed.

1. Records must be:
   o Accessible and complete
   o Clear, legible and permanent
2. Information must indicate:
   o All premises records
   o Frequency and results of monitoring and verification
   o Satisfactory follow-up when deviations found and documentation of actions taken

(A) Plant Blueprints and/or Process Flow Diagram

• Available
• Contacted Canadian Food Inspection Agency (CFIA) or responsible provincial authority of proposed major modifications, as required
• Verified regularly by management
  o changes reviewed and approved
  o no cross-connections or contamination risks

1.10.01.02 Plant Blueprints and Process Flow (HS=3)

(B) Process Flow Separation

• New registrations have separate rooms for incompatible products
• Adequate segregation of activities
• Control measures being used to reduce contamination risks
• Regulated process flow
  o from raw material receiving to finished product shipping
  o no contamination risk
  o pasteurized cheese production occurs prior to heat treated or raw cheese production or are processed on separate days
• Proper segregation of incompatible products
  o separate vessels and pipelines
  o physical breaks at connections
- separate areas/rooms (raw milk from pasteurized products; raw cheese from pasteurized cheese)
- no contact between raw product and product undergoing maturation or ripening
- If washes or mini-washes while connected to product double block & bleed valve arrangement, aseptic barrier for Aseptic Processing and Packaging Systems (APPS)

(A) Roof

- Drainage
  - Proper slope with no accumulation of water
  - Drain spouts at ground level directed away from building
- Surface
  - Free of leaks, cracks, openings
  - Cleanable type for powder plants
  - Clean, free of trash and vegetation

(B) Exterior Walls and Trim

- Sound
  - No openings, cracks
- Eavestrough and trim
  - No pest/bird harbourages

(C) Driveway and Parking Lots

- Properly graded, compacted, and well drained
- Surfaced with dust free material

(D) Surroundings

- Free of uncontrolled vegetation and stored items in close proximity to the establishment
- Building is not built near environmental contaminants or industrial activities that could pose a threat of contaminating dairy products

(A) Floors, walls, ceilings, stairs and elevators

1. Design
   - Hard
   - Smooth
o Impervious to moisture (exception: dry storage areas)
o Free of pitting, indentations, cracks, crevices and ledges
o Well joined or coved and, in the case of floors:
o Sloped

2. Clean and in good condition
   o Free from mold growth
   o Free from flaking material

3. Specific Areas of Interest
   o Hoseport
   o Can inlet and outlet

(B) Utility Lines

- Clean
- Identified
- Suspended away from work areas
- Free of flaking material
- No leaking
  - insulated to prevent condensation, where appropriate

(C) Doors & Windows

- Sealed or close fitting screens
- Tight fitting, self-closing; non-absorbent surfaces
- Glass windows protected against breakage in critical areas

(D) Loading Facilities

- Docks clean and in good condition
  - well lit
  - smooth and slightly sloped
  - free of cracks and crevices
- Proper temperature control
  - appropriate use of air curtains

(E) Lighting

1. Light bulbs, tubes or glass fixtures
   - Shatterproof
   - Clean

2. Intensity
   - Minimum illumination at the working area
     - 540 lux (50 foot candles) in grading and inspection areas, product inspection areas in the lab
     - 220 lux (20 foot candles) in the general
processing e.g. filling, and equipment cleaning areas (or work areas)
- 110 lux (10 foot candles) in other areas

(F) Ventilation

1. General
   - Air intakes outlets
     - General conditions
       - filtered
       - clean
       - well located; minimize air contamination
       - outlets not directly over product or sensitive area
     - Filters
       - clean
       - regularly monitored
   - Exhaust fans
     - Screened and/or self-closing louvres
     - Clean
   - Air treatment methods (where required)
     - Positive pressure

2. Operation
   - Air quality
   - Adequate ventilation
     - no mould growth
     - no condensation on walls, ceilings or equipment
     - no persistent strong odours

(G) Drains

1. Design
   - Adequate size
   - Individually trapped
   - No cross contamination from sewer lines or other parts of system
     - no cross-connection between sewage system and any other waste effluent in establishment; action plans in place to mitigate the risk of contamination if there are cross-connections (see text section for more details)
     - Sewage lines do not pose a contamination risk if located directly over or through production areas
   - Covered with removable covers
   - Interior surfaces of trench drains smooth and easy to clean
2. **Location**
   - Readily accessible for inspection and cleaning
   - No contamination risk to dairy products

3. **Maintenance**
   - Clean and sanitized
   - Odourless
   - Included as item in sanitation program
     - not cleaned by high pressure hoses

(A) **Sewage Disposal**

- No contamination potential
  - no pests
  - no odours
  - isolated from plant if independent treatment

(B) **Garbage Disposal**

1. **Inside the plant**
   - Containers
     - sufficient in number, clearly identified and leak proof
     - covered if contamination risk
     - regularly emptied, cleaned and sanitized
   - Garbage Storage Room
     - emptied daily
     - no odours
     - clean

2. **Outside the plant**
   - Compactors and Bulk Garbage Units
     - covers in place
     - sloped and drained, concrete ramp or platform
     - adequate disposal frequency

3. **Incinerators**
   - sufficient distance from plant

(C) **Whey Disposal & Handling (as waste product)**

- Storage tank - Loading area
  - on concrete platform; washable
  - well drained; sloped, suitable drains
  - clean surroundings
  - free of flies, insects and objectionable odours
- Added to sewage treatment system
  - written confirmation from appropriate government agency
• Operation
  o handling technique

(A) Hand Washing/Sanitizing Facilities

• Location
  o convenient & accessible
  o close to product handling areas
• Adequate number
• Components of facilities
  o remote-control type (foot, knee or timed) in production areas
  o hot & cold potable water
  o germicidal soap
  o sanitary hand drying supplies or device
  o cleanable waste receptacle
• Condition
  o clean and in good repair
  o trapped waste pipes to drain
• Hand sanitizing facilities
  o available in areas where personnel are in direct contact with product

(B) Employee Facilities (washrooms, lunchrooms, change rooms)

• Separated from food handling areas
  o pose no contamination risk
  o no direct opening to processing rooms; self closing doors
• Well ventilated
• Appropriate floor drainage
• Well maintained
• Washrooms have adequate hand washing facilities

(A) Appropriate Signs

1.10.01.07
Essential Signs
(HS=4)

• No smoking
• Unauthorized personnel
• Hand washing
• Hazardous materials

(B) General

• Adequate number
• Visible
- Posted in appropriate locations

(A) Equipment Cleaning and Sanitizing Facilities (e.g. Clean Out of Place (COP))
- Facilities constructed of corrosion resistant materials
  - easily cleaned
  - potable water, at adequate temperatures for chemical usage
  - temperature, time and chemical concentration monitored (either manually recorded or with a recording chart). Frequency of validation of COP cleaning is determined by the establishment and acceptable to CFIA inspector
  - adequately separated from food storage, processing and packaging areas; pose no contamination risk

(B) Other Rooms (boiler, compressor and mechanical rooms, retail operations)
- Separated from food handling areas
  - pose no contamination risk
- Properly maintained
- Free of pest harbourages
- Meets minimum building interior criteria (1.10.01.04)

(A) General - Water Quality
1. Documented Program
   - Monitors and controls the water (source, in-plant, re-use) and steam quality on an ongoing basis
   - Monitors for microbiological, chemical and physical contaminants
2. Action plan in the event of a boil water advisory/water safety alert/drinking water avoidance advisory
   - Includes investigation into the safety of prior products produced
3. Communication strategy with appropriate water authorities is recommended
   - Depending on jurisdiction

(B) Water Testing
1. Source Water
   - Supplied either by the municipality or private well
   - Meets requirements of official government body having jurisdiction
tested annually (micro) using acceptable sample size, sampling procedure, test methodology. Refer to Appendix 19 -12D.

- Maximum acceptable concentration for both total coliform and \textit{E. coli} is non-detectable per 100 mL sample. Results reported as <1 colony-forming units (CFU)/100mL (for membrane filter (MF) method) and <1.8 CFU/100mL (for multiple tube fermentation (MTF) method) are considered as meeting standards
- Corrective action taken for unsatisfactory results

- Chemical analysis maintained on file at time of registration; subsequent testing completed as needed
- Records of quality on file

2. In Plant Water

- Product contact water (e.g. ingredient water, water for flushing product, water for washing and sanitizing purposes)
  - Tested once per month (micro) using acceptable sample size, sampling procedure, test methodology. Refer to Appendix 19 –12D.
  - Maximum acceptable concentration for both total coliform and \textit{E. coli} is non-detectable per 100 mL sample.
  - Results reported as <1 CFU/100mL (for MF method) and <1.8 CFU/100mL (for MTF method) are considered as meeting standards.
  - Site selection is representative of areas in plant
  - Corrective action taken for unsatisfactory results. See Appendix 19 –12D
- Records of quality on file

(C) Operation

1. Water Filtration

- Water when used as an ingredient or for flushing product is filtered to remove hazardous extraneous material to a particle size of 2mm
- Water used for clean in place (CIP) purposes is free of rust, excessive scale and other foreign material.
- Filter location: supply end or central filtration system
  - Pipelines downstream from the filter are made of a material that does not cause addition of hazardous extraneous material e.g. not rusting, not flaking (corrosion free)

2. Design
o No cross connections between potable and non-potable water systems (see Appendix 19-10)

o Equipment and/or pipelines are designed and installed so that they do not jeopardize the safety of potable water
  - requirements of Appendix 19 - 12C are being met with regards to potential and actual risks regarding backflow
  - devices used for backflow prevention are tested at an appropriate frequency to verify that they are operational

o If water is used for cooling in the heat exchanger it is potable

o Water storage facilities prevent contamination of the water and allow for periodic cleaning and sanitizing
  - Canadian Water and Wastewater Association (CWWA) approved materials or as per manufacturer's guidelines

3. Water Treatment

  o May be treated to ensure potability

  o Disinfection method used is effective for intended purpose (see Appendix 19 - 12A)
    - method does not pose microbiological or chemical risk

  o Water treatment chemicals, where used, are acceptable

  o Disinfection method poses no risk
    - If automatic chlorinators used, the concentration of available chlorine is monitored and controlled twice daily

(D) Reuse Water

- Type and degree of reconditioning is effective for intended use of the water
- Does not jeopardize the safety or suitability of the product
- Frequency of monitoring is sufficient for intended purpose

1. Re-circulated water (if required)
   - If used, is treated, monitored and has a separate, identified distribution system

2. Reclaimed water
   - Meets the requirements of Appendix 19 – 12

(E) Steam Supply

1. Water/Steam
   - Potable water used
Acceptable boiler water additives required for dairies
  • if steam in direct contact with product
  • if steam used to sanitize product contact surfaces and not followed by potable water rinse

Traps are provided to ensure
  • adequate condensate removal
  • elimination of foreign materials

2. Culinary Steam
  • Complete, correct piping assemblies
  • Production supervised by trained personnel
  • Meets requirements of Appendix 19 – 1

(F) Water and Steam Hose Equipment

- Pose no contamination risk
- nozzles, ends and exterior: clean and in good condition
- stored off floor

(G) Records

1. Records must be:
   • Accessible and complete
2. Records must include:
   • Person responsible
   • Municipal water testing records (including chemical analysis)
   • Chemical analyses and results on well water
   • Water potability records (water source, sample site (date and time sample taken), analytical results, analyst, date)
   • Water treatment records (method of treatment, sample site (date and time sample taken), analytical results, analyst, date)
   • Reuse water records (re-circulated or reclaimed water)
   • Analyses and results indicated
   • Frequency and results of monitoring and verification
   • Satisfactory follow-up for out of specification findings
   • Updated as required

(A) Specific Areas of Interest

1.01.10
HVAC System Unit (heating, ventilation, and air conditioning system)(HS=3)

- Air intakes
  • filtered
  • clean
  • well located

- Filters
  • clean
• Fans
  o screened or self-closing louvers
  o clean
• Drip pans, drain lines
  o properly maintained

(B) Records

• H.V.A.C. unit
  o maintenance records to be kept
  o available; easily accessible
  o complete

(A) Documented Program

• Covers all glass areas
• Covers glass substitutes (e.g. plexi-glass)
• Specifies procedures to be followed
• Designates responsible personnel
• Updated as required

(B) Records

• Available; easily accessible
• Complete

1.10.02 - Transportation & Storage Program (including receiving)

Dairy establishments transport, receive, inspect and store ingredients/packaging materials and incoming materials in a manner which prevents conditions which may result in the contamination of food.

This documented program, as well as its effective implementation, will help control operational conditions within an establishment allowing for environmental conditions that are favourable to the production of safe food. It serves as a prerequisite program or universal-type CCP for a HACCP based program.

1.10.02.01 General

Dairy establishments and importers must have an adequate documented program in place which controls all the elements in this section, and maintain the appropriate records.
To ensure the production of safe food, it is necessary to know and control the type of incoming materials brought into the establishment. These materials include all raw products, ingredients, packaging materials, non-food chemicals and returned products. It is important that the carriers (vehicles) of these products be suitable and well maintained for the type of product they carry. The same requirements apply for carriers of finished product leaving the establishment. These requirements may be the direct or indirect responsibility of the processor; in either case the processor must outline a system to ensure the requirements are met.

Appropriate specifications for the incoming materials need to be defined to ensure that the materials supplied will minimize any biological, chemical, or physical hazards and be food grade. As these products are received into the establishment, they need to be screened for their acceptability according to the specifications. This may involve verifying if certification papers are present, performing product analysis through a regular monitoring program or a combination of these activities. Once these products are accepted into the establishment, they need to be stored and handled appropriately to minimize the contamination risk.

Adherence to the criteria is verified by examining the establishment's written program which specifies the requirements for food carriers; defines the specifications for all food grade ingredients, packaging materials and non-food chemicals; outlines the receiving requirements; and specifies storage and handling requirements for all incoming materials. The program must specify:

- areas to be inspected (what is done),
- tasks to be performed (how it is done),
- person responsible (who does it),
- inspection frequencies (how often or when it is done),
- records to be kept,
- parameters of acceptability/unacceptability (tolerances),
- results of monitoring,
- verification procedures (both on-site and record review),
- action to be taken for deviant situations.

The monitoring and verification procedures clearly define the preventative measures taken to prevent the re-occurrence of deviations. The person responsible for verifying the program must be different from the person performing the task. This program must be regularly reviewed and updated to assess its effectiveness under changing conditions.

The actual monitoring of the adequacy of this program will be done by monitoring and assessing tasks 1.10.02.02 to 1.10.02.08.

1.10.02.02 Transportation

A) Carriers used by the establishment must be designed, constructed, maintained, cleaned and utilized in a manner to prevent food contamination. Carriers must be suitable for the
transportation of food. This can be verified by visual inspection upon receipt by the manufacturer and prior to loading to ensure they are free from contamination and suitable for the transportation of food. Carriers permit effective separation of different foods or foods from non-food items where necessary during transport. Carriers provide effective protection from contamination, including dust and fumes. The manufacturer has a program in place or assurances to demonstrate the adequacy of cleaning and sanitizing. For example, the plant should have records that the carrier is properly cleaned and sanitized. Special attention should be given to carriers used to transport goat and sheep milk from the farm to the establishment to ensure that these meet the appropriate requirements.

In the event that the same carriers are used for a variety of different foods (e.g. egg albumen) or for raw and pasteurized dairy products, procedures must be in place to ensure that there is not a contamination risk to subsequent loads. For example, the manufacturer receives a cleaning certificate and a record of the previous material transported prior to loading or unloading dual use tankers. The manufacturer has a program in place to verify the adequacy of cleaning, e.g. tanker inspections, sensory evaluation of ingredients and/or analysis as appropriate.

The transportation of pasteurized dairy products in bulk multi-use containers without re-pasteurization is strongly discouraged as there is no guarantee that equipment is adequately cleaned. Re-useable plastic totes are not acceptable for the transporting of pasteurized product. For establishments who do not wish to re-pasteurize already pasteurized product, food carriers, tanks, transport lines and transfer pumps must be dedicated to pasteurized product only. This practice must be limited to certain products such as whey or condensed milk destined for drying, ice cream mix or cream cheese mix but would not be acceptable for fluid milk and cream. As well, documented protocol and written records for this practice are required to maintain the pasteurized product integrity. **This practice will have to be assessed on a case by case basis.**

Ingredients and finished product requiring temperature controls must be transported in a manner to prevent temperature abuse that could result in deterioration affecting product safety. Dairy products which require refrigeration are transported at a transport temperature of 4 °C or less; refrigerated ingredients at a transport temperature of 4 °C or less; frozen ingredients at a transport temperature that does not permit thawing. Transportation temperatures must be monitored and recorded to ensure proper temperatures for refrigerated and frozen ingredients. Finished product must be transported under conditions to prevent microbiological, physical and chemical deterioration.

To adequately assess this task, the written program must be examined to verify that the requirements for food carriers as outlined in the program are being followed, records are kept and acceptable deviation procedures occur when conditions are not met. It is important that dairy products are not transported in carriers that do not meet the requirements of the program, thereby posing a contamination risk to the product. This can
be verified with visual and organoleptic inspections of the carriers by the inspector and visual observations of personnel responsible for loading and unloading carriers.

B) Carts used for transportation of ingredients and finished products within the processing operation as well as forklifts used in the warehouse are subject to abuse so careful attention is required to the maintenance of these pieces of equipment. Forklifts and carts tend to have painted surfaces so it is important that the exterior of these items be free of flaking material that may contaminate the products. Transportation equipment must be frequently washed; carts should have sanitary drain cocks to prevent accumulation of water in the carts.

It is imperative that waste and scrap carts be clearly labelled to avoid adulteration of ingredients or product. Also the type of forklift dictates the area where it may be used. Propane may contaminate some stored food so electric forklifts should be used in food processing areas.

1.10.02.03 Incoming Material (ingredients & packaging)

This task assesses all incoming material except raw milk or cream. Milk and cream are assessed under task 1.10.02.04 - Raw Product Quality and non-food materials are assessed under task 1.10.02.08 - Non-Food Chemicals.

The receipt, storage and handling of incoming ingredients (e.g. freeze dried cultures, flavours, fruits and powders, protein concentrates, etc.) and packaging materials (includes preformed containers such as ice cream barrels, milk jugs, etc.) must be well controlled to ensure they do not pose any biological, chemical or physical hazards to the dairy products. Only sound, suitable raw materials are used.

The manufacturer must ensure that all food additives used are permitted for use in the particular food and meet all the requirements of the Food & Drug Regulations (assessed under task 1.10.07.02 - Manufacturing/Allergen Controls).

