

PUBLIC HEALTH ACT MILK PROCESSING REGULATIONS

PLEASE NOTE

This document, prepared by the *Legislative Counsel Office*, is an office consolidation of this regulation, current to September 1, 2013. It is intended for information and reference purposes only.

This document is **not** the official version of these regulations. The regulations and the amendments printed in the **Royal Gazette** should be consulted on the Prince Edward Island Government web site to determine the authoritative text of these regulations.

For more information concerning the history of these regulations, please see the *Table of Regulations* on the Prince Edward Island Government web site (www.princeedwardisland.ca).

If you find any errors or omissions in this consolidation, please contact:

Legislative Counsel Office Tel: (902) 368-4292

Email: legislation@gov.pe.ca



PUBLIC HEALTH ACT Chapter P-30.1

MILK PROCESSING REGULATIONS

Pursuant to section 72 of the *Public Health Act* R.S.P.E.I. 1988, Cap. P-30.1, Council made the following regulations:

DEFINITIONS

1. Definitions

In these regulations

- (a) "Act" means, except where the context otherwise requires, the *Public Health Act* R.S.P.E.I. 1988, Cap. P-30.1;
- (b) "contact surface" means any surface, including equipment, that comes into contact with milk or milk products during processing;
- (c) "contaminated product" means a product that has been exposed to contamination;
- (d) "contamination" means the introduction or occurrence in food or the food environment of any biological or chemical agent, pest, foreign material or substance that has the potential to compromise food safety or render the food unfit for human consumption or sale;
- (e) "**critical control point**" means a point or procedure in a milk processing plant where, with respect to the receiving of milk or the processing of a product, a failure to exercise control over the process at that point or a failure to follow a procedure in the process may result in a health hazard;
- (f) "**critical limit**" means identified tolerances in processing that shall be met to ensure that a critical control point effectively controls a health hazard;
- (g) "fluid milk product" means a milk product sold in liquid form, including 3.25% milk, 2% milk, 1% milk, skim milk, blend, table cream, whipping cream and flavoured milk;
- (h) "food grade steam" means steam made from potable water;
- (i) "HTST", in respect of pasteurization, means high temperature, short time;
- (j) "hygienic practices" means all practices and measures necessary in the production, processing, and distribution of products to ensure that the products are free from contamination and meet the requirements in these regulations, including Schedules I and III;

- (k) "license" means a license issued by the Minister under section 14 of the Act for the operation of a milk processing plant;
- (l) "license holder" means a person who holds a license to operate a milk processing plant and, for the purposes of these regulations, includes an agent of the license holder and a person to whom the license holder has delegated responsibility for the day-to-day operation of the milk processing plant;
- (m) "pasteurization" means the process of heating every particle of a product in equipment that is designed and operated to meet or exceed the required time and temperature relationships specified in these regulations with the object of reducing the level of pathogenic micro-organisms associated with that product in order to assure the safety of the product over its intended shelf life and storage conditions;
- (n) "pathogen" means any disease producing agent or micro-organism;
- (o) "potable" means water that is free from pollution, harmful organisms and impurities;
- (p) "**processing**" means the manufacture, modification, pasteurization, preparation, reconstitution, packaging or storage of products, and includes the cleaning and sanitizing of equipment and contact surfaces;
- (q) "**product**" means milk or a milk product that
 - (i) contains no oil or fat other than that of milk,
 - (ii) is prescribed in Schedule II to these regulations, or
 - (iii) contains a minimum of 50% milk ingredients by weight;
- (r) "sanitary" means a condition that prevents contamination by a microbiological, chemical or physical hazard;
- (s) "sanitize" means to kill any pathogenic bacteria;
- (t) "spoilage" means, in the case of raw milk and milk products, an action that renders the food unfit for human consumption:
- (u) "toxin" means a poisonous substance that is produced by living cells or organisms that can cause disease. (EC417/12; 559/13)

PART I — LICENSING REQUIREMENTS

2. License for milk processing plant

- (1) The Minister shall not issue or renew a license for the operation of a milk processing plant unless an application in respect of the license is received by the Minister, in the form required by the Minister, containing
 - (a) in respect of a new license, a description and blueprint of the site, building and equipment, a product flow diagram, information about the source of the raw milk, cleaning and sanitizing protocols, recall protocols, the products to be processed and the processes to be used; and
 - (b) in respect of the renewal of a license, information respecting any changes in the information provided for the issuance of the existing license that have not been reported to the Minister pursuant to subsection (6).

