Human Milk Banking Association of North America
Public Standards for Milk Banking 2026

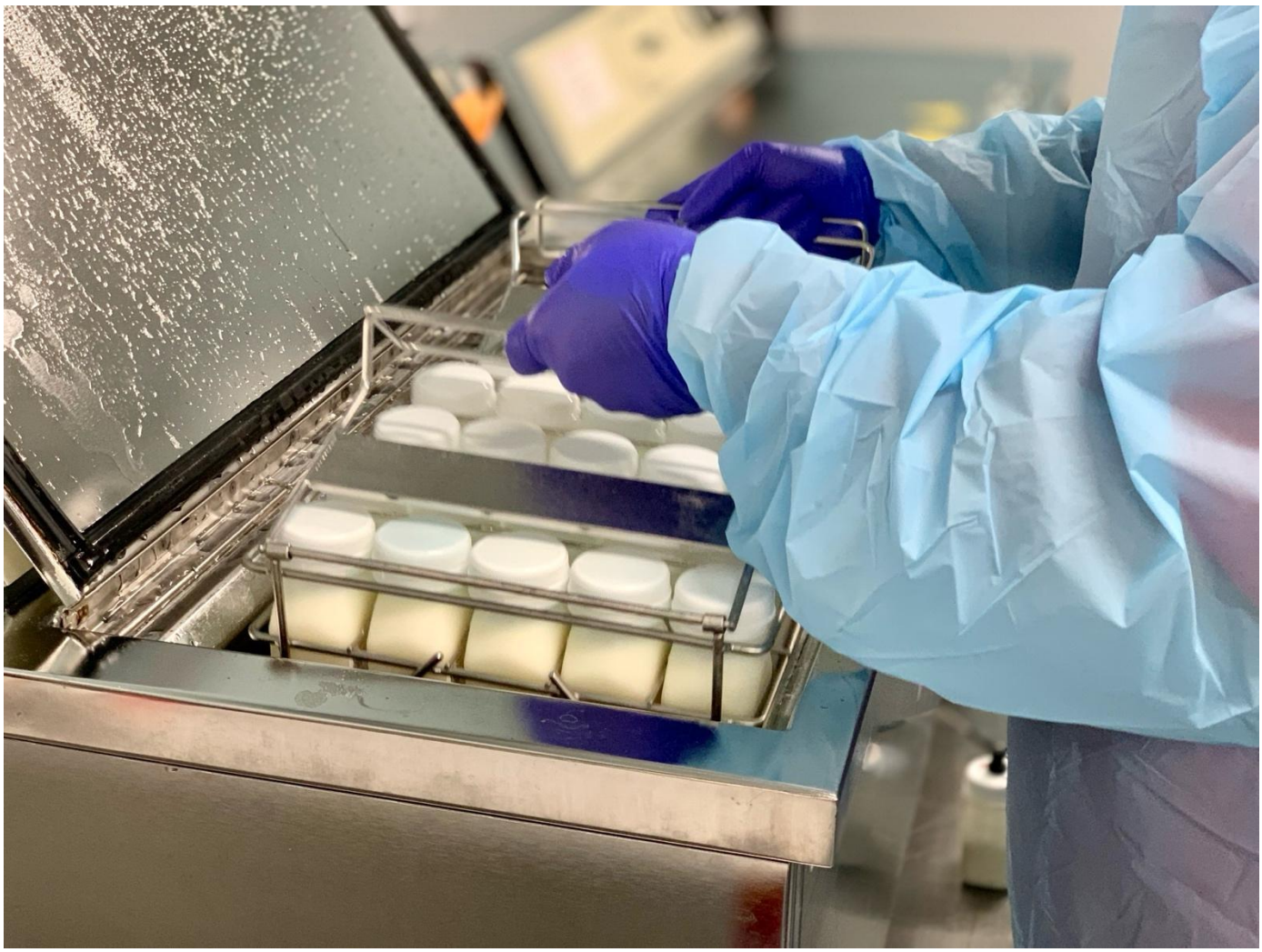


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Section 1. Preface

The Human Milk Banking Association of North America (HMBANA) Public Standards for Donor Human Milk Banking are measures that HMBANA-accredited milk banks utilize to ensure the safety and quality of pasteurized donor human milk, hereinafter referred to as donor milk. These evidence-based Standards are intended for reference by the medical community, government, health care and public health agencies, infant feeding advocates, and researchers.