Plants should procure all material according to specifications. Their compliance with these specifications is verified at a frequency determined by the establishment (assessed under task 1.10.07.03 - Microbiological controls and Records and 1.10.07.04 - Composition Control and Records). Establishments receiving dairy powders define specification requirements for incoming dairy powders and specify receipt of certification papers that product is either pasteurized, is alkaline phosphatase negative or is labelled for further processing. A program (which is assessed under task 1.10.02.01- General) must be in place to monitor the acceptability of incoming materials received in the plant; the degree of monitoring will depend on whether buying specifications are used and the supplier's record of performance. A control program is especially important in the case of glass containers which may contain fragments of glass or glass defects which are difficult to see.
Packaging design and materials provide adequate protection for products to minimize contamination and prevent damage. Packaging materials must be non-toxic and not pose a threat to the safety and suitability of food under specified conditions of storage and use. Packaging materials purchased are listed in the Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Products published by the CFIA or the manufacturer has a letter of no objection from Health Canada. The reference list can be consulted for further information.

Once the materials are received in the plant, they must be labelled and stored in a manner that protects their integrity and minimizes the risk of contamination. Ingredients requiring refrigeration must be stored at proper temperatures (4 °C or less) and frozen ingredients must be stored at temperatures that do not permit thawing; storage room temperatures must be monitored. Humidity sensitive materials must be stored under proper conditions. Rotation of ingredients and packaging material where appropriate is controlled to prevent deterioration and spoilage.

1.10.02.04 Raw Product Acceptability

This task assesses the acceptance, receiving, sampling and monitoring of raw milk, cream and other dairy products treated as raw ingredients and applies to these products from all species (e.g. sheep, goat, etc.). Other incoming food ingredients are assessed under task – 1.10.02.03 Incoming Material.

There are many biological, chemical and physical hazards in raw milk products that must be identified and controlled to ensure production of safe dairy products.

Raw milk products must meet the quality standards established by the appropriate provincial or federal authority. Specifically, it is critical that raw products are only accepted if they meet specifications related to odour, acidity levels, temperature, antibiotics and filtering. If not, the raw product may not be further controlled in the manufacturing process and therefore may pose a contamination risk.

The receiving of raw milk/cream must be well controlled to minimize growth of microorganisms/toxins that could affect food safety. Raw milk/cream must be received at a maximum temperature of 6 °C but preferably 4 °C or lower. Plant specific limits need to be set for raw milk/cream receiving temperature that establish the maximum conditions that will be allowed before product is received. These limits should have a scientific basis and must be monitored by a designated, trained person at a set frequency and recorded and actioned appropriately.

If raw milk/cream is received at a temperature greater than 6 °C the establishment must have deviation procedures in place to control the microbiological growth in the product. Deviation procedures might include cooling the product down to at least 6 °C; pasteurizing or processing the raw milk product within a specified time frame (e.g. 2 hours of receipt); odour evaluation; microbiological/toxin testing (e.g. S. aureus); notifying the provincial milk board or provincial government; rejecting the load.
If during an in-depth inspection the inspector noted that the establishment had on occasion received shipments of raw milk/cream with a temperature above 6 °C and deviation procedures were implemented and effective, records indicated that each load had been monitored for compliance to specifications and the temperature history of raw milk/cream illustrated for the majority of the shipments that receiving temperatures did not exceed 6 °C this criteria can be rated as satisfactory.

It must be a regular practice to make appearance and odour checks of each tanker load of bulk milk before unloading into storage tanks to allow segregation of milk with quality defects. This provides a check on the grading of the milk done at the farm before pumping into the bulk truck. It is important that such tests be performed and recorded before unloading each tanker of milk received.

Raw milk or cream samples should be obtained from each tanker for further testing. These samples must be stored in clean and sanitary containers placed on suitable racks and stored at the appropriate temperature prior to testing. Most provincial governments have regulations stating the length of time and temperature that milk and cream samples must be held prior to testing and under what conditions they must be held.

Raw milk or cream received at the plant must be subjected to grading and relevant laboratory tests, e.g. antibiotics, microbiological, sediment, titratable acidity, etc. The plant should have an effective follow-up program to exclude (or segregate) milk which is suspected to be contaminated until subsequent tests show correction of the problem.

It is a practice in some dairy establishments to rinse milk delivery trucks, milk silos and pipelines once emptied with water and reclaim this milk in their production. The purpose for doing this is to reduce the loss of milk due to adherence to the walls of the containers and ineffectual flow of pumps. The establishment must have a documented protocol and written records for this practice in order to maintain the product integrity. The protocol should include procedures to ensure the safety and compositional standards of the product. Some items to be considered in the procedures would be the sanitary quality of hoses, proper sanitation procedures, possible risk of chemical contamination, water potability, storage and end use of this product.

1.10.02.05 Raw Product/Mix Storage/Aging/Cooling/Returns and Rework

A) The storage time and temperature of raw milk/cream must be well controlled to minimize growth of microorganisms. Microbial growth could produce heat stable toxins and potentially pose a hazard that would not be controlled by the pasteurization step. Raw milk/cream must be stored at a maximum temperature of 6 °C but preferably 4 °C or lower. Manufacturers must have time controls in place to minimize excessive microbial growth (e.g. an established maximum storage time prior to processing which was determined to be safe). If raw milk/cream is stored at a temperature greater than 6 °C and/or for a prolonged length of time, the establishment must have deviation procedures in place to control the microbiological growth in the product. Deviation procedures might include cooling the product down to at least 6 °C; pasteurizing or processing the raw
milk product within a specified time frame; odour evaluation; microbiological/toxin testing (e.g. *S. aureus*). Plant specific limits need to be set for raw product storage time and temperature that establish the maximum conditions that will be allowed before product is held before further processing. These limits must be monitored by a designated, trained person at a set frequency and recorded and actioned appropriately.

Thermisation is the practice of heating up the raw milk for a specified time/temperature, e.g. 57-65 °C for 15 seconds, followed by refrigeration and storing it for an extended period of time prior to pasteurization. It is a mild form of heat treatment which can be used to extend the keeping quality of raw milk. The aim is to reduce the growth of psychrotrophic bacteria which may release heat-resistant protease and lipase enzymes into the milk. The milk that is treated this way is still considered to be raw but can be held for a longer period of time before pasteurization. A documented protocol and written records for this practice are required to maintain the raw product integrity. This practice will have to be assessed on a case by case basis.

B) The storage time and temperature of product requiring further processing (e.g. dairy product mix held at or below 4 °C) must be well controlled to minimize growth of microorganisms. This is pasteurized product which could be re-contaminated due to improper handling or poor sanitation of storage tanks and as such requires to be kept at refrigeration temperatures.

C) Certain dairy products require to be kept at temperatures that exceed 4 °C as part of their manufacturing process. These processes can include but are not limited to tempering, drying, curing and aging of dairy products. However, when these manufacturing processes are completed, these dairy products must be kept at 4 °C or less. If a plant is tempering product from a frozen state the preferred option would be a tempering room, however this is not always possible. An establishment that tempers product from a frozen state requires a written protocol of how the product will be handled so as to minimize the growth of microorganisms, including routine documented temperature/time checks and microbiological testing. This practice will have to be assessed on a case by case basis.

D) All pasteurized milk and milk products, except those to be cultured, must be cooled immediately prior to filling or packaging to 4 °C or less, unless drying is commenced immediately after condensing.

E) Dairy products that are returned to the establishment may be a source of contamination to the plant environment, equipment and other dairy products. Contamination can be prevented by proper control of such products as they arrive at the plant from external sources, e.g. retail outlets.

To properly control the handling of returns, employees must adhere to the policy regarding returns that has been established by the management. A policy to not accept any returns is the best. A plant that has an evident no return policy that can be substantiated is evaluated as satisfactory.
The policy must define what products are acceptable. It is recommended that only products which the establishment has retained ownership (e.g. undelivered product that has remained on the truck) be accepted as returns. If product that has not remained as property of the establishment (i.e. store returns) is accepted at the plant, it must be segregated from other plant operations. Fluid milk returns may be collected in a separate well identified tank; other by-products must be separately stored and identified while awaiting disposal and/or re-work if applicable. The handling of returned product must not compromise the safety of fresh product in any way.

The situation of excessive amounts of product being habitually returned to the establishment needs to be addressed by the management.

It is recommended that only the cheese for which the establishment has retained ownership should be accepted for shredding or grating. Cheese returns that are going to be used for shredding or grating must be well controlled and the integrity of the product must be demonstrated.

F) The manufacturer has controls in place to ensure that reruns or reworks do not contain ingredients that may be allergenic to sensitive individuals unless clearly identified on the label of the finished product. Reruns (for example: ice cream, chocolate milk) must be stored in covered and clearly labelled containers.

**1.10.02.06 Finished Product Storage**

Finished product must be stored and handled under conditions to prevent deterioration (e.g. spoilage) and damage (e.g. control of stacking heights and forklift damage).

Finished products requiring refrigeration must be stored at proper temperatures (4 °C or less) and frozen products must be stored at temperatures that do not permit thawing. As is always the case, if provincial requirements are more stringent, then those must be met. Storage room temperatures must be monitored. Humidity sensitive materials must be stored under proper conditions. Stock rotation must be controlled to prevent deterioration that could present a health hazard. Particular attention should be paid to periods of defrosting of refrigeration units, temperature abuse and overloading of the cold storage capacity.

If an establishment does not have the capacity to cool the finished product to 4 °C or less on-site at the establishment, it is acceptable (provided this practice does not contravene Provincial regulatory requirements) to ship the product to a public refrigerated warehouse in order to get the temperature down to an acceptable level. There must be written procedures in place and records kept to show the establishment has full control over the product. The tracking documents must include temperature/time during transportation on refrigerated trucks, temperature/time records at the public warehouse, and final control of product release to distribution. These records must be available to the inspector for review.
Products that can be stored at ambient temperatures are protected against external agents and contamination, e.g. direct sun, excessive heating, moisture, external contaminants, from rapid temperature changes which could adversely affect the integrity of the product container or the safety or suitability of the product.

In order to maintain the integrity of the product from pests, moisture, excess weight, etc. The stacking of dairy products is important. Containers must be well identified and stored in a manner to prevent them from falling over. Adequate cleaning and effective pest control can be achieved in storage areas by storing items a suitable distance from the walls and off the floor. Products stored longer than one month must be on pallets approximately 46cm (18in.) from the wall.

Equipment and other food products which are stored in a finished product storage room must pose no contamination risk to the dairy products or ingredients.

The storage of eggs in finished product storage rooms is not to be encouraged. Fish or other products that may transmit odours or undesirable attributes must not be present. Other acceptable products must be stacked on pallets or shelves in a neat and orderly manner.

Wooden pallets and wood 640's (with appropriate liners and pallets) used throughout the plant must be maintained in a manner that prevents them from becoming a source of contamination. Potential risks include: fragments of wood and insects, rodents and other contaminants that may be carried into the plant on the pallets. Improperly reconditioned or reused 640's without washing could promote a cheese mite problem. Wood 640's not well maintained may have splintered wood, mouldy wood, imperfections and splints. Steel frames may exhibit rust. An intensive maintenance program for 640's will assure the containers are in good condition at all times. An effective written program is required for the inspection, cleaning, replacement, storage and handling of these materials. Records must be kept. Employees who are responsible for inspecting and making decisions on the acceptance and rejection of the 640's need to be properly trained. Ideally, in processing and packaging rooms, non-wooden type pallets (e.g. Teflon, plastic, etc.) should be used.

Wood used for cheese shelves to cure bacterial surface ripened cheeses must be smooth and either unsealed or sealed with an approved sealant. The supports for the shelves must be stainless steel or a non-corrosive non-absorbent material. The establishment must have a written program in place to clean and maintain the shelves which needs to specify the frequency and methods of washing, checking for physical condition (splinters, cracks, mite infestation) and if required environmental sample monitoring of the product contact surfaces and the room environment. Records must be kept. See Policy for the Use of Wood in Dairy Establishments (Appendix 19 - 11).

1.10.02.07 Temperature and Humidity Control
Proper control of temperature and humidity is essential in various areas of the establishment. In storage areas the temperature is dependant on the product that is held there. In refrigerated storage areas it is necessary to maintain humidity conditions that prevent the formation of condensation and subsequent mould growth. In cheese salting and curing rooms the temperature and humidity conditions are also dependant on the type of cheese being manufactured. Control of the conditions in the salting and curing stages of the manufacturing process will ensure even distribution of salt, and optimal microbial and enzymatic activity in the ripening process. This task will be assessed twice for an establishment that manufactures cheese (once for the establishment and once for the salting and curing room).

Appropriate thermometers, hygrometers or automatic devices that do not pose a contamination risk (non-breakable thermometers) must be used. Replacement measuring devices should be available. Records that document temperature and humidity conditions are required to indicate that the product has been appropriately held. These may be manual records or automated charts.

The sanitary condition of the components of the refrigeration unit is important because improper maintenance may result in the formation of condensate and mould growth which may become a source of contamination. Pathogens have been found in drainage and condensate from cooling units; therefore, it is critical that condensate be well controlled.

1.10.02.08 Non-Food Chemicals

Chemicals purchased are listed in the Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Products published by CFIA or the manufacturer has a letter of no objection from Health Canada. The plant must have a documented list of all non-food chemicals that are used to enable verification of the products' acceptability for use in dairy plants.

Chemicals must be received and stored in such a manner that prevents contamination of food, food contact surfaces or packaging materials.

The storage of non-food chemicals in food plants takes place in two areas:

1. Long term storage of unopened containers in a warehouse; and
2. Short term storage of opened containers in areas separated but in close proximity to the food processing area.

This task will assess both types of storage.

Because the packaging of many cleaners and sanitizers resembles that of food products or ingredients, there is a possibility that such compounds could adulterate a food product through careless handling. These products must be stored away from any food ingredients or products. A special room or caged in area that is dry and well ventilated is preferred.
The use of a colour coding system will enable identification of non-food chemicals. Chemicals must be dispensed and handled only by authorized and properly trained personnel. Chemicals are to be used in accordance with the manufacturer's instructions.

Transportation and Storage program (Including receiving) Summary Table

<table>
<thead>
<tr>
<th>Task</th>
<th>Inspection Criteria</th>
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<tbody>
<tr>
<td></td>
<td>(A) Documented Program</td>
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<tr>
<td></td>
<td>● Covers food transport carriers and the receiving, storage and handling of all incoming material</td>
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<td></td>
<td>● Specifies food carrier requirements or assurances</td>
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<tr>
<td></td>
<td>○ written procedures for cleaning and sanitizing</td>
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<td></td>
<td>○ proper temperature controls</td>
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<td>○ certification papers (if required)</td>
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<td></td>
<td>○ protected from contamination</td>
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<tr>
<td></td>
<td>● Defines specification requirements for all incoming materials and verifies compliance to these specifications at a specified frequency</td>
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<td></td>
<td>○ raw product characteristics</td>
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<td></td>
<td>○ food grade ingredients</td>
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<td></td>
<td>○ packaging materials</td>
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<td></td>
<td>○ non-food chemicals</td>
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<td></td>
<td>● Specifies receiving requirements</td>
</tr>
<tr>
<td></td>
<td>○ certification papers (if required); acceptable type; not damaged; properly labelled</td>
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<td></td>
<td>○ appropriate monitoring program</td>
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<td></td>
<td>● Specifies storage and handling requirements</td>
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<td></td>
<td>○ according to supplier’s instructions</td>
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<td></td>
<td>○ proper temperature and humidity controls</td>
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<td></td>
<td>○ protected from contamination</td>
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<tr>
<td></td>
<td>○ non-food chemicals stored in separate, well ventilated area; pose no contamination risk</td>
</tr>
<tr>
<td></td>
<td>○ returned foods well identified, stored separately; pose no contamination risk</td>
</tr>
<tr>
<td></td>
<td>● Specifies person responsible, inspection frequencies</td>
</tr>
</tbody>
</table>
|                               | ● Specifies preventative measures to prevent the
re-occurrence of deviations
• Specifies parameters of acceptability/unacceptability (tolerances)
• Updated as required

(B) Records

A representative sampling of the plant's historical records must be assessed.

1. Records must be:
   o Accessible and complete
   o Clear, legible and permanent

2. Information must indicate:
   o All food carrier records
   o All incoming materials' receiving and storage records
   o Frequency and results of monitoring and verification
   o Satisfactory follow-up when deviations found and documentation of actions taken

(A) External Food Carriers

1. Operation
   o Carriers inspected on receipt and prior to loading to ensure:
     ▪ free from contamination, including dust and fumes
     ▪ suitable for transportation of food
     ▪ procedures for carriers hauling goat and sheep milk
   o Effective separation of different foods or foods from non-food items, where necessary
   o No contamination risk from carriers used for a variety of different foods or for raw and pasteurized dairy products e.g. cleaning certificate and a record of the previous material transported
   o Dedicated carriers, tanks, transport lines and transfer pumps for pasteurized product not being re-pasteurized and documented protocol and written
records kept for this practice
  o Adequacy of cleaning e.g. tanker inspections, sensory evaluation of ingredients and/or analysis as appropriate
  o Loaded, arranged and unloaded to prevent damage and contamination to food and non-food materials

2. Design
  o Bulk tanks
    ▪ proper drainage
    ▪ prevent contamination
  o Carrier construction suitable for food contact
  o Re-useable plastic totes not acceptable for transporting pasteurized product

(B) Temperature Control

- Dairy products which require refrigeration transported at 4°C or less
- Refrigerated ingredients transported at 4°C or less
- Frozen ingredient transportation temperature does not permit thawing
- Temperature is monitored and recorded
- Deviation procedures occur when conditions are not met
- No contamination risk of finished product during transportation

(C) Internal Transportation Equipment

- Appropriate type
- Exterior surfaces
  o no flaking material
- Clean
- Proper maintenance
- Waste carts clearly labelled

(A) Receiving of Materials

1.10.02.03 Incoming Material (ingredients & packaging) (HS=2)

- Operation
  o supplier's and processor's specifications met
o certification papers (if required)
o materials free of contamination/damage
o inspected upon receipt
o food grade ingredients
o packaging materials acceptable products (Reference listing can be found on the CFIA website)
o incoming materials are received in area separate from processing area
o cover re-useable containers to be used for milk ingredients or other ingredients

(B) Storage and Handling

- According to supplier's instructions
- Maintain integrity of material
  - proper temperature controls
    1. refrigerated ingredients stored at 4°C or less
    2. frozen ingredients stored at temperatures that do not permit thawing
  - proper humidity controls for sensitive materials
  - protected from contamination
  - not stored on floor
  - proper rotation of packaging material if required
- Shelf life respected
- Meets minimum building interior criteria (1.10.01.04)

(A) Raw Product Acceptance

- Each load monitored for compliance to specifications
  - temperature history of load
  - receiving temperature not to exceed 6°C; preferably 4°C or less
  - deviation procedures established (based on scientific rationale); if receiving temperature exceeds 6°C (e.g. product is cooled to at least 6°C; is pasteurized or processed within a specified timeframe; odour evaluation; micro/toxin testing)

1.10.02.04 Raw Product Acceptability (HS=2)
• graded for appearance and odour
  • antibiotic screening prior to processing

- All results recorded
- Appropriate action taken when deviations found

(B) Raw Product Receiving

- Filter present in receiving equipment
  • no hazardous extraneous materials (HEM) (2mm)
- Plant exhibits good control when using \textit{reclaimed} milk from milk delivery trucks, milk silos and pipelines
  • sanitary quality of hoses, sanitation procedures in place, no risk of chemical contamination from CIP system, water potability, storage, end use of product, written procedures and records to verify product integrity.