Compliance required

(2) In addition to the requirements of subsection (1), an applicant for a license or the renewal of a license for a milk processing plant shall comply with the applicable requirements of the Act and these regulations and pay the licensing fee set out in subsection (4).

Issuance of license

(3) A license for a milk processing plant shall be issued by the Minister in the form established by the Minister.

Fee

(4) The fee for a license or the renewal of a license is \$300.

Expiration

(5) A milk processing plant license issued under this section expires on December 31.

Requirement to report changes

(6) A license holder shall report any change in the information provided by the license holder for the purposes of subsection (1) that occurs within the term of the license to the Minister as soon as practicable.

License not transferable

(7) A milk processing plant license is not transferable.

Revocation and reissue of license

(8) The Minister may revoke a license that contains information that has changed as referred to in subsection (6) and may issue a new license to the license holder, based on the new information provided, on payment of the licensing fee set out in subsection (4).

Notice of terms and conditions

(9) Where the Minister imposes terms and conditions on a license issued under this section in accordance with subsection 14(4) of the Act, the Minister shall notify the license holder in writing respecting the terms and conditions being imposed.

Terms and conditions

- (10) The terms and conditions referred to in subsection (9) may be, but are not limited to, limitations or conditions respecting
 - (a) production processes;
 - (b) products that may be processed;
 - (c) use of equipment;
 - (d) employment in production processes of persons who are not fully qualified; or
 - (e) storage of raw materials prior to processing. (EC417/12; 559/13)

3. Suspension of license

- (1) The Minister may refuse to issue or renew, or may suspend a milk processing plant license for a term of up to 30 days, where
 - (a) the milk processing plant, its equipment or its operations do not meet the requirements of the Act or these regulations;
 - (b) the license holder does not comply with the provisions of the Act or these regulations;
 - (c) the Minister has reason to believe that public health will be endangered if the milk processing plant is allowed to continue operating; or
 - (d) the license holder has failed or is unable to take immediate corrective measures as referred to in clause (2)(b) to remedy a contravention or failure to meet the requirements of the Act or these regulations.

Notice of suspension

- (2) The Minister shall not suspend a license under subsection (1) unless
 - (a) a public health official has, at the time of the inspection, notified the license holder of the failure to comply with the relevant provision of the Act or these regulations;
 - (b) a public health official has provided the license holder with a copy of an inspection report prepared by the public health official that sets out the failure to comply with the relevant provision of the Act or these regulations, the required corrective measures and the dates by which those measures must be implemented in order to avoid suspension; and
 - (c) a notice of suspension of license is delivered to the license holder.

Suspension period

- (3) A suspension of a license under subsection (1) shall remain in effect
 - (a) until the required corrective measures have been taken and have been verified by a public health official; or
 - (b) throughout the period referred to in subsection (1) or a longer period imposed by the Minister under section 4. (EC417/12; 559/13)

4. License revocation

- (1) The Minister may revoke the license for a milk processing plant where
 - (a) the license holder has not implemented the required corrective measures within the 30-day period following the day on which the license was suspended or within any longer period of time allowed under subsection (2); or
 - (b) the application for the license contained false or misleading information.

Extension of time

(2) If it is not possible for the license holder to implement the required corrective measures within the 30-day period referred to in clause (1)(a), the Minister may, on the request of the license holder, allow a longer period of time that the Minister considers adequate to implement those measures if, in the opinion of the Minister, there is no significant risk to human health.

Notice of cancellation

(3) Revoked by EC559/13. (EC417/12; 559/13)

5. Appeal

(1) A person who is aggrieved by a decision of the Minister under subsection 3(1) or 4(1) or the imposition of terms and conditions on his or her license under subsection 14(4) of the Act may appeal the decision or imposition to the Supreme Court within 30 days after being served with notice of the decision or imposition.