The complete version of HMBANA Standards for Donor Milk Banking is proprietary and confidential and is provided to each HMBANA-accredited member milk bank.

HMBANA accreditation provides evidence that a milk bank is compliant with HMBANA Standards and maintains a comprehensive system of preventive controls, safety checks, verifications, validations, and corrective actions.

Any claim to adherence to these standards without an accreditation certificate rendered by HMBANA is not evidence of adequate safety or quality. Organizations that identify as milk banks, but lack HMBANA accreditation, have not passed required audits; they do not have access to the proprietary HMBANA Standards available only to member milk banks and cannot claim adherence to such standards.

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Section 2. Standards Committee

In 1985, the Human Milk Banking Association of North America (HMBANA) was founded to support development and sustainability of nonprofit milk banks, and to create a baseline of safety through donor screening and milk-processing standards. HMBANA's Standards Committee publishes the *Standards for Donor Human Milk Banking,* referred to in this document as Standards.

Standards Committee Members

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The Standards Committee draws from the expertise of professionals who advise specifically on safety implications of pharmaceuticals and supplements.

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The Standards Committee draws from the expertise of professionals who advise on scientific and medical issues relevant to milk banking.

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Section 3. Essential Definitions and Abbreviations

American Academy of Pediatrics (AAP): A membership organization of pediatricians in the United States, dedicated to the health and well-being of infants, children, and adolescents

Canadian Food Inspection Agency (CFIA): An agency responsible for safeguarding food, animals, and plants, which enhances the health and well-being of Canada's people, environment, and economy

Canadian Pediatric Society (CPS): A membership association of pediatricians and health professionals dedicated to advancing the health of children and youth

Centers for Disease Control and Prevention (CDC): The US government's leading science-based, data-driven, service organization responsible for protecting the public's health

corrective action: Action taken when controls or critical limits are not met, with the intent of eliminating the cause of an error to prevent reoccurrence

critical control point (CCP): A processing step where a control eliminates or reduces the risk of a food safety hazard (e.g., pasteurization reduces the biological hazard of bacterial/viral contamination of milk)

critical limits: Minimum and maximum values or parameters that are allowed during a CCP (e.g., time and temperature of pasteurization)

customer complaint log: A written or electronic record that documents and records the investigation and resolution of customer complaints

depot: An agency affiliated with a human milk bank that collects and stores donated milk that is then transported to the affiliated milk bank for processing

dietary supplement: A product that is added to a diet. A dietary supplement is taken by mouth and usually contains one or more dietary ingredients. Examples of dietary ingredients include vitamins, minerals, herbs, amino acids, and enzymes. Also called a nutritional supplement

distribution or dispensary site: An agency affiliated with a milk bank that stores and distributes pasteurized donor human milk (PDHM)

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Donor Human Milk Bank: A nonprofit service established for the purpose of recruiting, screening, and collecting milk from donors, and processing, storing, and distributing pasteurized donor human milk (PDHM)

exception: Documentation of a process, outcome, or occurrence outside of a milk bank's standard operating procedures or HMBANA Standards

food contact surfaces: All surfaces that contact donor human milk during the normal course of operations. These include work surfaces, utensils, and equipment

Food and Drug Administration (FDA): A US governmental agency that is responsible for protecting public health by ensuring the safety, efficacy, and security of food, drugs, biological products, and medical devices

food safety manager (FSM) or person-in-charge: A supervisor or manager responsible for daily food safety

Food Safety Modernization Act (FSMA): 2011 FDA Act to prioritize the prevention of foodborne illness

food safety plan (FSP): A written plan in a preventive controls food safety system. These documents provide a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury

good manufacturing practice/current good manufacturing practice (GMP/cGMP): FDA regulations requiring manufacturers of drugs, medical devices, food, and blood to establish controls to ensure that their products are safe, pure, and effective

hazard: A biological, chemical, or physical agent that is reasonably likely to cause injury in the absence of its control

hazard analysis critical care points (HACCP): A safety monitoring system that is used to identify and control biological, chemical, and physical hazards with the storage, transport, use, preparation, and distribution of food