(C) Raw Product Sampling and Handling

- Sanitary, clean and dry sample containers
- Samples stored and tested appropriately (as per provincial regulations)

(D) Raw Product Monitoring

- Meets the quality standards of the appropriate provincial or federal authority
  • antibiotics, microbiological, sediment, titratable acidity
- Appropriate monitoring program
  • periodic lab analysis to verify conformance to specifications
  • satisfactory follow-up on out of compliance product and documentation of action taken

(A) Raw Milk/Cream/Storage

\textbf{1.10.02.05 Raw Product/Mix Storage/Aging/Cooling/Returns and Rework (HS=2)}

- Documented time/temperature control
  • specific limits established
  • documented, written protocol to monitor the process of thermisation of
raw milk
  o monitoring frequency specified and carried out
  o designated person to monitor
  o deviation procedures established (based on scientific rationale); if storage temperature exceeds 6°C (e.g. product is cooled to at least 6°C; is pasteurized or processed within a specified timeframe; odour evaluation; micro/toxin testing)
  o appropriate action taken when deviations found
- Meets minimum building interior criteria (1.10.01.04)

(B) Frozen Dairy Product Mix Storage

- Mix cooled rapidly (within 1 hour)
- Product held at or below 4°C for prolonged holding
- No stagnant, unrefrigerated product kept for prolonged period during manufacturing interruption

(C) Product Aging

- Products may be held at temperatures above 4°C as part of their manufacturing process, e.g. tempering, drying, curing, aging
- Written protocol documenting temperature/time checks, micro testing when products tempered from a frozen state

(D) Product Cooling

- Pasteurized milk and milk products, except cultured products must be cooled immediately prior to filling or packaging to 4°C or less unless drying is commenced immediately after condensing

(E) Handling of Returns

1. Policy
   o Sound Policy
2. Returns
   o Segregated
     • away from fresh product, equipment and other plant operations
   o Refrigerated as required
     • identified
     • mode of disposal

(F) Reruns or Reworks

- Controls in place to ensure reruns and reworks do not contain ingredients which cause allergies to sensitive individuals
- Reruns stored in covered, clearly identified containers

(A) Operation

- Conditions acceptable to prevent deterioration
  o temperature, humidity, time
  o finished products requiring refrigeration stored at 4°C or less
  o frozen products stored at temperatures that do not permit thawing
- Conditions acceptable to prevent damage (e.g. periods of defrosting, cold storage facility not overloaded)
- Proper stock rotation
- Meets minimum building interior criteria (1.10.01.04)

(B) Stacking of Containers

- Well identified
- Off floor, appropriate distance from the wall

(C) Storage of Other Products

- No contamination risk

(D) Shelves, 640's, Pallets and Racks
• Appropriate design and maintenance
• Effective written program to inspect, clean, replace, store and handle
  o employees responsible to maintain these materials are trained
  o records kept
• Pose no contamination risk

(E) Wood Shelves for Cheese Curing (Bacterial Surface Ripened Cheeses)

• Appropriate design and maintenance
• Written program to clean and maintain shelves
• Records kept
• Pose no contamination risk

(A) Measuring Devices

• Accurate
• Pose no contamination risk

(B) Refrigeration Unit

• Free of excessive frost build up and dust and debris accumulation
• Connected to drain system so that condensate is efficiently removed

1.10.02.07 Temperature and Humidity Control (HS=3)

(C) Records (included as part of the storage records)

• Maximum/minimum limits are specified
• Documents (recording charts or log book)
  o date
  o location
  o frequency of monitoring
  o results
  o action taken if out of specification
  o initials of responsible person

(A) Receiving & Storage

1.10.02.08 Non Food Chemicals (HS=4)

1. Type
  o Suitable for use in food processing operations (CFIA/Health Canada (HC) reference list)
2. Receiving and Storage Area
Separate
Clean and dry
Free of debris and spilled chemicals
Well ventilated
No contamination risk

3. Containers
Clean
Correctly labelled
Disposed of properly when empty
Not used for measuring or transporting food products or ingredients
Covered or resealed after opening and between use
Dispensed and handled by authorized and trained personnel

4. Records
Documented list of all non-food chemicals
Reference listing can be found on the CFIA website.

1.10.03 - Equipment Program

This documented program as well as its effective implementation, will help control operational conditions within an establishment allowing for environmental conditions that are favourable to the production of safe food. It serves as a prerequisite program or universal-type CCP for a HACPP based program.

1.10.03.01 General

Dairy establishments and importers must have a documented program in place to monitor and control all the elements in this section, and maintain the appropriate records.

This task covers equipment and components which may affect the safety of the product. This task assesses:

1. The design and installation of equipment. For example, equipment is to be designed and installed to be accessible for cleaning, sanitizing, maintenance and inspection, to prevent contamination of product during operations, to prevent excessive condensation, permit proper drainage and has acceptable food contact surfaces. There must be a detailed plan showing the types and locations of equipment used in the establishment.
2. The maintenance of all equipment and its components. For example, the calibration of indicating thermometers, gasket and filter replacement program, testing for all critical processes (e.g. HTST, Batch pasteurizer, APPS), etc.

3. The establishment's control and use of equipment seals. There are many tasks within the critical processes (HTST, Batch pasteurizer, APPS) that require a particular device be sealed to maintain the safety of the product. There must be a program in place to monitor and control the use and replacement of these seals. Records must be kept by the establishment for the sealing of equipment, which identifies (e.g. sequential numbering system) and lists the seals used and their location, when the seals are broken, reason why the seal was broken, that the equipment is re-sealed and the person responsible. In order for an establishment to be able to identify which seal has been removed, replaced and recorded, i.e. identifiable, the seals themselves need to be coded. This is the only way for the establishment to exhibit control over the seals.

4. The documented program must specify:
   - protocols and methods of standardization (how it is done and what is done),
   - responsible personnel (qualified and trained) (who does it),
   - inspection frequencies (how often or when it is done)
   - records to be kept
   - parameters of acceptability/unacceptability (tolerances).
   - results of monitoring and verification (both on-site and record review),
   - action to be taken for deviant situations.

The monitoring and verification procedures clearly define the preventative measures taken to prevent the re-occurrence of deviations. The person responsible for verifying the program must be different from the person performing the task.

The equipment must be maintained to ensure that no physical or chemical hazard potentials result (e.g. inappropriate repairs, flaking paint and rust, excessive lubrication). Mechanical parts, lubricants, oils, etc. must not be stored in food containers. Metal detectors can be useful in detecting some physical hazards in foods. If the establishment does not have a metal detector, the inspector must assess if the establishment has control over metal hazards (e.g. inspector would look for high number of foreign object complaints that have been received, maintenance of screens/filters, employee training program to see if employees are trained to observe any equipment malfunctions, etc.).

The preventative maintenance program must be adhered to. When individual items are being assessed (e.g. storage tanks) and poor maintenance is observed and rated unsatisfactory, this task must be referenced to determine if the maintenance program requires updating.

This program must be regularly reviewed and updated as required when changes occur.

**1.10.03.02 Air Quality**
This task covers the air and inert gases that are added directly into the product or on the packaging; for example air used in drying, freezing, agitation (e.g. product storage tanks), and ice cream and fluid milk packaging. It covers both ambient air and compressed air sources.

Air when used for agitation, air blows, drying processes and incorporation into product (overrun) may be a vehicle that allows pathogenic organisms to enter the product. Poor quality air can also lead to product contaminated with particulate matter, condensate or oil.

Processing systems which incorporate air directly into the product, such as freezers, air blows and air agitation systems must be designed to reduce potential contamination and should be easily cleanable. All air used for processing must be filtered. Sanitary check valves should be provided as necessary to prevent product backup into air lines. Air blow and agitation equipment must be routinely checked for proper assembly and cleanliness. Most sanitary check-valves, air blows and agitation equipment are not satisfactorily cleaned by usual CIP methods and should be dismantled and manually cleaned and sanitized routinely.

The design of the compressing equipment must preclude contamination of the air with lubricant vapours and fumes. Oil-free air may be produced by one of the following methods or their equivalent:

1. Use of a carbon ring piston compressor.
2. Use of oil-lubricated compressor with effective provision for removal of any oil vapour by cooling the compressed air.
3. Water-lubricated or non-lubricated blowers.

Oils and lubricants used are listed in the Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Agents published by CFIA or the manufacturer has a letter of no objection from Health Canada.

The air supply must be taken from a clean space or from relatively clean outer air and pass through an air filter upstream from the compressing equipment. This filter is located and constructed so that it is easily accessible for examination. The filter should be protected from weather, drainage, water product spillage and physical damage. Filter size must be such that it is effective for the purpose it is designed. See Appendix 19 - 2 for various types of compressed air systems.

A process air system must contain appropriate filters to remove undesirable particulate matter. If this air is withdrawn from a room, the air supply to the room must be filtered. The air filters in the latter case are rated under task 1.10.01.04 Building Interior. A variety of air filters are available to the industry. Pressure differential prior and after the filter may be used as an indicator of the filter's effectiveness.
To ensure good air quality, the air filters must be cleaned appropriately. Coarse metal mesh filters are cleaned by boiling in an alcohol solution followed by a dip in special adhering oil. Oil coated, fiberglass filters are discarded after use. These filters are used in tandem; the second filter is moved up when the first becomes dirty. If a dirty second filter is observed, then the filters are not being cycled in a satisfactory manner. Common furnace type filters (usually one inch thick) are inefficient and are unsatisfactory.

1.10.03.03 Compressed Air Equipment

This task includes compressed air equipment that is used to operate valves and other equipment pneumatically. This air is not intended to be in direct contact with the product. If the air is in direct contact with the product or packaging, evaluate this under task 1.10.03.02 Air Quality.

For most purposes, the compressed air must be dry. This is achieved by passing the air under pressure through an oil-free filter and moisture trap for removal of solids and liquids. The filter and trap are located in the air pipeline downstream from the compressing equipment and air tank, if one is used. Filter size must be such that it is effective for the purpose it is designed. Air pipeline filters and moisture traps downstream from compressing equipment are not needed where the compressing equipment is of the fan or blower type (See Appendix 19-2).

1.10.03.04 Metal Detector

Metal detectors must be suitable for the specific product, associated hazard and the environmental conditions that the unit will operate in. If metal detectors are used, they must be designed, constructed, installed, calibrated and maintained in accordance with the equipment manufacturer's manual to ensure effective removal of metals. This may include: adjustment for product effect, selection of target metal and size and timing of the reject mechanism.

1.10.03.05 Critical Process Test Procedures

Plant management must ensure that the critical processes (e.g. HTST, Batch Pasteurizer, APPS, HHST/ESL) are tested in accordance with the Critical Process Test Procedures (Chapter 18), the appropriate Dairy Establishment Inspection Manual (DEIM) chapters, and Appendix 19-5 and 19-6 of the DEIM manual. This testing can be done by trained plant personnel or a reliable third party. The results of the testing should be recorded on the CFIA test procedures form. It will also be acceptable for the establishment or third party to use a different form to record the results of testing as long as the inspector assessing this task feels that the results can be easily interpreted, that the form has all the information present and that the test procedures are completed according to the test procedures.

The establishment must have a written procedure outlining what tests are being performed, how often, who is responsible (plant contact and third party, if used),
verification procedures (record and on-site review) to verify that the requirements are being met. If the requirements are not met, appropriate action is taken by the establishment to correct the non-compliant equipment. Depending on the non-compliance, an investigation into the safety of the product may have to be done. Records are being kept to show that testing was done and corrective action was taken. All test procedure results must be reviewed on a timely basis by a member of plant management.

To adequately assess this task, records for all critical processes in the establishment must be available for review. In addition, the inspector is to observe the testing of the equipment at an appropriate frequency to assure proper procedures are being followed. The inspector will be looking to see that the testing is done according to the procedures and frequencies outlined in Chapter 18. If the testing is contracted out a list of the contractors could be maintained and scheduling could be coordinated with the establishment in order for the inspector to observe the testing. A suggested frequency of observation could be once per contractor per area.

For the critical processes, the following tasks are associated with a specified frequency of testing: 1.11.04.03, 1.11.05.01, 1.11.06.02, 1.11.06.03, 1.11.07.01, 1.11.07.03, 1.11.08.04, 1.11.09.01, 1.11.09.05, 1.011.09.06, 1.11.10.04, 1.11.11.02, 1.11.11.06, 1.11.12.03, 1.11.15.04, 1.11.16.03, 1.11.18.02, 1.11.19.02, 1.12.03.03, 1.12.04.03, 1.12.05.05, 1.14.04.03, 1.14.05.01, 1.14.05.02, 1.14.06.02, 1.14.06.03, 1.14.07.01, 1.14.07.03, 1.14.08.03, 1.14.09.04, 1.14.09.05, 1.14.10.04, 1.14.11.01, 1.14.11.03, 1.14.11.04, 1.14.11.05, 1.14.12.01, 1.14.12.04, 1.14.14.01, 1.14.14.02, 1.14.17.02, 1.17.04.03, 1.17.05.01, 1.17.05.02, 1.17.06.02, 1.17.06.03, 1.17.07.01, 1.17.07.03, 1.17.08.03, 1.17.09.01, 1.17.09.04, 1.17.10.04, 1.17.11.04, 1.17.11.05, 1.17.12.01, 1.17.12.04, 1.17.14.01, 1.17.14.02 and 1.17.17.02. When assessing the frequency of testing, each individual task should be assessed as unsatisfactory if the frequency of testing is not adhered to according to those set out in the DEIM, not just once for the overall system. The overall written program for the Critical Process Test Procedures task 1.10.03.05 should also be reviewed to see if there is a concern with the written program and maintenance schedules being followed. In some cases, depending on the scheduling by the third party testing company the timeframes may not be exactly as stated in the DEIM so there should be some flexibility allowed as to the exact timeframe (Not exceeding one month).

<table>
<thead>
<tr>
<th>Equipment program Summary Table</th>
<th>Inspection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Task</strong></td>
<td><strong>Inspection Criteria</strong></td>
</tr>
<tr>
<td>1.10.03.01 General (HS=3)</td>
<td>(A) Documented Program</td>
</tr>
</tbody>
</table>

- Covers equipment and components related to food safety
- Designates responsible personnel
  - qualified
  - trained
- Detailed plan showing types and location of equipment used in plant
- Specifies design and installation criteria
• accessible for cleaning, sanitizing, maintenance, inspection
• prevent contamination of product during operations
• prevent excessive condensation, where necessary
• permit proper drainage and where appropriate is connected directly to drains
• food contact surfaces are smooth, non-corrosive, non-toxic, free from pitting, cracks or crevices, can withstand repeated sanitation
• acceptable coatings, paints, chemicals, lubricants
• Specifies type and procedures of maintenance
  o calibration (e.g. thermometers, scales)
  o replacement (e.g. gaskets, filters, hoses)
  o servicing (e.g. lubrication); acceptable food grade products
  o critical process test procedures
• Specifies procedures for the control, use and replacement of seals
  o seals are individually coded, i.e. identifiable
• Specifies frequency of maintenance
• Specifies parameters of acceptability/tolerances
• Specifies preventative measures to prevent the re-occurrence of deviations
• Minimizes any cross contamination risks
• No physical or chemical hazard potentials result (e.g. inappropriate repairs)
• If no metal detector, metal hazards are controlled (# of complaints related to foreign objects, equipment maintenance program, employee training)
• Preventative maintenance program is adhered to
• Updated as required

(B) Records

A representative sampling of the plant's historical records must be assessed.

1. Records must be:
   o Accessible and complete
   o Clear, legible and permanent
2. Information must indicate:
   o All equipment and components monitored
   o Equipment seal usage monitored
   o Frequency and results of monitoring and verification
   o Satisfactory follow-up when deviations found and
documentation of actions taken

**Note:** This task evaluates the presence of an Equipment Program. Individual task Inspection Criteria verify that the program is in place and is effective.

**(A) General**

- Not a source of contamination
- Food grade oil used as lubricant if in contact with product

**(B) Air Intakes**

- Filtered
- Clean
- Well located

1.10.03.02 Air Quality (HS=2)

**(C) Filters**

- Must be present
- Proper type
  - properly sealed against the frame and gaskets
  - tight fitting
- Maintenance
  - regularly scheduled

**(A) General**

1.10.03.03 Compressed Air Equipment (HS=3)

- Filters, traps and condensers
  - cleaned and replaced as required
- No build-up of water and oil

**(A) General**

1.10.03.04 Metal Detector (HS=2)

- Used in accordance with manufacturer=s manual
- Must be tested on a regular frequency
- Operator demonstrates hazard is controlled
- Test Records
  - accurate and complete; available; clear, legible and permanent
  - demonstrate equipment is capable of identifying test material
- Satisfactory follow-up when deviations found and documentation of actions taken

1.10.03.05 Critical (A) Requirements
Process Test Procedures (HS=2)

- Written procedure
- Testing by trained personnel
- In accordance with Critical Process Test Procedures
- Plant contact reviews test results

(B) Records

A representative sampling of the plant=s historical records must be assessed.

1. Records must be:
   - Accurate and complete; available
   - Clear, legible and permanent

2. Information must indicate:
   - All test procedure records
   - Frequency and results of monitoring and verification
   - Alterations and repairs done (and in a timely manner)
   - Satisfactory follow-up on out of specification findings and documentation of actions taken
     - product safety assessment required

1.10.04 - Personnel Program

The objective of the personnel program is to ensure safe food handling practices. The personnel program is to provide, on an ongoing basis, the necessary training to production personnel.

This documented program, as well as its effective implementation, will help control operational conditions within an establishment allowing for environmental conditions that are favourable to the production of safe food. It serves as a prerequisite program or universal-type CCP for a HACPP based program.

1.10.04.01 General

Every dairy establishment and importer must have a written training program for employees, providing adequate training in personal hygiene and the hygienic handling of food to all food handlers at the beginning of their employment. This training is to be reinforced and updated at appropriate intervals. An adequate personnel program monitors and controls all elements in this section and maintains the appropriate records.

Adherence to the criteria is verified by examining the establishment's written program that outlines the procedures that will be undertaken to ensure adequate training is maintained. The program must specify:
• areas to be inspected (what is done),
• tasks to be performed (how it is done),
• person responsible (who does it),
• inspection frequencies (how often or when it is done),
• records to be kept
• parameters of acceptability/unacceptability (tolerances)
• results of monitoring,
• verification procedures (both on-site and record review)
• action to be taken for deviant situations.