Decision on appeal

- (2) On hearing an appeal, the Supreme Court may
 - (a) confirm, revoke or vary the terms and conditions imposed by the Minister or the decision appealed from;
 - (b) refer the matter, or any issue, back to the Minister for further consideration; or
 - (c) provide any direction that it considers appropriate.

Costs of appeal

(3) The Supreme Court may make any order as to the costs of an appeal that it considers appropriate. (EC417/12; 559/13)

PART II — PROCESSING FACILITIES AND EQUIPMENT

6. Standards of construction

(1) An applicant for a license and a license holder shall ensure that the milk processing plant to which the license pertains at all times meets the standards set out in this section with respect to construction, layout and operation and continues to meet those standards in the course of, and following, any alterations or renovations.

Milk processing plant construction

(2) All access routes and exterior traffic areas shall be constructed of a dense material so as to prevent contamination from dust and mud.

Surrounding area

(3) The area surrounding the milk processing plant shall be maintained free of waste and refuse and of any other source that could contaminate the milk or milk products that are produced at the plant.

Construction materials

(4) The exterior of the milk processing plant shall be constructed of materials that are durable and maintained in good repair.

Doors, windows, etc.

(5) The building shall be equipped with doors, windows and other necessary openings that lead to the outside that have been designed and installed so as to prevent the entry of arthropods, birds, rodents or other vermin or contaminants from entering the milk processing plant and contaminating the product.

Floor

- (6) In order to prevent product contamination, open product handling areas within the milk processing plant shall have floors, walls and ceilings that are made of smooth, washable and waterproof material and are
 - (a) constructed in such a manner as to be easily cleanable;
 - (b) free of cracks and crevices; and
 - (c) with respect to floors,
 - (i) free draining to drains that are connected to sewer piping that will adequately carry the waste from the plant in a sanitary manner, and
 - (ii) joined to the wall so as to prevent the accumulation of dirt and liquids.

Design of waste system

(7) A milk processing plant shall be designed and constructed so that effluent or sewage lines do not pass directly over or through production areas unless they do not pose a contamination risk to production and storage areas.

Potable water

(8) A milk processing plant shall

- (a) have an adequate source of potable hot and cold water and food grade steam to serve the needs of the plant; and
- (b) be equipped with waste and sewage disposal systems to remove processing waste from the plant in a sanitary manner.

No cross-contamination

(9) A milk processing plant shall be designed so as to prevent cross-contamination between raw ingredients and finished products.

Portable processing facilities

(10) Portable processing facilities and processing facilities with drainage piping shall be connected to a drain.

Lighting

- (11) A milk processing plant shall be equipped with a lighting system in each area that is
 - (a) designed and installed to enhance production and handling operations as well as the cleaning and disinfecting of facilities and equipment; and
 - (b) protected in order to prevent the contamination of product or packaging, in the event of the breaking of a lighting element.

Ventilation

(12) A milk processing plant shall be equipped with a ventilation system that vents condensation, vapours and odours to the exterior and provides air flow that does not contaminate product.

Hand washing station, change areas

- (13) A milk processing plant shall be equipped with
 - (a) sanitary hand washing stations in working areas, equipped with hot and cold potable water under pressure, dispensed soap and either paper towels or electric hand dryers so as to facilitate the cleaning and disinfecting of hands; and
 - (b) for employees and visitors, a change area and washrooms that do not lead directly into processing and packaging areas of the plant, and are equipped with hot and cold potable water under pressure, toilets and sanitary hand washing sinks with dispensed soap and either paper towels or electric hand dryers so as to facilitate the cleaning and disinfecting of hands. (EC417/12)

7. Design, construction and installation of equipment

(1) A license holder shall ensure that all equipment used in a milk processing plant is designed, constructed, installed and operated in compliance with these regulations.

Safe and sanitary manner

(2) A license holder shall ensure that all parts of a milk processing plant, including the equipment, are maintained and operated in a safe and sanitary manner.

No cross-contamination

(3) A license holder shall ensure that all equipment used in the processing of products is designed, constructed, installed and operated so as to assure that there is no cross-contamination of pasteurized products by any other product.