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Health Insurance Portability and Accountability Act of 1996 (HIPAA): A Department of Human and Health Services (HHS) law that sets US standards to protect certain health information

Holder pasteurization: A low-temperature/long-time heat treatment method to pasteurize milk

human milk terms:

- **dairy-restricted milk:** Donor milk collected from milk donors who report strict adherence to a dairy avoidance diet
- **lactation stage:** Time since giving birth, which may affect components of the milk
- **pasteurized donor human milk (PDHM):** Donated milk from screened donors processed and pasteurized without additives, according to HMBANA Standards
- **pooled milk:** Milk from more than one donor
- **preterm milk:** Milk from a donor who delivered before 37 weeks' gestation expressed in the first month postpartum; milk collected after the first month is considered term milk
- **raw milk:** Expressed milk that has not been pasteurized or subjected to heat treatment
- **reduced fat milk:** Milk treated by simple removal of fat by gravity or centrifugation to achieve less than 1 gm/dL of total fat for infants with special nutrition needs
- **term milk:** Expressed milk from a donor who delivered at or after 37 weeks' gestation, or from a donor who delivered before 37 weeks' gestation but was collected after the first month
- **thawed milk:** Liquid milk with no ice crystals

licensed health care providers: Required for multiple decisions and approvals; for HMBANA purposes this refers to a registered nurse, nurse practitioner, physician, certified nurse midwife, or physician's assistant

milk donor: A healthy, lactating mother who voluntarily, without receiving remuneration from any party, donates her milk

pathogen abbreviations:

- hepatitis B virus (HBV)
- hepatitis C virus (HCV)

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- human immunodeficiency virus (HIV)
- human T-lymphotropic virus (HTLV)
- *Treponema pallidum* (syphilis)

Personal Information Protection and Electronic Documents Act (PIPEDA): A Canadian law governing how organizations conduct and protect electronic commerce by protecting personal information

Preventive Control Plan (PCP): Safe Food for Canadians Act required document that demonstrates how risks to food are identified and controlled

preventive controls qualified individual (PCQI): A trained and qualified individual who completes a formal PCQI Certification Program

processing: The use of evidence-based methodologies, including pasteurization, to prepare safe milk

processing fees: Fees assessed by the milk bank to offset the cost of milk processing

product recall: A formal process of managing dispensed milk that has not met CCPs, or that is considered to pose a safety risk

qualified individual: A member of staff with the education, experience, and training to safely process food

quality assurance program: A planned and systematic procedure for controlling hazards in food manufacturing

recall (FDA): A voluntary action and formal process to remove or correct products that may violate laws administered by the FDA and thus to protect public health

root cause analysis (RCA): A systematic problem-solving approach to investigate events and clarify fundamental causation of an error or near-miss event, identifying systemic weaknesses instead of individual mistakes

Safe Food for Canadians Act (SFCA): Enacted in January 2019 with the goal of improving food safety in Canada. The CFIA oversees food safety under the SFCA

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sanitation terms:

- **clean:** To physically remove dirt, debris, and microscopic contaminants by using detergents and water
- **disinfect:** To destroy or inactivate most microorganisms on hard surfaces
- **sanitize:** To reduce microbial load to increase safety and decrease risk of contamination without adversely affecting the product or its safety for the consumer
- **sterilize:** To destroy all microorganisms, including spores, via autoclave or other method(s) of sterilization

standard operating procedure (SOP): Instructions that document how to perform an activity and guide staff in a concise, consistent, and step-by-step manner

standards of identity (SOI): FDA and CFIA rules that are intended to protect consumers by outlining minimum required ingredients, optional ingredients, and the manufacturing process of foods

temperature and thermal monitoring terms:

- **accuracy:** The measure of how closely a thermometer's readings match the actual temperature
- **certificate of calibration:** A certificate that comes with a National Institute of Standards and Technology (NIST) reference or other formally calibrated and certified thermometer and provides details on calibration, accuracy, expiration, and other metrics
- **control bottle probe:** A thermometer inserted into a control bottle to measure milk temperature during the pasteurization process
- **National Institute of Standards and Technology (NIST):** A nonregulatory US government agency of the Department of Commerce that develops standards and technology in the field of measurement science (e.g., thermometers and calibration certificates)
- **one-point calibration:** Comparing the thermometer being calibrated against the reference thermometer at one temperature point