The monitoring and verification procedures clearly define the preventative measures taken to prevent the re-occurrence of deviations. The person responsible for verifying the program must be different from the person performing the task. This program must also be updated as required when changes occur.

Training must be adequate and suitable to the complexity of the manufacturing process and the tasks assigned. For example:

1. Personnel must be trained to understand the importance of the critical control points for which they are responsible, the critical limits, the procedures for monitoring, the action to be taken if the limits are not met, and the records to be kept.
2. Personnel responsible for maintenance of equipment impacting on food safety, are to be properly trained to identify deficiencies that could affect product safety and to take the appropriate corrective action i.e., in house repairs, contract repairs. Individuals performing maintenance on specific equipment must also be appropriately trained, e.g. closing machines, recorders. Personnel responsible for critical process test procedures are properly trained.
3. Personnel and supervisors responsible for the sanitation program must understand the principles and methods required for effective cleaning and sanitizing. Employees handling hazardous chemicals should be instructed in safe handling techniques.
4. Additional training needs to be provided as necessary to ensure current knowledge of equipment and process technology, e.g. specific technical training, apprenticeship programs, etc.

In order to minimize the risk that dairy products could be subject to while under control of the establishment, it is recommended that management provide training in food security awareness to encourage all staff to be alert to any signs of tampering or other malicious or terrorist actions or areas that may be vulnerable to such actions. Employees should be encouraged to be alert to the presence of unidentified or unknown individuals that are in areas to which they do not have designated access and report them to management.
This task will assess the written program and the records kept. The assessment of other inspection tasks will provide on-site verification of the effectiveness of the plant's training program.

1.10.04.02 Flow and Practices

This task will assess the movement or flow of both people and equipment throughout the establishment as well as the processing practices (good manufacturing practices) utilized.

To reduce the risk of contamination in processing and packaging areas the movement of personnel and equipment between areas must be restricted and well controlled. This applies to lab personnel, delivery and maintenance personnel as well as staff performing various processing activities. Generally speaking, personnel (including maintenance staff) may move freely from microbiologically clean areas to less clean ones but their movement back to a cleaner area must be restricted or very well controlled. Personnel in raw receiving areas **should not move into any** other areas of the plant unless strict procedures are followed (e.g. foot baths, hand dips, etc.). Employees responsible for the receiving of raw milk must not move throughout the plant as their clothing and shoes may be a source of contamination in clean areas. This also applies to all visitors to the plant such as farmers, salespersons and field personnel. The colour coding of clothing facilitates the monitoring of personnel flow.

With respect to equipment layout, a process flow that is straight and simple is preferable from a sanitation point of view. The movement of portable equipment (e.g. pallets, carts, etc.) from one area to another must also be restricted and controlled to minimize the potential for cross contamination. The same principle applies to equipment as to personnel flow; equipment should not move to or back from cleaner areas after being in less clean areas without appropriate controls.

Special attention must be made to control frequent personnel and equipment flow between wet areas of the plant to minimize the risk of spreading contamination. The use of strategically located and well maintained foot baths or sprays may be one method to minimize the risk of spreading contamination.

To evaluate the flow aspect uniformly:

1. observe if personnel/equipment move between activity areas.
2. observe if controls are in place (required if movement occurs from less clean to cleaner areas).
3. if controls are not adequate, assess the task as not satisfactory.

The manufacturer ensures good personal hygiene and hygienic behaviour and work procedures are followed to prevent contamination of food products.

1.10.04.03 Hygiene & Health
This task assesses the employee's hygiene as well as their personal behaviour and habits in areas where food is processed. Practices related to food handling are evaluated under task 1.10.04.02 Flow and Practices.

Clean and appropriate clothing, good grooming and habits as well as employee health monitoring reduce the possibility of milk, milk products, containers and equipment from becoming contaminated. Although no jewellery, including facial adornments is preferred, jewellery worn for religious, marital or health reasons must be properly secured and covered. These items have the potential to fall into or otherwise contaminate the dairy product and as such pose a food safety hazard. Clothing cleaned by a private service should be delivered clean and protected and stored separately from street clothes.

It is recommended that employee clothing should be white or light coloured or colour coded to distinguish work areas (e.g. red in raw receiving areas and white in the packaging room). It is recommended that hair nets that are used be obvious and shower type.

Poor hygiene and all unhygienic behaviours that would contaminate food must be prohibited. Personnel engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example smoking, spitting, chewing or eating, and sneezing or coughing over unprotected food. Personal effects and street clothing must not be kept in food handling areas and must be stored in a manner to prevent contamination. In-plant footwear and clothing is to worn only within the plant. Wearing in-plant footwear and clothing outside the plant and then returning to the plant could result in a source of contamination to the product or processing area. The establishment would develop policies and procedures to mitigate this requirement.

It is important that employees with obvious health conditions are not in direct contact with food products. Plant management must have a policy to prevent personnel known to be suffering from, or known to be carriers of a disease transmissible through food, from working in food handling areas. This policy could be part of the company's written training program directed to all new employees. Proper training and education of employees in food safety, maintenance of hand washing facilities and sanitary waste handling are measures that can be included in the preventing the spread of foodborne disease.

The manufacturer must require that employees advise management when they are suffering from a communicable disease likely to be transmitted through food. Employees should be encouraged to report to their supervisors whenever they have diarrhoea, sore throat, fever, a cold, or open skin lesions, or are jaundiced. Employees with cuts or wounds must be assigned to non-product work areas or their cut or wound must be protected by a secure, waterproof covering. Latex gloves are not recommended for use in a food establishment. There is evidence to suggest that for some individuals there is a potential allergy concern with the transfer of latex to food products. This is not a mandatory requirement, but only a recommendation that when establishments use sanitary gloves they choose a non-latex type.
The Health Surveillance and Management Procedures For Food-Handling Personnel Technical Report from the World Health Organization, dated 1989 is a good reference document on the hygienic approach to food handling. According to this document infections and intoxications potentially transmissible by food handlers include: Staphylococcus aureus infection, typhoid and paratyphoid fevers, non-typhi salmonellosis, Escherichia coli enteritis, Shigellosis, Cholera and Viral hepatitis A. Some other illnesses to be concerned with include those due to Campylobacter jejuni, Rotovirus, E. coli 0157:H7, Norwalk and Norwalk-type viruses, Streptococcus pyogenes, Yersinia enterocolitica and Giardia lambia. Since health examinations of food-handling personnel are not effective in preventing the spread of foodborne diseases, alternative measures might include surveillance of outbreaks of foodborne diseases, the use of a HACCP system within the food establishment, education and training of managers and food handlers in food safety and provision and maintenance of hand-washing facilities and the sanitary collection and disposal of wastes.

1.10.04.04 Handling of Materials

This task assesses how personnel handle the ingredients (e.g. fruits, nuts, powders, starter cultures, etc.) and packaging materials (glass containers, foil and plastic wrap, powder bags, etc.) during processing. It also assesses the manual formation of packaging containers such as ice cream cartons.

The materials must not pose a contamination risk as they are received into the processing area and when they are in use. If these materials are not properly handled they can be contaminated by dust, foreign materials, moisture and personnel; subsequently they can affect the safety of the product. Prior to filling, containers should be cleaned by air, suction or water.

Task 1.10.02.03, Incoming Material, evaluates the initial receipt of incoming ingredients and packaging material.

Personnel Program Summary Table

<table>
<thead>
<tr>
<th>Task</th>
<th>Inspection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Documented Training Program</td>
<td></td>
</tr>
<tr>
<td>1. Policy</td>
<td>Adequate and suitable training for all production personnel covering the following areas:</td>
</tr>
<tr>
<td>1.10.04.01 General (HS=3)</td>
<td>flow/controlled access of personnel and visitors</td>
</tr>
<tr>
<td></td>
<td>hygienic food handling</td>
</tr>
<tr>
<td></td>
<td>responsibilities for food safety controls (e.g. Hazard Analysis Critical Control Point (HACCP))</td>
</tr>
<tr>
<td></td>
<td>maintenance of equipment impacting on food safety</td>
</tr>
</tbody>
</table>
- sanitation
- technical training, where necessary
  - System to monitor the health, hygiene and habits of employees involved in food handling
  - System to assess adherence to policies
  - Specifies person responsible, inspection frequencies
  - Specifies parameters of acceptability/tolerances
  - Specifies preventative measures to prevent re-occurrence of deviations
  - Updated as required

(B) Records

A representative sampling of the plant's historical records must be assessed.

1. Records must be:
   - Accessible and complete
   - Clear, legible and permanent

2. Information must indicate:
   - All training, monitoring and verification (both on-site and record review) results
     - training has occurred
     - frequency and type of training
     - re-training activity
   - Satisfactory follow-up when deviations found and documentation of actions taken

(A) Policy

- Controls movement of personnel and equipment

(B) Flow

- No unauthorized personnel/equipment in areas
- Well controlled movement between areas
- Straight and simple process flow

(C) Practices

- Operational Practices
  - food
  - cleaning
  - wastes
- Duties to maintain food safety controls (e.g. HACCP)
(A) Hygiene

1. Clothing
   - Clean
   - Washable or disposable
   - Cleaned on-site or by private service only
   - No buttons or pockets above waist
   - Hair coverings and beard-coverings; properly worn so as to completely cover the hair
   - Footwear and clothing for in-plant use, where required
   - If required, sanitary disposable gloves

2. Grooming
   - Clean nails; no polish
   - No jewelry; wedding bands/medic alerts covered by appropriate glove or covering

3. Health Condition
   - No cuts or wounds exposed
   - Program that prevents an employee from being in contact with food while:
     - inflicted with skin infections, sores, diarrhoea, colds, etc.
   - Employees advise management when suffering from a communicable disease that could be transmitted through food

(B) Behaviour and Habits

- Hand washing/Sanitizing
  - starting and returning to work
  - after using toilet facilities
  - after hands soiled or contaminated
  - employees use hand dips, where required
- No eating; gum chewing
- No use of tobacco, no smoking
- No spitting
- No sneezing or coughing over unprotected food
- Personal effects and street clothing not stored in food handling areas

1.10.04.03 Hygiene & Health (HS=2)

1.10.04.04 Handling of Materials (ingredients, packaging materials) (HS=2)

(A) Receiving into processing area

- No evidence of pest contamination
- No dust, rust, etc.
- Outer wrappings cleaned and/or removed
(B) During processing

- Materials protected from aerosols, moisture, contamination
  - formed containers inverted
  - lids or protective coverings
- Sanitary handling
- Contaminated materials not re-used
- Unused portions resealed and returned to storage

1.10.05 - Sanitation Program

Every dairy establishment and importer has an effective sanitation program in place to prevent contamination of food. This task assesses the sanitation of all structures, equipment and utensils.

This documented program as well as its effective implementation will help control operational conditions within an establishment allowing for environmental conditions that are favourable to the production of safe food. It serves as a prerequisite program or universal-type CCP for a HACCP based program.

1.10.05.01 General

Each plant must have a documented cleaning and sanitation program which specifies:

- the cleaning policy (what is done),
- procedures used (how it is done),
- responsible personnel (who does it),
- type and frequency of cleaning (how often or when it is done),
- records to be kept
- parameters of acceptability/unacceptability (tolerances),
- results of monitoring,
- cleaning verification procedures (both on-site and record review),
- action taken for deviant situations.

The monitoring and verification procedures clearly define the preventative measures taken to prevent the re-occurrence of deviations. The person responsible for verifying the program must be different from the person performing the task. This program must also be updated as required when changes occur. Special sanitation and housekeeping procedures required during production must be specified, e.g. removal of product residues during breaks. Sanitation training is addressed under task 1.10.04.01 General.

Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning and chemical methods using detergents, alkalis or acids. Cleaning procedures generally involve removing gross debris.
from surfaces; applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension; rinsing with water to remove loosened soil and residues of detergent; and where necessary disinfection with subsequent rinsing unless manufacturers' instructions indicate otherwise.

Clean Out Of Place (COP) or hand cleaned refers to equipment that is disassembled for cleaning and inspection at a specified frequency, either after use or daily. Clean In Place (CIP) refers to equipment cleaned by an accepted CIP system and is disassembled for inspection at the frequency prescribed in the CIP. Chemicals are used in accordance with the manufacturer's instructions and are listed in the Reference Listing of Accepted Construction, Packaging Materials and Non-Food Chemical Agents published by CFIA or the manufacturer has a letter of no objection from Health Canada. Cleaning and sanitizing equipment is designed for its intended use and is properly maintained.

The cleaning policy should minimize cross contamination risks. For example, pipelines used for both pasteurized and unpasteurized cheese must be completely cleaned if pasteurized cheese is processed after unpasteurized cheese, pipelines used for both milk and non milk products must be completely cleaned if non milk products are processed after milk products.

Plant management must ensure that equipment and/or pipelines are not installed in a manner that will jeopardize the integrity of the CIP systems, resulting in cross-connections or processing problems. The concepts of Appendix 19 - 10 apply to CIP supply lines and return line circuits used for CIP cleaning and mini-washes.

Operations must not begin until after sanitation requirements have been met.

When individual tasks are being assessed (e.g. storage tanks) and poor sanitation is observed and rated unsatisfactory, this task must be referenced to determine if the sanitation program requires updating.

1.10.05.02 Plant Clean In Place (CIP) System

This technique is used for permanent installations with many pipes and tanks, which are practically impossible to clean by other means. It utilizes a combination of physical and chemical means to remove soil from product contact surfaces. Re-contamination potential is also reduced by this cleaning technique because it is a closed system.

For establishments that use their plant CIP system for both the raw and pasteurized product sides, the CIP system should be assessed under this task, not 1.10.05.03. Ideally, the plant should have independent CIP systems for raw and pasteurized product lines and equipment. If only one system is used, the pasteurized product lines and equipment must be cleaned first, followed by the raw product lines and equipment. When one CIP system is being used for both raw and pasteurized product lines and equipment the establishment should validate their procedure and chemical usage with their cleaning supplier to ensure the adequacy of the CIP Records of the validation should be kept and available to the
inspector upon request. Establishments should be encouraged to have two separate CIP systems, one for the raw product side and one for the pasteurized product side.

Cleaning conditions vary widely from one installation to another and therefore each system must be dealt with according to its specific requirements.

A CIP system can be an independent system or a partial system as in the case of the HTST circulated through the Constant Level Tank. In both cases, the effectiveness of CIP procedures is largely determined by:

1. time
2. temperature
3. concentration
4. velocity

In smaller establishments or in some instances, special demands have resulted in the establishment using equipment separate from the main CIP system to circulate cleaning and sanitizing solutions. These systems are often used to clean fluid fillers or product vessels and as such are normally smaller and may be mounted on wheels to facilitate relocation close to the equipment being washed after production. For example, the system may be as simple as a pump rolled up to a tank for the circulation of cleaning and sanitizing solutions. Baskets may be hung in the solution tank to wash filler parts at the same time as the circulation of cleaning and sanitizing solutions. In all cases the system must facilitate the monitoring of temperature, time and chemical concentrations to ensure these parameters are maintained until the end of the wash. If the system does not incorporate a recording chart, additional records must be kept to document that the temperature, time and chemical concentrations meet the minimum requirements. Although the velocity of the circulated solutions are not normally monitored per wash on these smaller systems, inadequate flows can have a detrimental effect on the quality of the wash and can be measured or calculated to meet the recommendations of the manufacturer of the cleaning compounds.

In order for the CIP technique to be effective, the materials used on devices must be resistant to corrosion and the surfaces in contact with the product must be smooth, free of cracks and capable of withstanding the effects of cleaning solutions. Each element in the manufacturing line or CIP circuit must be free of dead zones and easy to inspect. All return lines to CIP tanks must break to the atmosphere in order to prevent back siphonage. Swing elbows would be acceptable. The following are frequently encountered deficiencies in CIP cleaning systems:

1. Conventional fittings used rather than CIP fittings or welded joints.
2. Failure to provide slope or drainage.
3. Inadequate pipeline supports.
4. Supports should not allow electrolytic action between support and pipeline (supports to be made of stainless steel, or should have rubber or plastic contact points with the pipeline).
5. No automatic temperature control for solutions.
6. No recording thermometer.
7. Poor condition gaskets and dirty exterior surfaces.
8. Inadequate solution velocity.
9. Recording charts show variations from the established cleaning regimen.
10. Failure to monitor cleaning effectiveness.

To achieve satisfactory cleaning and to prevent pipeline corrosion, the recommendations of the cleaning compound manufacturer should be followed with respect to time, temperature and concentration of cleaning and sanitizing. These instructions should be posted or easily accessible for use.

**1.10.05.03 Truck / Raw Product CIP System**

For establishments that use their truck CIP system for raw product, the CIP system should be assessed under this task. If it is also to clean other pieces of equipment it should be rated under task 1.10.05.02 Plant CIP system.

CIP cleaning utilizes a combination of physical and chemical means to remove soil from product contact surfaces. Re-contamination potential is also reduced by this cleaning technique because it is a closed system.

In order for the CIP technique to be effective, the materials used on devices must be resistant to corrosion and the surfaces in contact with the product must be smooth, free of cracks and capable of withstanding the effects of cleaning solutions. Each element in the manufacturing line or CIP circuit must be free of dead zones and easy to inspect.

The effectiveness of CIP procedures is largely determined by:

1. time
2. temperature
3. concentration
4. velocity

The following are frequently encountered deficiencies in CIP cleaning systems:

1. Conventional fittings used rather than CIP fittings or welded joints.
2. Failure to provide slope or drainage.
3. Inadequate pipeline supports.
4. Supports should not allow electrolytic action between support and pipeline (supports to be made of stainless steel, or should have rubber or plastic contact points with the pipeline).
5. No automatic temperature control for solutions.
6. No recording thermometer.
7. Poor condition gaskets and dirty exterior surfaces.
8. Inadequate solution velocity.
9. Recording charts show variations from the established cleaning regimen.
10. Failure to monitor cleaning effectiveness.

To achieve satisfactory cleaning and to prevent pipeline corrosion, the recommendations of the cleaning compound manufacturer should be followed with respect to time, temperature and concentration of cleaning and sanitizing. These instructions should be posted or easily accessible for use.

**1.10.05.04 Pest Control**

Every dairy establishment and importer must have an effective pest control program in place to prevent contamination of food. This task assesses the control of the entry of pests, elimination of harbours and extermination of pests.

This documented program as well as its effective implementation, will help control operational conditions within an establishment allowing for environmental conditions that are favourable to the production of safe food. It serves as a prerequisite program or universal-type CCP for a HACPP based program.

Three different activities are involved in a pest control program. They are:

1. Prevention of entry of pests into the establishment,
2. Elimination of potential sites for harbourage of pests, and
3. Extermination of pests that do enter premises.