Contact surfaces of materials and equipment

(4) A license holder shall ensure that the contact surfaces of the material and equipment are

- (a) made of non-corrosive material;
- (b) smooth and have no crevices or loose parts;
- (c) non-toxic and resistant to damage from cleaning and disinfecting operations;
- (d) unaffected by products, and constructed in such a way so as not to alter the characteristics of the products; and
- (e) free of components or residue which may act as contamination agents for products.

Use of steam

(5) A license holder shall ensure that steam introduced directly into the products, or which comes into direct contact with the contact surfaces, is prepared from potable water and is free of harmful substances.

Accessibility of components for cleaning

(6) A license holder shall ensure that material and equipment constructed by assembly, other than by welding, is removable, and each component is accessible so as to allow cleaning, disinfection and inspection. (EC417/12)

8. Pasteurization

(1) Subject to subsection (2), no person shall sell a product unless the product has been pasteurized in accordance with Schedule I.

Un-pasteurized products sold for further processing

- (2) Subsection (1) does not apply to products that have not been pasteurized that
 - (a) are sold or distributed for further processing to a license holder in accordance with subsection 11.1(2) of the Act; and
 - (b) are clearly and prominently marked "Not for Retail Sale Product not Pasteurized".

Pasteurization equipment

(3) A license holder shall ensure that all pasteurization equipment is designed, constructed, and operated to ensure the proper pasteurization of products and the pasteurization equipment meets the requirements of these regulations.

HTST pasteurizers

- (4) HTST pasteurizers shall be designed to ensure that when in operation
 - (a) the flow diversion valve does not operate in forward flow unless the temperature of the product being pasteurized equals or exceeds that required for its proper pasteurization; and
 - (b) the product pressure in the pasteurized side of the regenerator is at least 14 kPa greater than the product pressure in the raw side of the regenerator.

Batch pasteurizers

- (5) All batch pasteurizers shall be equipped with
 - (a) indicating or recording thermometers;
 - (b) close coupled outlet valves and leak protector inlet and outlet valves provided with stops, or valves equivalent in effectiveness in preventing the mixing of unpasteurized and pasteurized product;
 - (c) mechanical agitation that is continuously maintained throughout the heating and holding operations; and

(d) covers adequate to prevent contamination.

Idem

(6) Where an indicating thermometer is used, a suitable recording procedure shall be established and maintained.

Airspace temperature

(7) During the minimum holding period, the airspace temperature in batch pasteurizers shall be at least 3°C above the minimum temperature set out in Schedule I.

HTST pasteurizers

- (8) All HTST pasteurizers shall be equipped with
 - (a) recording thermometer;
 - (b) a constant level tank;
 - (c) a regeneration section;
 - (d) a flow control device;
 - (e) a heating section;
 - (f) a holding device;
 - (g) a sensing chamber;
 - (h) a safety thermal limit recorder;
 - (i) an indicating thermometer;
 - (i) a flow diversion device;
 - (k) a pressure differential controller or pressure switch if a booster pump is used;
 - (1) a cooling section where applicable;
 - (m) a vacuum breaker; and
 - (n) components that ensure that the pasteurized product in the regeneration section will, at all times, be at a pressure greater than the pressure of the raw product in the same regeneration section.

Auxiliary equipment

- (9) Auxiliary equipment shall not be installed or operated in conjunction with an HTST pasteurizer so as to
 - (a) reduce the holding time below the minimum set out in Schedule I;
 - (b) influence the required pressure relationships within the regenerator; or
 - (c) function as a flow promoting device, except where the auxiliary equipment is inter-wired with the flow control device.

Cooling capacity

(10) All HTST pasteurizers shall be capable of cooling fluid milk and fluid cream to a temperature of 4°C.

Cooling period

(11) All batch pasteurizers shall be capable of cooling fluid milk and fluid cream to a temperature of 4°C after the end of the minimum holding period specified in Schedule 1.

Accuracy of temperature devices

(12) A milk processing plant license holder shall ensure that all temperature-indicating devices are accurate and maintained in working order. (EC417/12; 559/13)

PART III — PRODUCT STANDARDS

9. Raw milk received

- (1) A license holder shall
 - (a) ensure that all raw milk received at a milk processing plant
 - (i) is at a temperature of 6°C or less, and
 - (ii) tests negative for the presence of veterinary drug residues and inhibitory substance residues as tested by an approved screening method or tests below the maximum residue level permitted by a quantitative method approved by the Canadian Food Inspection Agency; and
 - (b) retain a copy of the information recorded in respect of the raw milk by the driver who delivered it.