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- **reference thermometer:** A thermometer certified to be accurate, generally with a five-point calibration certificate

World Health Organization (WHO): A specialized United Nations agency responsible for directing and coordinating international public health

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Section 4. Administrative Structure

Business and Regulatory Requirements

In the United States, HMBANA member milk banks are nonprofit organizations that maintain IRS 501(c)(3) status and good standing with their state's charitable bureau. In addition, US milk banks are required to register biannually as food facilities with the FDA.

In Canada, milk banks are designated by the Canadian Regulatory Authority as charitable organizations.

All milk banks are required to adhere to local regulations related to:

- Licensing or certification
- Food facility registration
- Zoning requirements
- Health department requirements

Personnel and Volunteers

Milk banks must be staffed to maintain safe operations. Dedicated, trained personnel must include:

- **director/coordinator:** This person actively manages the organization, serves as a liaison between HMBANA and the milk bank, and is responsible for ensuring adherence to HMBANA Standards and other regulatory requirements.
- **lab manager/person-in-charge:** Also known as a food safety manager, this person is responsible for safe operations and lab staff supervision on any given day, has in-depth knowledge of the Standards and other regulations, and manages all exceptions.
- **PCQI:** Each milk bank designates at least one preventive controls qualified individual (PCQI) who receives formal training and certification through an approved PCQI trainer, or equivalent training per FDA guidance. A PCQI approves the milk bank's Food Safety Plan and SOPs.

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- **lab technician:** An individual who receives extensive education and training in Current Good Manufacturing Practices (CGMPs), maintains current food handler certification, and meets the FDA's definition of a *qualified individual*.
- **donor coordinator/donor screener:** An individual who receives extensive training and demonstrates competencies related to donor communication and medical record keeping, assessing donors per HMBANA Standards, determining deferrals based on medication and health status, and maintaining privacy and confidentiality.
- **volunteers:** Unpaid individuals may be utilized for specific operational or administrative tasks once they have been vetted and trained. Volunteers must be supervised by milk bank staff and receive education about food safety and privacy practices.

Medical Oversight

Each milk bank must have:

- A medical director/adviser who is a physician licensed to practice medicine.
- A licensed medical professional who approves donors (registered nurse, nurse practitioner, physician, certified nurse midwife, physician's assistant).
- Milk bank medical advisers available for consultation, including specialists from the following disciplines: Pediatrics, Obstetrics, Lactation.

Privacy

Milk banks operate under rules of privacy and confidentiality as required by their country and state/ province.

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Section 5. Donor Qualifications

Donor screening is the first safety control in milk banking. The intent of initial and ongoing screening is to minimize risk to recipient infants by evaluating physical, biological, and chemical contaminants of human milk. Note that the term “donor” in this section includes those who may not yet be approved.
Donor qualifications are based on best practices and clinical data and are updated continuously to reflect emerging diseases, pharmaceutical treatments, and identified health risks and high-risk behaviors.
Adherence to HMBANA Standards is mandatory, including in the event of a medical or public health crisis.

Donor Screening Summary

General Guidance

- Screening is initiated by the lactating mother.
- Screening is never limited to electronic or written communication and must include verbal and written components.
- Screening includes providing donors with required educational materials.
- Screening includes assessment of donor infant’s health status to ensure there are no medical, infectious, or other factors that could result in a deferral or disqualification of the donor.
- Screeners obtain signed documents regarding the donor’s known health/medical risks and medications/vaccines/supplements from their licensed health care providers (e.g., physicians, physician’s assistants, advanced practice nurses, midwives).
- Screening includes obtaining a signed consent from the donor.

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Donor Incentives

Milk banks do not pay milk donors for their donation. Milk donors may be provided supplies to allow them to express, store, and transport their milk safely.

Screening for Medical Risks

Screening for Medication Use

Potential donors are thoroughly questioned regarding medication use. This includes administered therapeutics, prescription and over-the counter medications, vaccines, and supplements. Approved donors are instructed to notify milk bank staff if they begin taking any medication or supplement; staff discuss any relevant deferral dates with the donor. HMBANA's Standards and Medication Advisory Committees provide a confidential medication tool containing defined deferral periods for substances.