Activities (a) and (b) are evaluated with respect to individual inspected tasks, e.g. grates on sewer drains that prevent rodents from gaining entry to the plant are evaluated with task 1.10.01.05 Waste Disposal. Accumulation of dust and debris that provides a harbourage for pests is also evaluated under specific tasks, e.g. task 1.10.01.04 Building Interior, would evaluate dust accumulations on high exposed beams in the ceiling that provide insect harbourage spots.

The plant should consider the following items when developing their effective written pest control program for the premises and equipment:

- The name of the person at the establishment responsible for pest control (who is doing it).
- Where applicable, the name of the pest control company or the name of the person contracted for the pest control program.
- The list of chemicals used, the concentration, the location where applied, method and frequency of application (when and what is being done and how often it is done).
- A map of trap locations.
- The type and frequency of inspection to verify the effectiveness of the program (on-site and record review). The person responsible for verifying the program must be different from the person performing the task.
parameters of acceptability/unacceptability (tolerances)
- records and results of monitoring and action taken for deviant situations.
- the monitoring and verification procedures define the preventative measures taken to prevent the re-occurrence of deviations.

This program must also be updated as required when changes occur.

Proper understanding of the techniques used to exterminate pests is required so that only acceptable chemicals and devices are used in the proper areas, and that application methods do not contaminate products, equipment or packaging material. The plant may have an in-house pest control program or contract out this activity to professionals. Pesticides used are registered under the **Pest Control Products Act** and **Regulations** (PMRA) and are listed in the Reference Listing of Accepted Construction, Packaging Materials and Non Food Chemical Agents published by CFIA. Pesticides are used in accordance with the label instructions and are regularly inspected and maintained by the contractor, the plant or both. Properly located and well maintained electric insect killers are acceptable. Knock down type sprays or prolonged insect strips must not be used in product handling areas. Bait stations with exposed poison are also not acceptable. Air curtains with properly maintained air pressure may be used as a method to prevent pest entry. Treatment of equipment, premises or ingredients to control pests must be used in accordance with label instructions. Birds and animals are excluded from establishments.

The effectiveness of the program is evaluated by observing if live pests are present, monitoring the records and making observations with regards to the population of exterminated pests.

**Sanitation Program Summary Table**

<table>
<thead>
<tr>
<th>Task</th>
<th>Inspection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(A) Documented Program</strong></td>
<td></td>
</tr>
<tr>
<td>• Covers all areas and equipment&lt;br&gt;  - structure&lt;br&gt;  - equipment&lt;br&gt;  - utensils&lt;br&gt;  - any others impacting on food safety</td>
<td></td>
</tr>
<tr>
<td>• Designates responsible personnel&lt;br&gt;  - qualified</td>
<td></td>
</tr>
<tr>
<td>1.10.05.01 General (HS=3)</td>
<td></td>
</tr>
<tr>
<td>• Specifies cleaning procedure&lt;br&gt;  - chemicals used and concentration; acceptable types&lt;br&gt;  - temperature requirements&lt;br&gt;  - procedures used; steps and methods (COP, CIP)&lt;br&gt;  - equipment used</td>
<td></td>
</tr>
<tr>
<td>• Specifies frequency of cleaning and sanitizing</td>
<td></td>
</tr>
<tr>
<td>• Cleaning policy&lt;br&gt;  - minimizes cross contamination risk</td>
<td></td>
</tr>
<tr>
<td>• Verifies cleaning effectiveness</td>
<td></td>
</tr>
</tbody>
</table>
• Specifies parameters of acceptability/tolerances
• Specifies preventative measures to prevent re-occurrence of deviations
• Updated as required
  o new/modified equipment or processing techniques
  o ineffective cleaning
  o adherence and effectiveness to sanitation program is monitored/verified (e.g. swabs, sensory inspection, direct observation)

(B) Operation

• Instructions available and used
• Cleaning/sanitizing equipment properly maintained
• No processing until sanitation requirements met

(C) Records

A representative sampling of the plant's historical records must be assessed.

1. Records must be:
   o Accessible and complete
   o Clear, legible and permanent
2. Information must indicate:
   o Date and person responsible
   o All equipment, structure and utensils' cleaning records (temperature, time, concentration, etc.)
   o Frequency and results of monitoring and verification
   o Microbiological tests where appropriate
   o Satisfactory follow-up when deviations found and documentation of actions taken

Note: This task evaluates the presence and usage of a Sanitation Program. Individual task evaluations for cleanliness will determine if the program is used and effective.

(A) Circuit Diagram (for CIP)

1.10.05.02 Plant CIP System (more to follow) (HS=2)

• Available; complete and up-to-date (includes all pipelines)
• No cross connections
  o prevent mixing of CIP solutions with products and potable water for final rinse

(B) Components

1. Pumps
Solution and return pumps
  - centrifugal type
Chemical feed pump
  - positive displacement type

2. Tanks (solution and rinse)
  - Stainless steel or corrosion resistant
  - Kept covered
  - Stainless steel or corrosion resistant baskets for parts washed in tank at same time (if applicable, for mobile CIP systems)

3. Pipelines and valves
  - Rigid
  - Sloped to enable draining
  - Pipelines equipped with line screens or filters
  - Food grade hoses designed for CIP use or regularly disassembled for inspection/cleaning (if applicable, for mobile CIP systems)

4. Thermostat
  - Indicating thermometer (optional)
    - located on return solution tank
    - may be located in return line or in baskets when parts being washed (if applicable, for mobile CIP systems)
  - Recording thermometer and charts
    - located in return solution line
    - located in return line or in baskets when parts being washed (if applicable, for mobile CIP systems)

5. Temperature controller
  - Located on return solution tanks
  - If not present for mobile systems, manual records kept for time, temperature and concentrations; recorded at start and end of CIP

(C) Operation

1. Independent raw, pasteurized systems or one system with appropriate cleaning protocol (pasteurized first)
2. Cleaning instructions posted or easily accessible and followed
  - Connecting/disconnecting information for equipment
3. Charts/Records
  - For each cleaning cycle
  - Record of temperature and time
  - Dated; operator's signature
  - Record of solution concentrations
4. Program to verify system effectiveness
o Equipment inspected
o Charts checked
   • temperature; time; solution concentration
o Compare with product quality records
o Verify CIP system in operation
   • review of records, proper operation of the CIP programming

(A) Circuit Diagram

- Available; complete and up-to-date
- No cross connections
  o prevent mixing of CIP solutions with raw milk and potable water for final rinse

(B) Components

1. Pumps
   o Solution and return pumps
     • centrifugal type
   o Chemical feed pump
     • positive displacement type

2. Tanks (solution and rinse)
   o Stainless steel or corrosion resistant
   o Kept covered

3. Pipelines and valves
   o Rigid
   o Sloped to enable draining
   o Pipelines equipped with line screens or filters

4. Thermometers
   o Indicating thermometer (optional)
     • located on return solution tank
   o Recording thermometer and charts
     • located in return solution line

5. Temperature controller
   o Located on return solution tanks

(C) Operation

1. Cleaning instructions posted or easily accessible and followed
   o Connecting/disconnecting information for truck equipment hook-up

2. Charts/Records
   o For each cleaning cycle
   o Record of temperature and time
   o Dated; operator's signature
3. Program to verify system effectiveness
   o Equipment inspected
   o Charts checked
     ▪ temperature; time; solution concentration
   o Verify CIP system in operation
     ▪ review of records, proper operation of the CIP programming

(A) Documented Program

1. Complete
   o Prevent entry
     ▪ appropriate use of air curtains and insect electrocutors
     ▪ area under loading sealed
   o Eliminate harbourages
   o Exterminate pests

2. Designated responsibility
   o Plant contact person and extermination company (if applicable) names
     ▪ familiar with insecticide applications and rodent control methods
   o Inspect and service traps and bait stations at specified frequency
   o Maintain appropriate records

1.10.05.04 Pest Control (HS=3)

3. Specifies procedures
   o Chemicals and concentrations; acceptable types
   o Procedures used; steps and methods
     ▪ location of where applied
     ▪ frequency of application
   o Map of trap locations

4. Monitored to evaluate effectiveness
   o Type and frequency of inspection
   o Specifies parameters of acceptability/tolerances
   o Specifies preventative measures to prevent re-occurrence of deviations
   o Updated as required

(B) Operation

- No pests
- Equipment/traps
  o acceptable type; well maintained; well located
- Chemical use avoids contamination
not to exceed limits prescribed on the label

(C) Records

A representative sampling of the plant's historical records must be assessed.

1. Records must be:
   o Accessible and complete
   o Clear, legible and permanent

2. Information must indicate:
   o Date of service; date of fumigation
   o Number, type and location of stations
   o Type of chemical used and method
   o Person responsible
   o Survey of pest population observed and exterminated
   o Frequency and results of monitoring and verification
   o Satisfactory follow-up when deviations found and documentation of actions taken

1.10.06 - Recall Program

This task assesses a manufacturer's and importer's written recall procedure to ensure an effective recall of any lot of food from the market. This procedure helps to minimize the confusion that may result during a recall. The information in this document must be kept current. It should include details about the retrieval of information that is typically required during a recall. This includes:

- The person or persons responsible (who does it).
- The roles and responsibilities for coordination and implementation of a recall (what is done).
- Methods to identify, locate and control recalled product (how and when it is done).
- A requirement to investigate other products that may be affected by the hazard and that should be included in the recall.
- Procedure for monitoring the effectiveness of the recall, e.g. effectiveness check to the appropriate level of distribution specified in the recall notice.
- Immediate notification to the CFIA Area Recall Coordinator in the area or region where the manufacturer is located, or in the case of a provincially licensed establishment, the appropriate provincial authority. A list of CFIA Area Recall Coordinators is available on the CFIA website.

Flow charts are useful to summarize the steps involved in a recall.
Manufacturing records must be detailed enough to trace back a particular lot of product and even a specific ingredient or additive added to the product. Distribution records must be able to account for the total quantity of the lot produced. Parts of a lot that are on hand, on hold or reworked must also be referenced in the records. The distribution list should be product and lot code specific. If the distribution list is not specific, the manufacturer must be prepared to do a wider recall to bring back all implicated products.

The manufacturer must be capable of producing accurate information on a timely basis to verify that all affected product can be rapidly identified and removed from the marketplace. This can be demonstrated by complete manufacturing and distribution details for every lot.

The establishment must assess the effectiveness of their notification. This should include the number of accounts that were notified, the number of accounts that were contacted or checked to see if they had received the recall notification, method of confirming that the accounts were notified. A statement describing how they determined if the recall notification was effective, a statement of the recall notification effectiveness, i.e. satisfactory, not satisfactory, and a statement of corrective action to be taken where it is determined that the recall was not satisfactory.

Periodic testing (minimum of once per year) of the recall program must be done to verify the capability of the procedure to rapidly identify and control a code lot of potentially affected product and reconcile the amount of product produced, in inventory and in distribution. The establishment should be able to demonstrate the traceability of the affected product to the distribution centre level. Any deficiencies in the recall procedure must be identified and corrected.

An establishment must have a standard documented procedure which details the action taken when complaints are received on dairy products. The complaint should be taken by a designated individual. The complaint file should include recording of the initial complaint information, investigating the complaint and recording the findings and taking action based on the investigation findings. The investigation should be investigated by a trained person. When all the investigation findings are collected a decision of the action to be taken must be made. In some instances, a complaint investigation by the establishment may reveal that the product should be withdrawn from the market. This recall of product is undertaken when a product is considered to be a potential health hazard or in violation of government regulations. Should an establishment be unsure of the need for a recall or to ensure the action/decision is correct, they should contact the CFIA for consultation. The decision must include what to do with the affected product(s) and how to correct the problem.

Once the recall is complete and all the non-compliant product is removed from the marketplace, the manufacturer or importer must perform an assessment to determine the root cause of the recall. The establishment must develop and implement appropriate corrective measures to prevent the re-occurrence of the deficiencies or a similar violation which may result in future recall action. The establishment must review the current
written procedures used in the manufacture/importation or sale of the non-compliant product and the appropriate changes must be made to prevent the re-occurrence. Detailed records must be kept by the establishment documenting that the assessment was completed and what corrective action was taken.

For further information on this task please refer to the Recall Plan - Manufacturers' Guide

Additional guidelines on food emergencies can be found in the Canadian Food Inspection Agency - Food Investigation Response Manual (CFIA).

Recall Program Summary Table

<table>
<thead>
<tr>
<th>Task</th>
<th>Inspection Criteria</th>
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</thead>
<tbody>
<tr>
<td>(A) Documented Program</td>
<td></td>
</tr>
<tr>
<td>1. Recall Procedures</td>
<td></td>
</tr>
<tr>
<td>o Identifies all personnel and alternates (phone numbers)</td>
<td></td>
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<tr>
<td>• lists roles and responsibilities</td>
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<tr>
<td>o Outlines step-by-step procedures</td>
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<td>• extent and depth of recall</td>
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<tr>
<td>o Specifies communication target groups, methods and channels</td>
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<tr>
<td>o Specifies methods of control of returned product</td>
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<tr>
<td>• instructions for product disposition</td>
<td></td>
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<tr>
<td>• requirement to investigate other products affected</td>
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<tr>
<td>o Includes methods to monitor recall effectiveness</td>
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<tr>
<td>• number of accounts that were notified of the recall</td>
<td></td>
</tr>
<tr>
<td>• number of accounts that were contacted or checked to see if they received the recall notification</td>
<td></td>
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<tr>
<td>• method of confirming that the accounts were notified</td>
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<tr>
<td>• statement describing how they determine if recall was effective</td>
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<tr>
<td>• statement of recall effectiveness, i.e. satisfactory, not satisfactory</td>
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<tr>
<td>• corrective action to be taken if recall not satisfactory</td>
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<tr>
<td>o Testing of recall program (mock recall)</td>
<td></td>
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<tr>
<td>• to be tested a minimum of once per year</td>
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<tr>
<td>• to demonstrate the traceability of the affected product to the distribution centre level</td>
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<tr>
<td>• description of test scenario</td>
<td></td>
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<tr>
<td>• date of test</td>
<td></td>
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<tr>
<td>• problems identified during the test</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1.10.06.01 Recall Program (more to follow) (HS=3)</td>
<td></td>
</tr>
</tbody>
</table>
changes made to correct the problem

- Immediate notification to the CFIA Area Recall Coordinator including the following information:
  - amount of product produced (inventory and distributed)
  - name, size, code, or lot number of recalled food
  - distribution area
  - reason for recall
- Self-assessment and implementation of corrective measures to determine root cause
  - satisfactory follow-up
  - documentation of action taken

2. Manufacturing (Production) Details
   - Product identification
   - Code, lot (permanent, legible)
     - establishment identification
     - day, month, and year produced
   - All ingredients/additives (code trace back)
   - Quantities (components and end product)
   - Initials of responsible operator

3. Distribution Details
   - Name, address and phone number of all lot receivers
   - Location of non distributed lots
   - Date shipped

4. Complaint File
   - Initial complaint information
     - taken by a designated individual
   - Investigation of the complaint and record of findings
     - by a trained person
   - Action taken

(B) Records

A representative sampling of the plant's records must be assessed.

1. Records must be:
   - Accessible and complete
   - Clear, legible and permanent

2. Information must indicate:
   - Recall incidences and follow-up
     - reason
     - recalled product identification
     - amount of recalled product involved
     - areas of distribution
     - information on other products implicated
   - Manufacturing (production) and distribution details for
1.10.07 - Process Control Program

The objective of this program is to ensure the production of safe food. By having controls in place throughout the manufacturing process to monitor product formulation, labelling and preparation, shelf life and finished product analysis, the likeliness of having to recall product after it has left the establishment could be reduced.

This documented program as well as its effective implementation, will help control operational conditions within an establishment, allowing for environmental conditions that are favourable to the production of safe food. It serves as a prerequisite program or universal-type CCP for a HACCP based program.

1.10.07.01 General

Dairy establishments and importers (where applicable) must have a documented program in place to monitor and control all elements in this section, and maintain the appropriate records.

The process controls that must be covered in this program include product formulae, food additives, nutritional requirements, label accuracy, product preparation, shelf life studies, product and environmental monitoring (including Health Canada's (HC) Policy on Listeria monocytogenes in Ready-to-Eat Foods – HC Listeria monocytogenes (Lm) Policy) and laboratory facilities and practices.

Adherence to the criteria is verified by examining the establishment's written program that outlines the procedures that will be undertaken to ensure satisfactory conditions are maintained. The program must specify:

- assigned risk categories for ready-to-eat foods (HC Lm Policy),
- areas to be inspected (what is done),
- tasks to be performed (how it is done),
- person responsible (who does it),
- inspection frequencies (how often or when it is done),
- sampling procedures and lab methodologies,
records to be kept,
parameters of acceptability/unacceptability (tolerances),
results of monitoring,
verification procedures (both on-site and record review),
action to be taken for deviant situations,
trend analysis (HC Lm Policy)

The monitoring and verification procedures clearly define the preventative measures taken to prevent the re-occurrence of deviations. The person responsible for verifying the program must be different from the person performing the task. This program must be updated as required when changes occur.

The actual monitoring of this program will be done by assessing tasks 1.10.07.02 to 1.10.07.05.

1.10.07.02 Manufacturing /Allergen Controls and Records

This task assesses if the plant has good control over its product formulae, food additives, nutritional requirements and label accuracy. In order to rate this task as satisfactory the inspector must do an on-site observation to determine if product is being manufactured in accordance with written procedures for components listed in A - E.

A) Product Formulae: The manufacturer has written formulae available for each product processed that are current, permitted by the standard and provide a basis for assessment and control of food additives, nutritional requirements and food allergens (ingredients which may cause adverse reactions). The formulae contain all details of the formulation as follows:

- identification of specific ingredients and additives (e.g. concentration, type)
- amounts of additives and ingredients

The production worksheet identifies all ingredients (including re-runs and re-work) for each batch. Although it is not required, a double sign-off procedure is one way manufacturers can exhibit control over the ingredients being used. This is usually done at two separate stages of processing by two separate people, first when ingredients are measured out and secondly when added to the formulation or mix tank. The manufacturer has verified he has control over the ingredients and additives through calculations, ingredient inventory balance sheets and finished product testing.

B) Food Additives: Food additives are controlled to meet the requirements of the Food and Drugs Act and Regulations. Inadequate control of food additives could result in chemical or biological hazards. The manufacturer ensures that all food additives used are permitted for use in the particular food and meet the requirements of the Food and Drug Regulations. The specifications for all food additives are on file. As part of the product formulations, the manufacturer can show with calculations and has verified that food additives are used within the maximum level specified in the Food and Drug
Regulations. Certificates of Analysis from the ingredient suppliers stating all food additives used in an ingredient meet the requirements of the Food and Drug Regulations would be satisfactory for the sub-ingredients within an ingredient.