Protection from spoilage and contamination

(2) A license holder shall ensure that all raw milk received at a milk processing plant is stored in a manner so as to be protected from spoilage and contamination.

Use of non-milk ingredients

- (3) A license holder shall ensure that non-milk ingredients and supplies used in the processing of products
 - (a) conform to the requirements of the *Food and Drugs Act* (Canada) and the regulations made under that Act; and
 - (b) are protected from contamination.

Storage of raw materials and ingredients

(4) A license holder shall ensure that all raw materials and ingredients, during their use, are fit for human consumption and, before their use, are stored so as to be kept free of contamination and infestation.

Labelling of raw materials and ingredients

(5) A license holder shall ensure that containers of raw materials and ingredients are labelled to identify the type of raw materials and ingredients they contain.

Cooling of products

(6) Products that require refrigeration shall be kept at all times at a temperature that does not exceed 4°C.

Exception for processing

(7) Products whose manufacturing processes include processing at a higher temperature than that required under subsection (6), including but not limited to drying, curing and aging, shall be processed at the appropriate temperature for that product and, when processing is completed, kept as required under subsection (6).

Frozen products

(8) Products that are intended to be consumed as frozen products must be maintained in a frozen state at minus 18°C at all times. (EC417/12)

10. Processed milk standards

A person shall ensure that all processed fluid milk products offered for sale or sold are

- (a) properly pasteurized;
- (b) stored, held for sale or displayed at a temperature not greater than 4°C;
- (c) transported at a temperature not greater than 4°C; and
- (d) stored, transported, distributed, displayed or held for sale under clean and sanitary conditions. (EC417/12)

11. Food-borne pathogens and microbial toxins

(1) A license holder shall ensure that each product does not contain detectable levels of food-borne pathogens and microbial toxins except as provided for in Schedule III and meets the microbiological, chemical and temperature standards as prescribed in Schedules I and III.

Pathogenic bacteria

(2) No person shall knowingly sell, offer for sale, distribute or supply to any person a product that contains pathogenic bacteria or any foreign substance in excess of the limits set out in Schedule III to these regulations. (EC417/12)

PART IV — ADDITIVES

12. Additives

(1) No license holder shall add to a product any substance other than those substances approved as additives under the *Food and Drugs Act* (Canada) and the regulations under that Act.

Additive requirements

(2) A license holder shall ensure that all products meet the food additive and labelling requirements specified in the *Food and Drugs Act* (Canada) and the regulations under that Act. (EC417/12)

PART V — RECORDS

13. Records

(1) A license holder shall establish and maintain written protocols to ensure a particular lot of a product can be identified and traced from the point of purchase of the raw product to the point of distribution.

Required information

- (2) A license holder shall ensure that process control records for batch pasteurizers provide the following information for each pasteurization process:
 - (a) plant name and address or license number;
 - (b) date, shift and batch number where applicable;
 - (c) vat number;
 - (d) a record of the time of filling and emptying the vat and record of holding period;
 - (e) a reading of the air space thermometer in the pasteurizer during pasteurization;
 - (f) a reading of the indicating thermometer during pasteurization;
 - (g) amount and name of product represented by each batch or run;



- (h) time of any unusual occurrence and operator's comments respecting and reasons for the occurrence; and
- (i) signature or initials of operator.

Prohibition

(3) The reading of the indicating thermometer referred to in clause (f) shall never be lower than the recording thermometer reading during the holding period.

Temperature records

(4) A milk processing plant license holder shall maintain a complete and accurate record of the temperature used in pasteurization for each lot of pasteurized product.