Screening for Illness Restrictions

Potential donors are screened for acute and chronic illnesses that may affect human milk. Temporary or permanent deferrals may be assigned based on the illness, exposure to the illness, or treatments, both prescribed and over the counter.

Blood testing

All donors must test negative for HIV, HTLV, Hepatitis B, Hepatitis C, and syphilis. Donors are deferred permanently for blood testing confirming active/ongoing/chronic infection that may pose a risk.

Permanent or Temporary Deferrals

Deferrals may be assigned for many reasons, including but not limited to:

- Chronic infection(s) or a history of past infections or viruses that have the potential for transmission through breast milk

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- Acute infections that have short- or long-term effects on breast milk, or whose treatments present known or potential risks of transfer via breast milk
- Recent history of sexually transmitted diseases
- Communicable diseases such as varicella, herpes, or zoster
- Exposure to communicable diseases, such as Ebola virus
- Smoking or use of tobacco products
- Alcohol consumption
- Use of illegal recreational drugs
- Use of cannabis or CBD products
- Recent history of blood transfusion
- Organ or tissue transplant
- At-risk sexual practices

Donor Approval and Continued Assessment

- Completed donor applications are approved by two qualified screeners, one of whom must be a licensed health care provider.
- Approval verifies that all steps of screening were taken and that the Standards have been met.
- Milk banks engage donors in continued assessment.
- Donors are instructed to communicate any changes in their medical or lifestyle status, supplement or medication use, and general health, including any exposures to infectious or communicable diseases routinely throughout the donation process.
- An approved donor may be deferred at any time when updated information suggests a risk.

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Milk-Handling and Storage Restrictions

- Milk is stored in food-grade containers.
- Milk is not accepted if it has been heat treated in any way.
- Milk is not accepted if storage exceeds 96 hours (four days) in the refrigerator.
- Milk expires 12 months from date of collection.

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Section 6. Donor Education

Education Regarding Milk Safety, and Potential Risks and Deferrals

Milk banks are responsible for providing the following education to all milk donors:

- Implications of donor health factors, including recent or chronic illnesses and infections, recent surgeries, exposures to infectious diseases or harmful substances.
- Implications of medications and supplement use.
- Dates of deferral for milk previously collected.
- Information on when and how to contact the milk bank about new exposures, medications, or diagnoses.
- Clean technique for milk collection, including handwashing and cleaning and sanitizing equipment.
- Proper identification/labeling of milk containers, including date of expression.
- Avoidance of adding anything to, heating, or altering milk in any way other than freezing.
- Best practice for freezing milk.
- Best practice for packing and transporting milk to the milk bank or depot.

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Section 7. Food Safety, Equipment, and Calibration

Food Safety

Milk banks in the United States are regulated and inspected as food manufacturers by the US FDA. All US milk banks must comply with the Food Safety Modernization Act (FSMA) and register biannually with the FDA as a food manufacturer.

In Canada, nonprofit milk banks are treated as food facilities and must comply with the Food and Drugs Act and Safe Food for Canadians rules, under Health Canada and CFIA oversight for safety, labeling, and sanitation.

All milk banks must comply with CGMPs, HMBANA Standards, and food safety regulation:

- Identify a food safety manager (FSM) and a preventive controls qualified individual (PCQI) who receive formal training in food safety.
- Create and maintain a food safety plan (FSP) team to identify hazards and preventive controls.
- Maintain a customer complaint log.
- Provide comprehensive staff training about CGMPs and food safety.
- Review federal and local food statutes, updating training and documents annually.
- Keep records that demonstrate adherence to food code and HMBANA Standards.

Standard Operating Procedures

Milk banks maintain detailed SOPs available to all staff. Staff have a clear understanding of the SOPs related to performance and safety.

Personnel

- Staff are responsible for accessing current FDA/CFIA regulations regarding food facility personnel and conducting annual reviews for new information.