C) Nutritional Requirements: The addition of nutrients (with respect to vitamin and mineral fortification) to food products is controlled to meet the requirements of the Food and Drug Act and Regulations. The manufacturer has control over the formulation to ensure that all nutritional requirements and claims are met. Formulation controls are necessary to prevent hazards which could result from excesses, inadequacies and omissions of nutrients, for example, infant formulae, fortified foods, foods for which there are nutritional claims (example calorie-reduced, low sodium). Nutrients used are permitted in accordance with the Food and Drug Regulations. The nutrient content of the product is accurately reflected on the label. The manufacturer has specifications for nutrients. The manufacturer has received certification from the supplier as follows:

- a certificate of analysis accompanies each lot of nutrient
- for nutrients used in foods that are the sole source of nutrition, each certificate is verified through analysis

The manufacturer has verified and can demonstrate through calculations that nutrients are used within the limits specified in the Food and Drug Regulations.

D) Label Accuracy: The manufacturer ensures that the label information accurately represents the composition of the products packaged at the facility. Controls are necessary to prevent the presence of undeclared allergens in the product. Accurate labels inform and protect segments of the population which may be allergic to certain foods. Procedures are in place to ensure that labels accurately represent product formulation and composition. The following are such procedures:

- new label review
- incoming label review for accuracy/correctness
- formulation changes/substitutions
- procedures are in place to prevent the product mis-labelling at time of packaging, example, effective separation of product types during changeovers, labels are visually checked prior to use, proper storage of labels
- weighed out ingredients used during the formulation process are properly labelled and segregated (where required)

It is recognized that it is common industry practice that the development of the label is completed at corporate office but it is expected that the checks for label accuracy, incoming label review, formulation changes and controls to prevent mis-labelling are all responsibilities of the processing establishment and thus require procedures to ensure accuracy.
E) Product Preparation: In order to avoid contamination with ingredients which may cause adverse reactions, for all products packaged in the facility, the establishment must provide proper training to ensure:

- that during product preparation no ingredient substitution occurs;
- that internally processed ingredients (re-runs and re-work material) do not contain ingredients that may result in adverse reactions unless the finished product label clearly indicates the presence of these ingredients;
- that controls are in place to ensure that when different flavours of dairy products are processed successively common equipment (such as mix transport lines, freezing machines, molds, novelty lines and hoppers) is free of undeclared ingredients which may result in adverse reactions that could be carried over into the next production;
- controls are in place to ensure that when milk/non-milk products are processed in the same establishment, there is no carry-over into the next production (no dead ends/pockets/cross connections allowing for the introduction of milk between dairy and non-dairy production runs, CIP systems are adequate);
- controls are in place for establishments that process both pasteurized and heat treated or raw milk cheese to ensure that all pasteurized product is processed first followed by the raw product with a complete wash with sanitizing prior to the processing of pasteurized product.
- controls are in place to ensure that raw milk cheese is labelled with the manufacturing date to ensure the 60 day period of maturation (Food and Drug Regulations B.08.042 - B.08.048).
- controls are in place to avoid mixing different ingredients during storage and handling;

It is recommended that manufacturers package in containers with tamper evident seals that will ensure the security and integrity of their products once they are produced, until they are purchased by the consumer.

1.10.07.03 Microbiological Control and Records

This task assesses if the plant has good microbiological control over its products and environment. Microbiological control programs are used to verify the production of safe food.

Product Shelf Life Studies:

Microbial growth is dependent upon many environmental conditions such as: ingredients, nutrients, water activity, pH, presence of preservatives (e.g. curing salts), competitive microorganisms, gas atmosphere, redox potential, storage temperature and time. Control of these conditions can therefore be used to limit microbial growth.

Product shelf life is an inherent control measure that, in many cases, is crucial for the safety and suitability of the product. There are a number of reasons for shelf life testing:
to assure consumer acceptability, to test compliance with regulatory standards, to establish viability in the marketplace, to verify quality assurance procedures, to compare different processors' products and to determine effects of abuse on products.

Product shelf life is influenced by a number of factors, such as:

- Product formulation (might include decreased pH, decreased water activity)
- Scheduled heat or other preservation treatments,
- Applied hurdles (e.g. water activity, pH), including storage temperature,
- Cooling methods applied to product,
- Type of packaging (e.g. hermetically sealed or not, Modified Atmosphere Packaging),
- Level of post process contamination and type of contamination

Product shelf life studies must be determined and re-formulated for all products with a mandated best before date, for new products, when formulations change, when processing and equipment changes occur, when significant alterations have been made to the scheduled process and when the best before date is changed. If plant documentation and records show that changes made do not affect the already established shelf life study on a product there would be no need to conduct another shelf life study. For example, if a filling machine was replaced by another filling machine this would not necessarily constitute a shelf life study. However, if the type of packaging system changed for example to an extended shelf life system there would need to be a shelf life study done.

When establishing product shelf life, it is the responsibility of the manufacturer to assure and to demonstrate that the safety and suitability of the milk product can be retained throughout the maximum period specified, taking into consideration the potential for reasonably anticipated temperature abuse during manufacture, storage, distribution, sale and handling by the consumer. This means that any regulatory microbial limits must not be exceeded up to the last day of the product's shelf life.

Shelf life determination should be carried out at the establishment by testing products submitted to the storage conditions specified or by predicting microbial growth in the product under the specified storage conditions. Reasonable anticipated temperature abuse can be integrated into the study or be taken into account by applying an appropriate safety factor (e.g. by shortening the maximum durability specified in the labelling or by requiring lower storage temperatures). To determine shelf life potential, for example many establishments hold samples of processed milk in unopened consumer packages for seven, ten and/or fourteen days at 7.2 °C (45°F) to the sell-by-date or beyond. This temperature is considered to simulate potential conditions under which milk is exposed during distribution and home storage prior to consumption. After a chosen holding period the milk is often evaluated for odour and taste. Bacterial tests may also be performed at this time. Ideally, coliform and Standard Plate Counts (SPC) should not increase significantly during storage when compared with fresh samples.
For longer shelf-life products, where shelf-life studies are commonly performed on unopened packages, it is recommended that the manufacturer applies a *consume within...* statement to the package to assist the consumer in making informed choices on the quality of the product once opened.

Product and Environmental Monitoring:

Food processing and environmental conditions are monitored to determine adherence to good manufacturing practices, conformance to standards, adherence to Health Canada's Policy on *Listeria monocytogenes* in Ready-to-Eat Foods and for the detection of contaminants. It is the dairy establishment's responsibility to verify compliance to regulatory standards, to ensure the safety of the product and for verification that the HACCP based program is working.

The food establishment may perform analyses in house or use outside laboratory services. It is recommended that certified laboratories be used when possible. It is important when sampling to have a representative number of samples depending on the size of the lot and the type of analysis being conducted. Sample selection should be as random and representative as possible. When sampling for microbiological analysis aseptic sampling techniques (using sterile containers and equipment, clean clothing, sterilized gloves) need to be followed so as to not contaminate the samples. Procedures with respect to representative number of samples based on lot size, suitable sample size, random sampling, aseptic sampling procedures are outlined in the Dairy Sampling Procedures of the Dairy Product Inspection Procedures.

Acceptable test methodologies (methods which reliability, accuracy, reproducibility, lab variation have been statistically established) must be used when conducting the analysis so as to provide accurate and meaningful results, e.g., AOAC methods. The Standard Methods for the Examination of Dairy Products by the American Public Health can be consulted for methodologies. Preference should be given to methods which have been validated for the commodity concerned preferably in relation to reference methods elaborated by international organizations.

While methods should be the most sensitive and reproducible for the purpose, methods to be used for in-plant testing often sacrifice to some degree sensitivity and reproducibility in the interest of speed and simplicity. They should, however, have been proved to give a sufficiently reliable estimate of the information needed. The Health Canada website provides a reference of laboratory methods within the *Compendium of Analytical Methods*.

If an establishment is using a blend of both in-house indicator testing and validation/verification using the official testing procedures, this can be rated by the inspector as satisfactory. Whenever confirmation of a result is needed the official method of testing needs to be used as well as an acceptable method and lab.
For microbiological monitoring samples where the degree of non-compliance is minimal or non-existent it would be acceptable for the 5 sub-samples to be composited and still maintain the 3 class sampling plan. The document on how to evaluate composited results can be found in the Dairy Sampling Procedures of the Dairy Product Inspection Procedures. If results come back out of compliance on the composited sample, then the 5 sub-samples would have to be re-analyzed individually to ensure compliance to regulations.

It is most effective to test products in the condition the consumer purchases the product, for example after being packaged and cooled, not hot from the vat or churn. Products must be tested at a frequency sufficient to determine compliance to regulatory standards, adherence to good manufacturing practices, to ensure product safety (free from potential pathogens), as well as to meet the safety and suitability requirements at the end of the shelf life. It is up to the establishment to define the frequency of sampling and should be based on product history, risk of the product, type of process (batch vs. continuous), consumer complaints, volume of product produced, the intended use of the product, the category of consumers concerned. It will be up to the inspector to assess if the frequency is adequate based on the establishment's criteria. The Dairy Sampling Procedures of the Dairy Products Inspection Procedures can be used as a guide to determine what type of analysis could be performed on various types of products.

The following analyses should be considered:

I. Product testing:

1. As an indication of overall sanitation and shelf life:
   - total coliform and *E. coli*,
   - SPC,
   - yeast and mold
2. For compliance to regulatory standards and for product safety:
   - pathogens such as (but not limited to) *Salmonella*, *Listeria*, *S. aureus* or verotoxigenic strains of *E. coli*
3. To verify the suitability of incoming raw materials and ingredients and their compliance to supplier specifications.
4. Phosphatase Testing: For the manufacturers of dairy powders, where there is no HTST system, each lot is tested for alkaline phosphatase using a validated method such as Official Method (MFO)-3, Charm Paslite or Flurophos by in-house or accredited labs. Acceptable procedures are included in the manufacturer's product monitoring program. Product is labelled accordingly depending on the processing treatments received.

II. Environmental monitoring:

The establishment has a written program in place to monitor the environmental conditions and food contact surfaces within the establishment. Environmental monitoring is a tool to verify good manufacturing practices, effective sanitation and prerequisite
programs within an establishment. Health Canada's policy on *Listeria monocytogenes* in Ready-to-Eat Foods (HC Lm Policy) clearly defines the roles of industry and government and can be found on Health Canada's website. Persistent contamination of product contact surfaces in the plant environment is an indication of inadequate good manufacturing practices and may lead to finished product contamination.

III. Application of Health Canada's Policy on *Listeria monocytogenes* Ready-to-Eat Foods

The HC Lm Policy describes *Listeria* verification activities for RTE foods in both the plant environment and in finished products. The verification activities assess the effectiveness of Good Manufacturing Practices (GMP) or the HACCP system to minimize potential sources of food contamination. Dairy processors producing RTE foods are responsible to test their environment for *Listeria spp.* and confirm whether any product is contaminated with Lm when environmental findings are unsatisfactory. With respect to this policy and the criteria listed under task 1.10.07.01, the establishment's written program specifically includes the following:

- assigned risk categories for RTE products,
- acceptable sampling procedures and methodologies of analysis,
- sampling sites, monitoring frequencies and rationale for these frequencies,
- trend analysis,
- notification to CFIA and submission of a corrective action plan for unsatisfactory situations

The establishment is responsible for determining the risk categories of their RTE foods and establishing sampling frequencies to monitor their environment and products throughout the year. Sampling frequency of environmental (Food Contact Surface (FCS) and non-FCS) and finished product should be based on an internal risk assessment that takes into consideration specific criteria such as product risk categories, volume produced, processing conditions, equipment design, history of compliance etc.

Environmental sampling (*Listeria spp.*) is to include FCS sites taken during production (including final packaging step) and non-FCS based on the complexity of the process as per the HC Lm Policy. The Dairy Sampling Procedures of the Dairy Product Inspection Procedures needs to consist of 5 sub-samples (at least 100 g each) and it is recommended these be taken at the same time as the FCS environmental sampling. Acceptable testing methods are to be used (see HC's Compendium of Analytical Methods)

It is also recommended for the establishment to hold product until results are received.

The establishment is to notify the CFIA of positive results for Lm or persistent L. spp. findings on a FCS (for all RTE foods). A corrective action plan is to be submitted by the establishment. Appropriate follow up actions (HC Lm Policy Figures 1, 2 and 3) are to be followed.
Industry is also responsible to perform trend analysis of environmental and product sampling results. This could include an on-going review and analysis of data for *L. spp.* from routine monitoring to detecting trends and improving controls before major issues develop. For example, the use of quality control methods and statistical methods, e.g. control charts, Pareto diagrams, etc. are recommended.

All records must indicate satisfactory frequency of monitoring and must be complete and available at the plant. Out of compliance results must trigger action that is documented in the records. Follow up investigations on any out-of-specification results must look for the root cause and be well documented.

### 1.10.07.04 Composition Control and Records

This task assesses if the plant adequately controls product composition.

Composition records must provide this assurance. Composition analyses can be performed in house or contracted out. It is important when sampling to have a representative number of samples depending on the size of the lot and the type of analysis being conducted. Sample selection should be as random and representative as possible. Procedures with respect to representative number of samples based on lot size, suitable sample size and random sampling procedures are outlined in the Dairy Sampling Procedures of the Dairy Products Inspection Procedures.

Acceptable test methodologies must be used when conducting the analysis so as to provide accurate and meaningful results. It is most effective to test products in the condition the consumer purchases the product, example after being packaged and cooled, not hot from the vat or churn.

It is the dairy establishment's responsibility to verify compliance to regulatory standards. Products must be tested at a frequency sufficient to determine compliance to regulatory standards. Records must be complete and available at the plant and indicate satisfactory frequency of monitoring and that appropriate action is taken for the products out of compliance. Follow up investigations on any out-of-specification results must be looking for the root cause and be well documented.

### 1.10.07.05 Laboratory Facilities and Practices

Lab facilities must not provide a contamination risk to food products. If the lab is conducting micro and pathogen testing the lab facilities must be well isolated from processing areas of the plant; if not isolated then the lab facilities must have negative pressure. Isolation and enumeration of pathogenic microorganisms must not pose a risk of contamination to the product or to the plant environment. Therefore, pathogenic testing should be done in a separate building.
Lab practices must be controlled to ensure that no contamination risk exists to food products. The techniques used to take samples in the processing line must not pose a contamination risk. Proper disposal of laboratory samples and materials is required.

### Process Control Program Summary Table

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<thead>
<tr>
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| 1.10.07.01 General (HS=3) | |
|---------------------------| |

### (B) Records

A representative sampling of the plant's historical records must be assessed.

1. Records must be:
   ○ Accessible and complete
   ○ Clear, legible and permanent

2. Information must indicate:
   ○ All process control records
   ○ Frequency and results of monitoring and verification
   ○ Satisfactory follow-up when deviations found and documentation of actions taken

| 1.10.07.02 Manufacturing / (A) Product Formula | |

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Allergen Controls and Records (HS=2)(more to follow)

- Written master formulae available, permitted by the standard and current for all products being processed
  - identifies specific ingredients and additives (e.g. concentration, type)
  - identifies amounts of additives and ingredients
  - production worksheet identifies all ingredients used, including re-run or re-work for each batch
  - control over ingredients being measured out and ingredients being added
  - calculations, ingredient inventory balance sheets, finished product test results on file

(B) Food Additives

- Documented written procedures
  - all food additives used are permitted for use in a particular food
  - specifications for all food additives
  - calculations on file showing that food additives used are within the maximum level specified in the Food and Drug Regulations (Certificates of Analysis on file for sub-ingredients of ingredients)

(C) Nutritional Requirements (with respect to vitamin/mineral fortification)

- Documented written procedures
  - nutrients used are permitted in accordance with the Food and Drug Regulations
  - label accurately reflects nutrient content of the product
  - specifications for nutrients on file
  - supplier certification
  - calculations on file showing that nutrients are used within limits specified in the Food and Drug Regulations

(D) Label Accuracy

- Documented written procedures
- Labels for products packaged at the facility accurately reflect product formulation, composition and regulatory requirements
  - new label review
incoming label review for accuracy/correctness
formulation changes/substitutions
controls in place to prevent mislabelling of products
weighed out ingredients are properly labelled and segregated (where required)

(E) Product Preparation

- Documented written procedures to ensure proper handling during product preparation (including training) for all packaged products in a facility
  - no ingredient substitution occurs during production
  - internally processed ingredients added to different dairy products are clearly indicated on finished product label
  - controls in place to ensure no carry-over of flavours on common equipment
  - controls in place in establishments producing milk/non-milk products and in establishments producing pasteurized cheese/heat treated or raw milk cheese
  - controls in place to ensure 60 day maturation period for raw cheese (date of manufacture on the label)
  - controls in place to avoid mixing different ingredients during storage and handling

(A) Shelf Life Studies

- Required for products with mandated best before dates
  - new studies may be required for new products, formulation and/or processing equipment changes and when best before date modified, depending on if the changes affect the already established shelf life
- Documented demonstration of maximum shelf life
  - anticipates potential abuse from manufacturing, storage, distribution, sale and consumer handling and/or applies safety factor
  - data and testing supports established shelf life
  - regulatory limits not exceeded at end of shelf life

(B) Product and Environmental Microbiological Monitoring
• Products monitored
  o representative number of samples based on lot size and type of analysis
  o random and representative sample selection
  o aseptic sampling procedures followed
  o establishment defines frequency of sampling based on specific criteria such as product risk, history of compliance volume produced, type of process, etc.
  o under true marketing conditions
  o regulatory microbiological requirements
  o food product safety
  o verification of HACCP based program
  o phosphatase testing each lot of dairy powders with acceptable method when no HTST (High Temperature Short Time) system; labelled according to treatments received
  o verification of incoming raw materials and ingredients to supplier specifications
• Environmental conditions and food contact surfaces monitored
  o verification of good manufacturing practices, effective sanitation, and prerequisite programs
• Documented list of laboratory methods, testing procedures and sampling procedures used
  o acceptable test methodologies used
  o regulatory product standards or acceptable limits listed

(C) Application of HC's Policy on Lm in RTE Foods

• frequency of environmental (Food Contact Surface (FCS) and non-FCS) and product sampling based on specific criteria such as product risk categories, volume produced, processing conditions, equipment design, history of compliance etc.
• frequency of monitoring is respected
• acceptable sampling and testing methods used (HC Compendium of analytical methods)
• documented follow-up action was appropriate and timely
• CFIA was notified and a corrective action plan was submitted for all positive results (Lm or persistent Listeria spp. findings on FCS (for all RTE foods)
• trend analysis of environmental and product sampling
results was completed

(D) Records

- Available (at plant) and accessible
- Complete (including trend analysis for listeria)
- Satisfactory frequency and results of monitoring
- Satisfactory follow-up on out of compliance findings and documentation of action taken

(A) Product Monitoring

- Representative number of samples based on lot size and type of analysis
- Random and representative sample selection
- Establishment defines frequency of sampling based on specific criteria such as history of compliance, volume produced, type of process, etc.
- Products are monitored for regulatory composition requirements

1.10.07.04 Composition Control and Records (HS=3)

- Documented list of laboratory methods testing procedures and sampling procedures used
  - acceptable test methodologies used
  - product standards or limits are listed

(B) Records

- Available (at plant) and accessible
- Complete
- Satisfactory frequency and results of monitoring
- Satisfactory follow-up on out of compliance product and documentation of action taken

(A) Lab Facilities

- Isolated from processing area and if not isolated must have negative pressure (applies if micro and pathogen testing is being done in the lab)
- No contamination risk to food products

1.10.07.05 Lab Facilities and Practices (HS=3)

(B) Lab Practices

- Proper sampling techniques
- Sample disposal
  - plates and materials used for the isolation and enumeration of pathogens autoclaved
Secondary menu

Food

Acts and Regulations

Information for Consumers

- Food Recall Warnings

Dairy Products

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2014-02-17

- hygienic disposal of other samples
- No contamination risk to food products
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Hygienic Design of Food Processing Facilities

By Frank Moerman, M.Sc.