Records retention

- (5) A license holder shall ensure that temperature records are retained at the milk processing plant for not less than twelve months and contain the following information:
 - (a) the name of the milk processing plant;
 - (b) the date;
 - (c) the serial numbers of both pasteurizer and recorder;
 - (d) the temperature of pasteurization as shown by the indicating thermometer during the holding period;
 - (e) the name and signature of the pasteurizer operator;
 - (f) the products processed;
 - (g) the flow diversion valve position, whether forward or divert;
 - (h) the cut-in and cut-out temperature recorded by the operator at start-up, when a new set point is selected or at the beginning of each product run.

Training records

(6) A license holder shall maintain records of the training completed by each employee while that employee is employed at the milk processing plant. (EC417/12)

PART VI — EMPLOYEES AND VISITORS

14. Employee training

(1) A license holder shall ensure that all employees who work with processing equipment are trained and competent to carry out their assigned duties or functions.

Entry restrictions

(2) A license holder shall ensure that entry to the processing, manufacturing, reprocessing, storage, packing and repacking areas of a milk processing plant is restricted to authorized personnel.

Hygienic practices

(3) A license holder shall institute hygienic practices in the milk processing plant and require all employees who work with processing equipment and all visitors to comply with those practices so as to ensure the sanitary processing of products.

Process workers

- (4) A license holder shall ensure, for the purpose of eliminating cross-contamination between unpasteurized and pasteurized product, that employees who work with processing equipment
 - (a) wear work apparel that shows dirt easily and that has no pockets or buttons above the waist:
 - (b) wear a head covering in order to completely cover the hair and ears and a beard-cover to cover the beard, if any, while working in the plant;
 - (c) before moving from a high potential cross-contamination area to an area with less potential cross-contamination,
 - (i) change soiled clothing or cover clothing,
 - (ii) clean footwear in a sanitary footbath provided for the purpose, and
 - (iii) clean hands at a hand washing station; and
 - (d) do not wear watches or exposed jewellery within the product processing areas.

Prohibitions

- (5) A license holder shall not allow
 - (a) any person who has a notifiable disease that is transmissible through food to be or to work in a food contact area;
 - (b) any product to be handled by a person who has a notifiable disease that is transmissible through food;
 - (c) any product to be handled by a person who has an open sore unless that person is wearing a waterproof protection on the wound that prevents contamination of the product, ingredients, or contact surfaces. (EC417/12)

PART VII — SAFETY AND SANITATION

15. Contaminated products

(1) A license holder shall not sell any product for human consumption that is contaminated.

Documentation

- (2) A license holder shall establish and maintain written protocols to ensure that products processed and stored in the milk processing plant are not contaminated, including
 - (a) the identification of critical control points;
 - (b) the critical limits for all critical control points;
 - (c) the procedures required to ensure adherence to the critical limits; and
 - (d) actions to be taken in the event that critical limits are not met. (EC417/12)

16. Cleanliness

(1) A license holder shall ensure that milk processing plant facilities, material and equipment are kept clean.

Written procedures

(2) A license holder shall establish and maintain written protocols for the milk processing plant's sanitation program.

Sanitation program

- (3) The sanitation program for a milk processing plant shall include
 - (a) cleaning and sanitizing requirements and protocols for the milk processing plant, including equipment; and
 - (b) identification of cleaning and sanitizing agents and their concentrations and use in accordance with the requirements of the Canadian Food Inspection Agency. (EC417/12)

17. Cleaning materials and agents

- (1) A license holder shall ensure that hand cleaning of equipment
 - (a) is carried out with non-metallic materials; and
 - (b) all cleaning agents, disinfectants, insecticides, pesticides and other methods of fighting pests shall conform to the requirements of the Canadian Food Inspection Agency.

Storage of cleaning agents, etc.

(2) Subject to subsection (3) all cleaning agents, disinfectants, insecticides and pesticides shall be stored in an enclosed area or compartment, outside the product handling areas, and the containers for these products shall be labelled to identify the nature of the contents.

Storage of daily use products

(3) In cases where, as part of the daily operation, it is necessary to make constant use of a cleaning agent, disinfectant, insecticide or pesticide referred to in this section, the containers identified as being for daily use may be stored in an enclosed compartment located inside the product processing areas. (EC417/12)

PART VIII — STANDARDS

18. Analysis methods

A license holder shall ensure that all analysis of products is conducted by methods outlined in the most recent edition of Standard Methods for the Examination of Dairy Products published by the Canadian Public Health Association or the most recent edition of the Official Methods of Analysis of the Association of Official Analytical Chemists. (EC417/12)

19. Adoption of standards

(1) The standards set out in Schedules I and III are hereby adopted and form part of these regulations.