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- All milk bank staff and volunteers who handle milk must have current food handling safety certification or training per state/province regulations.
- All staff and volunteers are trained on health, hygiene, and illness reporting.
- All staff and volunteers working in direct contact with milk, milk-contact surfaces, and milk-packaging materials adhere to strict hygienic practices to protect milk from contamination.

Pest Control

Pest control monitoring programs include:

- SOP outlining inspection, monitoring, reporting, and corrective actions.
- Routine on-site inspections.
- Food manufacturing-specific services as appropriate.

Sanitation

Sanitation programs include:

- Cleaning schedules and logs.
- Sanitation SOPs that address cleaning schedules, sanitation agents and their storage.
- Use of food-safe sanitizers for food prep contact surfaces.
- Use of non-food-safe disinfectants with caution to prevent chemical residue on food contact surfaces or inadvertent exposure to milk.

Food Facility Design

Milk banks are responsible for accessing current FDA/CFIA regulations regarding food facility design.

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Equipment

- Equipment manuals are readily accessible to milk bank personnel.
- Equipment is used only for milk banking purposes.
- Clean, sanitize, and maintain equipment according to manufacturer's instructions.
- Ensure that equipment and utensils are made from non-corrosive food-grade material and can be cleaned and sanitized.
- Use BPA-free food-grade plastics when storing and processing human milk.

Pasteurizers

- Pasteurizers are calibrated and maintained to meet HMBANA time and temperature critical limits.
- Clean and sanitize pasteurizers at least once daily.

Freezers and Refrigerators

- Maintain temperature of freezers at –18°C/0°F or colder.
- Maintain temperature of refrigerators at 4°C/40°F or colder.

Analyzers

- Maintain the instrument according to the manufacturer's directions.
- Report annually to recipient hospitals about what instrument is used for analysis and what calculation is used for energy content.

Warewashers

- Commercial warewashers reach boost temperature of 82°C/180°F with every final cycle.
- Confirmation of successful sanitation is verified daily.

Autoclaves

- Autoclaves are calibrated per equipment manufacturers' instructions in compliance with milk bank SOP.

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Thermometers and Thermal Monitoring

Thermometers

- Thermometers are used for verification of cold storage, warewasher, and water faucet temperatures, pasteurization verification, and other purposes.
- All milk bank thermometers must be accurate and certified by either National Institute of Standards and Technology (NIST) or similar agency, or calibrated onsite.
- Frequency of thermometer calibration is determined by several factors: accuracy, thermometer role in critical limits, and reliability.

Reference Thermometer

- Milk banks maintain at least one certified reference thermometer.

Cold Storage Thermometers

- A minimum of two calibrated thermometers are required to monitor temperatures in freezers and refrigerators.
- Freezer/refrigerator thermometers are accurate to +/– 1°C.

Pasteurization Thermometers

- Data logging thermometers are used in a control bottle during pasteurization to verify milk temperature and:
    - Are accurate to +/– 0.5°C.
    - Generate digital records that are attached to the batch record.
    - Are verified against a reference thermometer.

Thermometer Verification and Calibration Procedures

- Technicians who perform thermometer verifications and calibrations must receive and document adequate training and supervision.
- Maintain calibration records that include tested thermometer temperatures, reference thermometer temperatures, and corrective actions if the tested thermometer is out of specification.

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- Thermometers are calibrated per schedule or if there is any question of accuracy.
- All newly purchased control bottle probe thermometers and those with a new NIST certificate must be verified by the milk bank reference thermometer before placing unit into service.

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Section 8. Processing and Pasteurization

A milk bank receiving, processing, bottling, and the critical pasteurization steps are key elements of milk banking that assure a safe and high-quality pasteurized donor human milk (PDHM) product.

Milk Processing

Receiving

- Trace each donation to a specific, approved milk donor.
- Inspect each donation to ensure milk meets quality and safety standards.
- Maintain detailed logistics data.

Thawing Raw Milk

- Thaw milk in a manner that prevents adulteration or contamination and adheres to thermal standards.

Straining Raw Milk

- Raw milk is strained using a food-grade, sanitized strainer.

Pooling Raw Milk

- All pools must be multi-donor pools.
- Pools are prepared under clean conditions.
- The expressed milk sample with the earliest date of expression will be used to calculate the expiration date for the pool and, eventually, the batch of milk.