Increasing consumer demand for fresh foods has led to the development of processing and preservation methods that have minimal impact on either the nutritional or sensory properties of foods. Freshly prepared foods often contain less salt, acid, sugar, additives and preservatives. Since the use of mild preservation technologies primarily results in pasteurized products, hygienic processing equipment and a hygienic process environment are needed to prevent microbial, chemical and physical contaminants from affecting these products while preventing product exposure to sources of filth (pests, dust, etc.). Combating product contamination may occur not only at the equipment level but also at the factory level. Incorporation of hygienic design into your food processing facility can prevent development of pests and microbiological niches; avoid product contamination with chemicals (e.g., cleaning agents, lubricants, peeling paint, etc.) and particles (e.g., glass, dust, iron, etc.); facilitate cleaning and sanitation and preserve hygienic conditions both during and after maintenance. The facility infrastructure can be so designed and constructed that it cannot contaminate food products, whether directly or indirectly.

**Barrier Technology**

To control food safety, providing barriers to food contamination is a generally applied concept. The first barrier refers to outside premises, such as fencing, to prevent unauthorized access to the facility. The access of transport vehicles with raw materials and end-products, personnel, domestic and non-domestic animals should be monitored and controlled. Factory site drainage and storm water collection must be sufficient; areas within a 3-m perimeter of the factory must be kept vegetation free to avoid pest breeding and harborage sites; a 10-cm thick concrete curtain wall around the factory foundation at least 60 cm below ground discourages rodents from entering the building; effluent
treatment plants and waste disposal units should be sited such that prevailing winds do not blow microbial and dust aerosols into manufacturing areas.

The second barrier concerns the closing of factory buildings. All entrances/exits (i.e., window and door openings, openings for vents, air circulation lines, floor drains, etc.) must be designed for control over access, flow or exit of personnel, raw and finished food products, air, process aids (process water, process steam, food gases, etc.), waste, utilities (plant cooling and heating water, plant steam, compressed air, electricity, etc.) and pests (insects, birds, rodents, etc.). Floor drains must be screened to avoid rats from entering the food plant via sewers; ventilator openings, including vents in the roof, should be screened to prevent the entry of roof rats, insects and birds; gaps at the entrances of electrical conduits, process and utility piping, which are convenient pathways for roof rats, must be closed.

The third barrier is the segregation of restricted areas (zones) within the plant, each of which have different hygienic requirements and controlled access. The fourth barrier is the processing equipment (including storage and conveying systems), which must have an adequate hygienic design and must be closed to protect the food product from external contamination.

**Zoning: A Cornerstone in Prevention of Food Contamination**

*Zone B* is an area in which a basic level of hygienic design requirements suffices. It encompasses areas in which products are produced that are not susceptible to contamination or that are protected in their final packages. A B0 zone is the area outside the buildings within the perimeter of the site where the objective is to control or reduce hazards created by unauthorized personnel entry and hazards created by water, dirt, dust and presence of animals. B1 zones include warehouses that store both raw materials and packed processed products, offices, workshops, power supply areas, canteens and redundant buildings/rooms. The objective for a B1 zone is to control or reduce hazards created by birds and pests.

*Zone M* is an area in which a medium level of hygiene suffices. It includes process areas where products are produced that are susceptible to contamination, but where the consumer group is not especially sensitive and where no further microbial growth is possible in the product in the supply chain. In this area, product might be exposed to the environment, during sampling and during the opening of equipment to clear blockages. The objective for zone M is to control or reduce the creation of hazardous sources that can affect an associated area of higher zone classification. Another objective is the protection of the interior of food processing equipment from contamination when exposed to the atmosphere.

*Zone H* applies to an area where the highest level of hygiene is required. A “High Hygiene” room, which, in food processing is the equivalent of a cleanroom, must be completely contained. Zone H is typical for open processing, where even short exposure of product to the atmosphere can result in a food safety hazard. Products and ingredients that are processed or stored and are destined for a highly susceptible consumer group
(e.g., infant nutrition), are instant in nature or ready for consumption. They must be handled in a refrigerated supply chain, as they are susceptible to growth of pathogenic microorganisms. The objective for H zones is to control all product contamination hazards and to protect the interior of food processing equipment from exposure to atmosphere. Filtered air must be supplied to this area.

These areas should be limited in size, must have a simple equipment layout to facilitate process, cleaning and maintenance operations and should have utilities located outside. However, investing in an enclosed line that brings barriers very close to the product is more logical than trying to create a complete cleanroom around a partially open line.

Zoning and the establishment of barriers to ensure that product of acceptable hygienic quality is produced should only be applied where their use will help significantly to protect products. Designing the entire factory as a cleanroom is not the purpose of food area segregation to protect both product and consumer. Zoning and barrier technology must be applied in an appropriate and consistent way, thereby avoiding unnecessary investment.

Construction of Facilities: Appropriate Layout
The layout and design of the food factory must be adapted to the hygienic requirements of a given process, packaging or storage area. The interior of the factory must be designed so that the flow of material, personnel, air and waste can proceed in the right direction. As they become incorporated into food products, raw materials and ingredients should move from the ‘dirty’ to the ‘clean’ areas. However, the flow of food waste and discarded outer packaging materials should be in the opposite direction. Before building begins, simulation of the flow of people, materials, products and waste can help the designer determine the most appropriate place for installing the process equipment and where the process and utility piping should enter the process area. Even the simulation of maintenance and cleaning operations can be useful to determine the most appropriate factory layout. Graphical computer-aided design and 3D visualization programs can help in the hygienic design, positioning and routing of processes, process supports and utility systems. These programs allow the observer to “walk through” the facility, seeing the inside of the facility from different angles and locations. To save building and renovation costs, potential problems can be solved before the onset of construction. Additionally, in the development of high hygiene areas, computational fluid dynamics can help simulate and visualize expected airflows.

To meet a possible increase of processing activities within the food plant in the future, the building and its food processing support systems should be designed so they can either be expanded, or another building and/or utilities can be added. Oversizing the main utility systems is a common practice. If possible, the factory should also be made adaptable (i.e., the ability to modify the production area for other manufacturing purposes) and versatile (i.e., the ability to do different things within the same room).

Construction of Facilities: Pest Prevention
To exclude flooding and the entry of rodents, factories should be built at a higher level
than the ground outside. Exterior doors should not open directly into production areas, and windows should be absent from food processing areas. The number of loading docks should be minimal and be 1–1.2 m above ground level. Preferably, outside docks should have an overhanging lip, with smooth and uncluttered surfaces that are sloped slightly away from the building to encourage water run-off. Areas beneath docks should not provide harborages for pests, should be paved and should drain adequately. To provide protection for products and raw materials, docks can be shielded from the elements by roofs or canopies. However, these structures can become a serious sanitation problem due to roosting or nesting of birds. Bird spikes or nets can solve that problem. To prevent the entry of insects, dock openings should be provided with plastic strips or air curtains, and external lighting to illuminate these factory entrances should be placed in locations away from the factory building. Intruding insects can still be attracted and killed within the food factory by strategically positioned ultraviolet (UV) light electric grids or adhesive glue board traps.

**Construction of Facilities: Interior Hygienic Design Construction Materials**

Construction materials for equipment and utility piping should be hygienic (smooth, non-absorbent, non-toxic and easily cleanable), chemical-resistant (to product, process chemicals, cleaning and sanitizing agents), physically durable (unbreakable, resistant to steam, moisture, cold, abrasion and chipping) and easy to maintain. Materials used to construct process and utility systems located in the non-food contact area may be of a lower grade than those applied in the food contact zone. Surfaces that are frequently wet should not be painted as the paint can crack, flake and chip.

Lead, mercury and cadmium should not be used within the factory. However, as part of many electric components, it is very difficult to exclude their presence. In the food contact area, electric components must always be enclosed in junction boxes, casings, closed cable housings, cabinets, etc. or should be installed in non-product contact zones or in technical corridors. Alloys for food contact may only contain aluminium, chromium, copper, gold, iron, molybdenum, nickel, platinum, silver, titanium, zinc, carbon, etc. However, zinc, copper, aluminium, bronze, brass, carbon and galvanized and painted steel have poor resistance to detergents, disinfectants, acidic food and steam and must be avoided in food contact areas.

Polytetrafluoroethylene, polyethersulfone, polyvinylidene fluoride, phenol-formaldehyde, urea-formaldehyde, melamine-formaldehyde, epoxy and unsaturated polyester resins are used in the construction of electric components, while other plastics like polypropylene (PP), low-density polyethylene (PE), polyvinyl chloride (PVC), polyurethane (PU), ethylene propylene diene monomer (EPDM), silicone, etc. are applied as jacket materials for electrical cables or for the construction of pneumatic hoses and compressed air tubing. PP, PE and PVC are also used to construct drain pipes, while shields of polycarbonate can protect the food area below light sources from shattered glass after accidental breakage of lamps. Silicone, nitrile, PU, EPDM and butyl rubber are largely used as materials for gaskets, seals, etc. Epoxy is widely used as floor, wall and ceiling coatings. Remember that many plastics perform differently at -25 °C than they do at 20 °C.
**Integration of Piping**

Utility piping in technical corridors or zone H areas should be integrated into wall compartments or the ceiling. If this is not possible, it is recommended to use open racks, fixed to the ceiling, or walls and columns close to the ceiling. However, sufficient clearance must be provided between pipe runs and adjacent surfaces so that both are readily accessible for cleaning and maintenance. The pipe racks must be designed hygienically to minimize the presence of horizontal ledges, crevices or gaps where inaccessible dirt can accumulate.

Food processing support piping should be directly routed from service rooms to process areas and should always be logical and simple. The amount of utility piping should be minimized and should have—like process piping—a slope of 1/200 to 1/100. Especially in process, hot water and process steam piping, standing “pools” of liquid that can support the growth of microorganisms must be avoided. To remove condensate, steam traps should be located at all low, convenient points along any extended pipe length. Steam purges for relief of steam condensate in a drain should be closely connected to that drain. In open systems, the steam vapor coming out of a drain can cause humidity and odor problems within the factory. Discharge of condensate from the system should be via an air break to prevent back-siphonage. Neither process nor utility piping should have dead legs.

Like process piping, utility piping should be grouped together in easily accessible pipe trains whenever possible. The points of use should also be grouped, in an attempt to minimize individual ceiling drops. Vertical entrance of piping into the equipment or equipment jacket is more hygienic than horizontal utility piping runs. Running of process and utility piping over open equipment in food preparation areas cannot be accepted, and nesting of ductwork should be avoided. Piping should not clutter the ceiling. When necessary, suspended racks that run over a product zone shall be equipped with a drip pan that protects the product zone below and can be readily removed for cleaning. Bumper guard construction can also be installed in heavy traffic areas to protect piping from external mechanical forces.

Piping should be installed at least 6 cm from walls and floors to encourage thorough cleaning around it. Piping in corners should be avoided, as it hampers thorough cleaning. Process equipment shall be installed such that enough space is provided to facilitate pipe cleaning.

As piping (utility and process) can affect or disrupt the airflow pattern in zone H rooms, a fog test can control airflow patterns. The geometry of the utility piping can destroy the desired air pattern (e.g., piping with a square or rectangular profile is less favorable than circular). Square and rectangular shapes create turbulence and depressions where dust can accumulate, but cylindrical profiles make cleaning easier.

**Penetration of Piping through Walls, Ceilings and Floors**

Piping that transports dirty fluids should not run in the vicinity of or cross utilities that transport process aids, especially if these process aids are in direct contact with the food.
to be processed. Like process piping, food processing support piping should run unidirectionally, with the support piping running from the cleanest area toward the least clean areas. Support systems should deliver a certain process aid first in the process area with the highest hygienic risk (zone H) and last in the zone of lowest hygienic risk (zone L).

Pipeline penetration through walls, ceilings and floors should be minimized, as holes in these areas can lead to sanitation problems and can invite the entry of insects and rodents. Openings in floors for pipes should be guarded with a sleeve to avoid spill of cleaning solutions onto a lower floor. When several pipes penetrate the floor, a larger curbed floor can replace several pipe sleeves to improve the cleanability of the surrounding process environment. However, that curbed floor may create a large opening where pests may harbor, and where dirt, water, etc. may accumulate. It must be a completely closed curb with a cover that leaves no gap around the penetrating piping.

Holes in walls for pipe traverse need not be sealed water- and air-tight when both sides of the wall are in rooms of the same hygienic zoning, but any opening should be large enough for access and cleaning. However, if a wall separates rooms of different hygienic zoning, all holes for pipe traverse must be sealed. The exterior surfaces of the pipes that traverse walls or ceilings should then have water- and air-tight contact with the wall or ceiling. Foaming-in-place is an appropriate method to close the gaps formed between pipe surfaces and walls as are the applications of plastic caps around the piping and flashing flanges. If running of process and utility piping through walls or ceilings in zone H rooms cannot be avoided, the apertures through the walls and ceilings shall be properly closed against air leakage, as they give excessive air volume losses which may affect product.

Sanitary Insulation of Piping
Hot piping should not run in the neighborhood of piping that transports cold food products, cold process water, etc. The warm-up of these cold liquids can give rise to the growth of food pathogens. Insulation of hot piping is required, not only to economize on energy, but also to prevent excessive heating of the food production environment above acceptable temperatures. Poorly insulated ethylene glycol and cold/chilled water piping can sweat or be covered with ice, resulting in dripping water. To avoid ingress of dust, vermin, etc. into the insulation, it is highly recommended fully welded metal cladding or plastic covering be installed. It should be impossible to walk on the insulation during maintenance. Damage to insulation can be inhibited by covering the pipe insulation with a smooth, hard, non-electrostatic, plastic cover, rather than steel sheet cladding.

Hygienically Designed Transfer Panels
Flexible hoses can be used for performing transfers within a given process area. However, hoses are impractical to perform transfers between rooms, especially if these rooms have a different level of “cleanliness.” To make connections between different processing units in adjacent rooms, the use of hygienically designed transfer panels is recommended. Interconnection between the different ports should be made with sanitary U- and J-bends. Piping behind the transfer panel and the panel ports must be sloped to
ensure proper drainage of residual liquid toward a drain pan. For the same reason, the whole transfer panel can tip a little bit forward. Ports should be capped when not in use to prevent any potential spill or contamination.

Chemical and Wear-resistant Floors
Floors should be sloped toward drains and provided with curbed wall floor junctions, with the curbs having a 30-degree slope to prevent accumulation of water, dust or soil.

Concrete flooring, including the high-strength granolithic concrete finishes, are especially suitable in warehouses where excellent resistance to heavy traffic is critical. However, untreated concrete can be dusty if dry and highly susceptible to damage from water and acids when wet. Concrete flooring is not recommended for high-care production areas, because it can spall and absorb water and nutrients, allowing microbial growth below the surface.

Epoxy flooring provides a durable, seamless, chemical-resistant and readily cleanable surface. However, over time the coating can crack and buckle due to exposure to cleaning chemicals or wear caused by heavy traffic. Once this happens, moisture pockets under the coating can create a microbiological niche.

Tile flooring is an excellent surface for food plants. However, with heavy wear and in more aggressive cleaning environments, tiles may lose some of their grouting, allowing the penetration of water beneath them. Plastic or asphalt membranes may be laid between the underlying concrete surface and the tiles. Brick floors also may be satisfactory but tend to be somewhat fragile and, unless vitrified, permit water penetration.

Welded PVC sheets have excellent chemical resistance. However, they are not suitable in hot and wet areas, and the welded PVC may be damaged by heavy cart traffic. Steel plates may be used on balconies, for example, and on loading docks and walkways in the vicinity of the process. However, they may corrode and are difficult to bond to concrete. Wood floors are satisfactory in packing and warehouse areas; however, the wood should be impregnated and coated with a durable plastic such as PU. Generally, wood floors may become worn, porous and absorbent, requiring expensive maintenance, and thus are not typically installed in modern food plants.

Pocket-free Drains
Drains should have appropriate capacity to avoid “ponding” of water and hence contamination in the area to be drained. The drain bodies must be free of pockets that can hold food soil; otherwise, they will cause odor problems. Only drains with an internal P-trap and atmospheric break should be used. P-traps create a water-lock that keeps sewer gases out of the plant.

Balanced Air Supply and Exhaust System
Exhaust systems should have sufficient capacity to remove excess heat, dust, vapor, aerosols, odors and bioburden from process rooms. However, a positive overpressure must always be maintained. The supply of filtered air in the room by the heating-
A ventilation-air conditioning system must thus be large enough, otherwise the exhaust system will attempt to draw the required amount of air from adjacent less clean areas through doorways and windows. Exhaust fans must be located outside the building to maintain a negative pressure in the portion of the duct system located within the building. If they are installed in the exhaust hood, the exhaust air is pushed through the duct and not pulled out. By pushing vapors, fumes, etc. through that duct, the system puts the exhaust duct under positive pressure, which can force dirty air back into the room through holes and gaps in the duct work.

**Hygienically Designed Lighting**

Lighting must illuminate horizontal and vertical working surfaces evenly, without causing glare and at an intensity of about 300–500 lux at normal working height. Walls and ceilings should be light-colored because that permits fast detection of dirt and soil on their surfaces. In contrast, dark-colored walls and floors require additional lighting.

Preference should be given to lighting mounted on ceilings rather than on walls, because process equipment, storage racks, etc. can form shadows that make cleaning and inspection of floor, walls or ceilings difficult. For the same reason, overhead piping may not obstruct lighting.

Selected lighting should produce little heat and UV light to prevent attraction of insects. Because high-intensity discharge lamps (metal halide, and high- and low- pressure sodium lamps) have high penetration depth, they are used as high-bay lighting in warehouses; fluorescent luminaires are preferred as low-bay lighting, giving good illumination with less glare when covered with a prismatic cover or opalescent diffusing panel.

Lighting systems and their supports may not create horizontal ledges, legs or surfaces. To avoid projections that can accumulate dust, they can be built into the ceiling or wall with a hermetically closed seal, a procedure that is typical for cleanroom areas where lamps are changed via the technical area.