License holder's responsibility

(2) A license holder shall ensure that the standards set out in Schedules I and III are met during processing in the milk processing plant. (EC417/12)

20. "Manual", defined

(1) In this Part, "Manual" means the provisions of the Dairy Establishment Inspection Manual developed by the Canadian Food Inspection Agency, as amended from time to time, which

pertain to the types of equipment that shall be used in the receiving, processing, pasteurizing, manufacturing, packaging, storing and dispensing of milk and milk products.

Adoption of Manual

(2) The Manual is hereby adopted and forms part of these regulations.

License holder's responsibility

(3) A license holder shall ensure that the milk processing plant, its equipment and its operations meet the applicable requirements set out in the Manual.

Conflict

(4) In the event of a conflict between a provision of the Manual and a provision of these regulations, the provision of the Manual prevails to the extent of the conflict. (EC417/12)

PART IX — ENFORCEMENT AND PENALTIES

21. Seizure or Detention

- (1) Where a public health official seizes or detains a product or any other thing pursuant to the Act or these regulations, the public health official shall affix to the product or other thing a detention tag on which the following is clearly marked:
 - (a) the words "UNDER DETENTION" in letters of at least 24 point font;
 - (b) an identification number;
 - (c) a description of the product or other thing;
 - (d) the reason for the seizure or detention;
 - (e) the date of the seizure or detention;
 - (f) the name of the public health official, in block letters, and the signature of the public health official.

Prohibition

(2) No person shall alter, deface or remove a detention tag attached to a product or any other thing unless the person is authorized to do so by a public health official. (EC417/12; 559/13)

22. Notice of detention

- (1) A public health official shall, after seizing or detaining a product or any other thing in accordance with section 21, forthwith deliver or mail a notice of detention
 - (a) to the person having the care or custody of the product or other thing at the place where it was detained and to the person having the care or custody of the product or other thing at the place where it is being detained; and
 - (b) to the owner of the product or other thing that was seized or detained, or to the owner's agent.

Idem

- (2) A notice of detention referred to in subsection (1) shall state that the product or other thing was seized or detained pursuant to the Act and these regulations and shall set out
 - (a) the detention tag identification number;
 - (b) a description of the product or other thing;
 - (c) the reason for the seizure or detention;



- (d) the date of the seizure or detention;
- (e) the name of the public health official, in block letters, and the signature of the public health official;
- (f) the place of detention; and
- (g) the telephone number to call for further information in respect of the seizure or detention. (EC417/12; 559/13)

23. Preservation of detained product

A product or other thing seized or detained under the Act and these regulations shall be detained at the owner's expense under storage conditions appropriate to the preservation of the product or other thing. (EC417/12)

24. Notice of release

If a public health official releases a product or other thing after determining that it meets the requirements of the Act and these regulations, the public health official shall deliver or mail one copy of a notice of release to each of the persons to whom a copy of a notice of detention referred to in section 22 was delivered or mailed. (EC417/12; 559/13)

25. Product recalls

A license holder shall establish and maintain a written protocol for the recall of products that do not meet the requirements set out in these regulations, indicating

- (a) the person responsible for carrying out the program;
- (b) methods of identifying batches or lots of the products;
- (c) notification and other procedures to effect the recall;
- (d) subject to the direction of a public health official, disposition of the product recalled; and
- (e) steps to be taken to avoid similar recalls in the future. (EC417/12; 559/13)

26. Danger to public health

The Chief Public Health Officer shall order a Level I or II recall of a product in accordance with section 27 or 28 where the failure of the product to comply with the standards set out in these regulations constitutes a danger to public health, including but not limited to circumstances where the product is contaminated with any of the following:

- (a) pathogens, including but not limited to listeria and salmonella;
- (b) chemical contaminants;
- (c) extraneous matter, including but not limited to glass and metal fragments; or
- (d) food ingredients not permitted under the *Food and Drugs Act* (Canada) or these regulations. (EC417/12; 559/13)

27. Level I (high risk) recalls

(1) The Chief Public Health Officer shall issue a Level I recall order to a license holder in respect of a product that does not meet the standards set out in these regulations when there is a high risk that eating or drinking that product will lead to serious health problems or death.

Public warning

(2) The Chief Public Health Officer shall issue a public warning for a Level I recall when the product is available for sale or could be in a consumer's home. (EC417/12; 559/13)

28. Level II (moderate risk) recalls

(1) The Chief Public Health Officer shall issue a Level II recall order to a license holder in respect of a product that does not meet the standards set out in these regulations if eating or drinking that product will probably lead to short-term or non-life-threatening health problems or where the chance of any serious health symptoms is low.

Public warning

(2) The Chief Public Health Officer may issue a public warning for a Level II recall based on the Chief Public Health Officer's assessment of risk and other criteria that are appropriate in the opinion of the Chief Public Health Officer, including but not limited to the expected severity of symptoms in vulnerable populations such as children, pregnant women and seniors. (EC417/12; 559/13)

29. Level III (low and no risk) recalls

The Chief Public Health Officer may issue a Level III recall order to a license holder in respect of a product and request that the license holder recall the product in accordance with section 26 where the product does not meet the standards set out in these regulations but eating or drinking that product will probably not result in any undesirable health effects. (EC417/12; 559/13)

SCHEDULE I

MINIMUM PASTEURIZATION PARAMETERS FOR BATCH AND HTST PASTEURIZERS

Product	Pasteurization Type	Minimum holding period	Minimum temperature during holding period	
Milk Based Products - below 10% MF	Batch/Vat	30 minutes	63°C	
Milk Based Products - below 10% MF	HTST	15 seconds	72°C	
Milk Based Products - 10% MF or higher, or added sugar (fluid cream, chocolate milk, flavoured milk)	Batch/Vat	30 minutes	66°C	
Milk Based Products - 10% MF or higher, or added sugar (fluid cream, chocolate milk, flavoured milk)	нтѕт	15 seconds	75°C	
Frozen Dairy Product Mixes, Eggnog	Batch/Vat	30 minutes	69°C	
Frozen Dairy Product Mixes	нтѕт	25 seconds	80°C	
Eggnog	нтѕт	15 seconds	83°C	

(EC417/12)



SCHEDULE II

For the purposes of section 11.1(2) of the Act, the milk products that may be processed or manufactured in a milk processing plant are as follows:

Fluid milk products, including:

3.25% milk;

2% milk;

1% milk;

skim milk;

blend;

table cream;

whipping cream;

chocolate milk and other flavoured milk.

Frozen dairy product mixes

Frozen products

Eggnog

Cheese

Fermented products, including:

Buttermilk;

Yogourt;

Sour cream.

Butter

(EC417/12)



SCHEDULE III

STANDARDS FOR PRODUCTS

Product	Bacteria	n	С	m	М
Cheese (pasteurized milk)	S. aureus E. coli	5 5	2 2	100 100	10,000 (/g) 1,000 (/g)
Cheese (pasteurized) without ripening, including fresh cheeses, lactic curd with a minimum of 50% moisture	Coliform	5	2	10	100 (/g)
Fermented products (e.g. buttermilk, yogourt, sour cream)	Coliform	5	2	10	100 (/g or ml)
Pasteurized milk, cream and other non-fermented products	Mesophilic aerobic bacteria (32°C) Coliform	5 5	2 2	10,000 1	25,000 (/ml) 10 (/ml)
Frozen products	Mesophilic aerobic bacteria (32°C) Coliform	5 5	2 2	10,000 10	50,000 (/ml) 100 (/ml)
Butter	Mesophilic aerobic bacteria (32°C) Coliform	5 5	2 2	10,000 10	50,000 (/g) 100 (/g)

Where:

n = number of sample units to be examined per lot;

c = maximum number of sample units per lot that are permitted to have a bacterial concentration higher than the value for "m";

m = maximum number of bacteria per g or ml of product that is acceptable;

M = maximum number of bacteria per g or ml of product that, if exceeded in any one sample unit, renders the product contaminated.

(EC417/12)