**Hygienic Supply and Application of Electricity**

In zone M areas, installing individual cables or multiple cables of small diameter, sharing the same route, in conduits is recommended. When two or more cables partly share a common route but go to different termination points, the creation of unsealable openings that allow the cable(s) to enter or exit the conduit is possible. However, this practice is only recommended for short distances. For long distances, straight line, non-bundled electric cables should be mounted on wire trays, preferably separated from each other. Vertical cable trays are less prone to dust accumulation, and are more accessible for inspection and cleaning. The use of horizontal racks for electrical cabling should be minimized, or they should be protected by a removable lid or installed vertically (on their side) to minimize horizontal surfaces.

When two or more cables partly share a common route, but go to different termination points, unsealable openings allowing cable(s) to enter or exit the conduit should be
avoided. Conduits should be suitably sealed at both ends with a proprietary cable/sealing gland where a cable does pass through. In the food contact and splash areas, cables can also be protected from dirt, penetrating liquid and damage by encapsulating them in hermetically closed cable housings. However, the use of pipe rather than conduit should be discouraged because of the difficulties in maintaining the integrity of the piping system at cable entries and exits. Cable mounting in pipes still creates a hollow body and hence a hygienic risk.

Electric components should be enclosed in dust- and water-tight cabinets or field boxes with all connections made at the bottom. Connections of cables and wires to housings must be sealed. The enclosures should be spaced away from equipment or walls and should be provided with an easily drainable 30° top roof. The heat generated by the electrical installations within these enclosures, and concomitantly the dust that penetrates the electrical installation during its cooling by means of fans, should be ventilated toward a technical area or a central ventilation system.

Control Panels
Control panels with high ingress protection rating should be provided with hygienically designed control and indicator devices. However, the more modern and hygienic membrane panels or touch-screen display panels now often replace these older, non-computer-based control panels.

Conclusions
Many food manufacturers only make use of the classic food preservation approach to control food safety. In the past two decades, however, the European Hygienic Engineering & Design Group has demonstrated that hygienic design of food process equipment and factories can contribute significantly to enhanced food safety. Hygienic food factory design starts with the selection of an appropriate location and the application of a hygienic building concept that prevents the entry of pests. The factory layout must permit the correct flow of materials, waste, air and personnel without compromising food safety as well as the installation of hygienic zones that offer maximal protection to the food produced. Process equipment and process and utility piping must be designed from food-grade materials that are compatible with the food product produced and the cleaning agents and disinfectants applied to sanitize the production environment. To avoid the introduction of new contaminants, equipment and piping must be hygienically integrated within the factory’s premises. Walls, ceilings and floors must have an appropriate finish, lighting must provide sufficient illumination and drains should guarantee proper drainage to facilitate cleaning and to maintain hygienic conditions within the factory. The aim of this article is to serve as an introduction to proper hygienic food facility design.

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7. ESTABLISHMENTS FOR SEAFOOD PROCESSING

In this chapter some requirements for establishments for (sea) food processing will be discussed. A number of books (Shapton and Shapton 1991, Hayes 1985, ICMSF 1988) and official regulations (e.g. EEC 1991b) give detailed information on requirements for buildings, equipment and processing procedures and these should be consulted if new establishments are being constructed. Some of the more important aspects are considered below.

7.1. PLANT LOCATION, PHYSICAL ENVIRONMENT AND INFRASTRUCTURE

Early considerations in building a new plant is the identification of a suitable location. A number of factors should be considered such as physical, geographical and infrastructure available.

A plant must be located on a plot of adequate size (for present needs and future developments), with easy access by road, rail or water. An adequate supply of potable water and energy must be available throughout the year at a reasonable cost. Special considerations must be given to waste disposal. Seafood processing plants usually contain significant amounts of organic matter which must be removed before waste water is discharged into rivers or the sea. Also solid waste handling needs careful planning, and suitable space, away from the plant, must be allocated or be available.

Assessment of pollution risk from adjacent areas must also be considered. Contaminants such as smoke, dust, ash, foul odours (e.g. neighbouring fish meal plant using poor raw material) are obvious, but even bacteria may have to be considered as airborne contaminants (e.g. proximity of a poultry rearing plant upwind may be a source of Salmonella sp).

The immediate physical surroundings of a seafood factory should be landscaped and present an attractive view to the visitor (or potential buyer of products). However, this should be done in a way so rodents and birds are not attracted. Shrubbery should be at least 10 m away from buildings and a grass-free strip covered with a layer of gravel should follow the outer wall of buildings. This allows for thorough inspection of walls and control of rodents.
7.2. BUILDINGS, CONSTRUCTION AND LAYOUT

A food processing plant shall provide (quoted from Troller 1983):

- Adequate space for equipment, installations and storage of materials.
- Separation of operations that might contaminate food.
- Adequate lightning and ventilation.
- Protection against pests.

The requirements of external walls inclusive roofs, doors and windows are that they should be water-, insect- and rodent proof. Internal walls, on the other hand, should be smooth, flat, resistant to wear and corrosion, impervious, easily cleanable and white or light coloured. Also the floors should ideally be impervious to spillage of product, water and disinfectants, durable to impact, resistant to disinfectants and chemicals used, slip resistant, non-toxic, non-tainting and of good appearance and easy repairable. Floors should be provided with slope to drains to prevent formation of puddles. The technical requirements, choice of materials, cost etc. to obtain these goals may be found in a number of publication such as Shapton and Shapton (1991), Imholte (1984), Troller (1983).

The general layout and arrangements of rooms within a processing establishment is important in order to minimize the risk of contamination of the final product. A large number of bacteria (pathogens and spoilage bacteria) enter with the raw material. To avoid cross contamination, it is therefore essential that raw material is received in a separate area and stored in a separate chillroom. From here the sequence of processing operations should be as direct as possible - and a “straight line” process flow is regarded as the most efficient (Hayes 1985). This layout minimizes the risk of recontamination of a semi-processed product.
A clear physical (e.g. a wall) segregation between “clean” and “unclean” areas is of prime importance. “Unclean” areas are those where raw material is handled and often a cleaning operation (wash) or e.g. a heat treatment (cooking of shrimp) is marking the point, where the process flow goes from “unclean” to “clean” areas. Thus a “clean” area is defined by ICMSF (1988) as an area where any contaminant added to the product will carry over to the final product, i.e. there is no subsequent processing step that will reduce or destroy contaminating microbes. Other terminologies used for “clean” areas are “High Care Areas”.

Also cooled rooms must be separated from hot rooms where cooking, smoking, retorting etc. are taking place. Dry rooms must be separated from wet rooms and ventilation must be sufficient to remove excess humidity.

The separation between the clean and unclean areas must be complete. There should be no human traffic between these areas, and equipment and utensils used in the unclean areas should never be used in the clean area. This means that there should also be separate wash and hygiene facilities for equipment and personnel in these areas. For easy identification the personnel should wear different coloured protective clothing for different operations (e.g. white in the clean area and blue in the unclean).

Equally important in layout and design of food factories is to ensure that there are no interruptions and no “dead ends” in the product flow, where semiprocessed material can
accumulate and remain for a long time at ambient temperature. Time/temperature conditions for products during processing are extremely important critical control points (CCPs) in order to prevent bacterial growth. This means that a steady and uninterrupted flow of all products is necessary in order to have full control of this critical factor. If any delays in product flow are necessary, the products should be kept chilled.

In addition to facilitate product flow, the factory layout and practices should ensure that:

- All functions should proceed with a no of criss-crossing and backtracking.
- Visitors should move from clean to unclean areas.
- Ingredients should move from “dirty” to “clean” areas as they become incorporated into food products.
- Conditioned (e.g. chilled) air and drainage should flow from “clean” to “dirty” areas.
- The flow of discarded outer packing material should not cross the flow of either: unwrapped ingredients or finished product.
- There is sufficient space for plant operations including processing, cleaning and maintenance. Space is also required for movement of materials and pedestrians
- Operations are separated as necessary. There are clear advantages in minimizing the number of interior walls since this simplifies the movement of materials and employees, makes supervision easier, and reduces the area of wall that needs cleaning and maintenance (the list is partly after Shapton and Shapton 1991).

Some of the principal requirements for an ideal establishment are outlined in Figure 7.2.
7.3. UTENSILS AND EQUIPMENT

A great variety of utensils and equipment is used in the fish industry. There is an abundance of advice and regulations available concerning the requirements for equipment. All of them agree that the food equipment should be non-contaminating and easy to clean. However, the degree of stringency in hygienic requirements must be related to the product being processed. Raw fish for example, do not require the same standard of hygiene as cooked and peeled shrimp. Criteria for hygienic design are particularly important for equipment used in the later stages of processing and particularly after a bacteria-eliminating processing step.

There are seven basic principles for hygienic design agreed upon by a working party appointed by Food Manufacturers Federation (FMF) and Food Machinery Association FMA (FMF/FMA 1967) as quoted by Hayes (1985):

1. All surfaces in contact with food must be inert to the food under the conditions of use and must not migrate to or be absorbed by the food.
2. All surfaces in contact with food must be smooth and non-porous so that tiny particles of food, bacteria, or insect eggs are not caught in microscopic surface crevices and become difficult to dislodge, thus becoming a potential source of contamination.
3. All surfaces in contact with the food must be visible for inspection or the equipment must be readily disassembled for inspection, or it must be demonstrated that routine cleaning procedures eliminate possibility of contamination from bacteria or insects.

4. All surfaces in contact with food must be readily accessible for manual cleaning, or if not readily accessible, then readily disassembled for manual cleaning, or if clean-in-place techniques are used, it must be demonstrated that the results achieved without disassembly are the equivalent of those obtained with disassembly and manual cleaning.

5. All interior surfaces in contact with food must be so arranged that the equipment is self emptying or self draining.

6. Equipment must be so designed as to protect the contents from external contamination.

7. The exterior or non-product contact surfaces should be arranged to prevent harbouring of soils, bacteria or pests in and on the equipment itself as well as in its contact with other equipment, floors, walls or hanging supports.

In the design and construction of equipment it is important to avoid dead areas where food can be trapped and bacterial growth take place. Also dead ends (e.g. thermometer pockets, unused pipe work T-pieces) must be avoided, and any piece of equipment must be designed so the product flow is always following the “first in first out” principle.

Cleanability of equipment involves a number of factors such as construction materials, accessibility and design. The most common design faults which cause poor cleanability are (Shapton and Shapton 1991):

- Poor accessibility (- equipment should be placed at least 1 m from wall, ceiling or nearest equipment).
- Inadequately rounded corners (minimum radius should be 1 cm, but 2 cm is regarded as optimum by the American 3-A Sanitary Standards Committee (Hayes 1985).
- Sharp angles.
- Dead ends (including poorly designed seals).

One general problem of food processing involves the extremes of temperature, abundant use of water, condensation and contamination of food from overhead pipes and surfaces. Equipment design must consider this and include proper protection.

Equipment design is one of the major problems in modern food hygiene. A great number of new machines and equipment are designed and constructed without proper attention to the fact that these tools have to be cleaned and sanitized. The EEC Directive 89/392/EEC (EEC 1989) addresses machinery safety and hygiene regulations. Some of the highlights are:

- Machinery containing materials intended to come in contact with food must be designed and constructed so these materials can be cleaned before each use.
• All surfaces and their joinings must be smooth, with no ridges or crevices that could harbor organic materials.
• Assemblies must be designed to minimize projections, edges and recesses. They should be constructed by welding or continuous bonding, with screws, screwheads and rivets used only where technically unavoidable.
• Contact surfaces must be designed to be readily cleaned and disinfected, and built with easily dismantled parts. Inside surfaces must be curved in a way to allow through cleaning.
• Liquid derived from foods, as well as cleaning, disinfecting and rinsing fluids should be able to be readily discharged from machinery.
• Machinery must be designed and constructed to prevent liquids or living creatures - primarily insects - from entering and accumulating in areas that cannot be cleaned.
• Machinery must be designed and constructed so that ancillary substances, such as lubricants, do not come in contact with food.

The directive also sets out a certification system where machinery is checked for compliance and tagged with an EC mark if found to be satisfactory. Certification is not retrospective and manufacturers have two years to bring new machinery into compliance.

Apart from literature already cited, additional useful material and information on hygienic design are found in Anon. (1982, 1983), Milledge (1981) and Katsuyama and Strachan (1980).

7.4 PROCESSING PROCEDURES

Processing procedures are Critical Control Points (CCP-2) in the processing of all food products. All processing techniques and procedures therefore must be designed and aimed at management of contamination and/or growth of microorganisms in food. Such procedures are termed “Good Manufacturing Practices” (GMP).

Detailed codes for GMP must be elaborated for each factory and each processing line (like the HACCP-concept). However a number of details to be included in the GMP-codes have been elaborated by regulatory agencies and international organizations. The most comprehensive example is the work undertaken by the “Codex Alimentarius Commission” of the United Nations, who has published a series of Recommended Codes of Practices (Codex Alimentarius 1969-) including general principles of food hygiene (Vol. A) and a number of fish products(Vol. B) including codes for fresh fish, canned fish, frozen fish, shrimp, molluscan shellfish, lobsters, crabs, smoked fish, salted fish and minced fish. These codes are continuously updated and should be consulted for detailed information on recommended processing procedures.

7.5. PERSONAL HYGIENE
Personal hygiene is a CCP-2 in preventing microbial contamination or any foreign body contamination of fish products. A list of 15 basic points related to personal hygiene has been drawn up by Thorpe (1992) and are shown below:

**Personal hygiene requirements for personnel working in production areas and materials warehouses**

1. **Protective clothing, footwear and headgear** issued by the company must be worn and must be changed regularly. When considered appropriate by management, a fine hairnet must be worn in addition to the protective headgear provided. Hair clips and grips should not be worn. Visitors and contractors must comply with this regulation.
2. **Protective clothing** must not be worn off the site and must be kept in good condition. If it is in poor condition, inform your supervisor immediately.
3. **Beards** must be kept short and trimmed and a protective cover worn when considered appropriate by management.
4. **Nail varnish, false nails and make up** must not be worn in production areas.
5. **False eyelashes, wrist watches and jewellery** (except wedding rings, or the national equivalent, and sleeper earrings) must not be worn.
6. **Hands** must be washed regularly and kept clean at all times.
7. **Personal items** must not be taken into production areas unless carried in inside overall pockets (handbags, shopping bags must be left in the locker provided).
8. **Food and drink** must not be taken into or consumed in areas other than the tea bars and the staff restaurant.
9. **Sweets and chewing gum** must not be consumed in production areas.
10. **Smoking or taking snuff** is forbidden in food production, warehouse and distribution areas where ‘No Smoking’ notices are displayed.
11. **Spitting** is forbidden in all areas on the site.
12. **Superficial injuries** (e.g. cuts, grazes, boils, sores and skin infections) must be reported to the medical department or the first aider on duty via your supervisor and clearance obtained before entering production areas.
13. **Dressings** must be waterproof and contain a metal strip as approved by the medical department.
14. **Infectious diseases** (including stomach disorders, diarrhoea, skin conditions and discharge from eyes, nose or ears) must be reported to the medical department or first aider on duty via your supervisor. This also applies to staff returning from foreign travel where there has been a risk of infection.
15. **All staff must report to medical department when returning from both certified and uncertified sickness**.

**7.6. APPLICATION OF THE HACCP-PRINCIPLE IN ASSESSMENT OF ESTABLISHMENTS**

A great variability exists in the size and extent of handling in fish processing establishments. Accordingly the hygienic requirements and the design in fish handling
areas may vary considerably. Quite obviously the requirements to a small establishment which is only repacking fish in ice and catering for a local market are different from the hygienic requirements to a large establishment, processing a variety of sophisticated products including heat treated and composite products and exporting to countries all over the world. However, all the requirements commonly listed in legislation and codes of practice are not equally important. The more important factors include: facilities for water supply, waste disposal and cooling and cold storage facilities and -capacity. Of less importance are buildings, ventilation, factory location, clothes changing facilities, lightning and roadways (ICMSF 1988).

The forms shown in Figure 7.3 have been utilized in assessing fish factories using the HACCP-principle. Only the most important factors are evaluated and given a rating from A to C, where A and B are expressions of degrees of excellence and niceties, while a rating of C is given to a condition which is unacceptable and needs immediate correction before further operations can take place. Thus it is an attempt to “distinguish between the nice and the necessary” which is the same approach as applied in the HACCP-principle.

ASSESSMENT OF FISH FACTORY

<table>
<thead>
<tr>
<th>Name of factory</th>
<th>Type of production</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of assessor</td>
<td>Date for visit</td>
</tr>
</tbody>
</table>

**FIXED INSTALLATIONS**

<table>
<thead>
<tr>
<th>FACTORY</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site (tidiness, pollution)</td>
<td>A</td>
</tr>
<tr>
<td>General design, lay-out flow of goods</td>
<td></td>
</tr>
<tr>
<td>Separation between clean/unclean processing areas</td>
<td></td>
</tr>
<tr>
<td>Easy to keep clean</td>
<td></td>
</tr>
</tbody>
</table>

**EQUIPMENT**

| Sanitary installations and amenities (toilets, handwashing facilities etc.). | A | B | C |
| Numbers, construction, position | | | |
| Laboratory facilities | | | |
| Water supply (quantity, quality (safe), hot, cold) chlorination | | | |
| Boxes and containers | | | |
| Machinery | | | |
| Wast disposal | | | |

**CHILLING/FREEZING CAPACITY**

| Ice supply | A | B | C |
| Chill room (numbers, size/capacity) | | | |
Freezers/frozen storage (numbers/size/capacity)

OTHERS REMARKS

<table>
<thead>
<tr>
<th>VARIABLE FACTORS</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAW MATERIAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>quality, handling, control with -</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROCESS/PROCESS-CONTROL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flow, markings</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Temperature/temperature control</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Work routines (GMP/BMP). general tidiness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process control, delegation of responsibility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PERSONAL HYGIENE</td>
<td></td>
<td></td>
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<tr>
<td>Dress</td>
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<td></td>
</tr>
<tr>
<td>General understanding of hygiene principles</td>
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</tr>
<tr>
<td>CLEANING AND DISINFECTION</td>
<td></td>
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<tr>
<td>Organisation of routine</td>
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<td></td>
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<tr>
<td>Methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control with -</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>QUALITY ASSURANCE</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Principles, organisation, delegation of responsibility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring of CCP's, records</td>
<td></td>
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<td></td>
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<tr>
<td>Procedures for out of control situations</td>
<td></td>
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</tr>
</tbody>
</table>

OTHER REMARKS

A) Excellent, good or only minor deficiency
B) Less good, serious deficiencies
C) An unacceptable situation, which may result in an unwholesome product representing health of safety threats.

Figure 7.3 Example of simplified form used in assessing fish factories.