Adequacy of Mixing

- Annual testing to ensure consistent macronutrient distribution throughout the batch is required.

Batch

- A batch is a set of bottles from the same pool that fits into a single pasteurizer.
- Each batch is given a unique batch number.

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Bottling

- Use BPA-free, food-grade bottles and caps that maintain integrity at freezing and pasteurization temperatures.

Milk Pasteurization

Pasteurization Control Bottle

- Place a temperature probe into the control bottle strategically located to accurately record pasteurization temperature.

Pasteurization

- Pasteurize capped bottles of milk in a preheated water bath.
- All milk undergoes Holder pasteurization at 62.5°C for 30 minutes.
- Control bottle thermometer time and temperature are recorded via electronic monitoring.

Cooling

- Cool milk rapidly after completion of heat treatment.
- Transfer cooled bottles to refrigerator or freezer.

Post Pasteurization Bacteriological Testing

Testing Procedure

- Testing to validate successful pasteurization must be conducted on every batch.
- Remaining milk from the test bottle is discarded or used for research and not dispensed.
- Post-pasteurization bacteriological testing is conducted by a third-party accredited lab.
    - Clinical labs maintain Clinical Laboratory Improvement Amendments of 1988 (CLIA) or equivalent certification.
    - Food testing labs meet ISO/IEC 17025 standards.

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Batch Approval

- Approve batches if pasteurization time and temperature critical limits are met and post pasteurization culture is negative/no growth.
- Two qualified individuals approve all batches; one must be a PCQI or FSM.

Batch Rejection

- Reject batches that do not pass pasteurization critical limits or microbiologic testing.
- Rejected milk is discarded and not dispensed.

Shipping

- Pack bottles using clean technique.
- Follow shipping vendor's guidelines to ensure that milk arrives at its destination intact and in a frozen state.
- Use dry ice or other products to keep milk frozen.
- Train staff on dry ice handling and use appropriate documentation on shipping materials.

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Section 9. Standards of Identity and Labeling

Standards of Identity

Standards of identity (SOI) for food are FDA and CFIA rules that are intended to protect consumers by outlining minimum required ingredients, optional ingredients, and the manufacturing process of foods.

Nomenclature

The name of the food is “Pasteurized Donor Human Milk” (PDHM).

Description

Donated milk is the mammary secretion obtained by the expression of breastmilk by volunteer milk donors after a pregnancy. PDHM is a pooled product from multiple donors and has no additives or additional ingredients. It has been heat treated to remove harmful pathogens and is culture-negative prior to dispensation. PDHM is a food intended for infant feeding in the absence of mothers’ own milk. Donated milk can be approved up to 12 months from the time milk was expressed, and no restriction regarding the lactational stage of the milk (time since delivery) is mandated. However, consideration should be given to pooling practices, macronutrient changes with lactational stage, and the intended recipients.

HMBANA Approved Products

The following products are subjected to HMBANA Standards and accreditation, and they are the only products supported by HMBANA Standards.

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- **pasteurized donor human milk:** Donated milk from screened donors processed and pasteurized without additives, according to HMBANA Standards.
- **reduced fat milk:** Milk treated by simple removal of fat to achieve less than 1 gm/dL of total fat for infants with special nutrition needs. Methods may include natural separation or equipment used to facilitate separation such as centrifuge.

Labeling

- PDHM bottles and caps require water resistant labels affixed securely to each bottle of milk before it is dispensed.
- Labels should be clear, legible, and indelible.
- Labels must include the following:
    - Milk type/product name
    - Unique batch number
    - Milk bank of origin
    - Expiration date/Use by/Best by/Best before
    - Volume of milk

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Section 10. Milk Bank Records

Records must:

- Reflect compliance with milk bank SOPs, HMBANA Standards and federal/state/provincial regulations.
- Be retained electronically or on paper.

Required Staff Records

- Professional licenses and certifications.
- Food safety training certifications.
- Annual education regarding health, hygiene, and illness reporting.
- HMBANA technical skills checklists, updated as appropriate.
- Evidence of education and training relevant to role.
- Staff records are kept for the duration of employment and per state/province and federal requirements.

Required Milk Donor Records

- Documentation of written/electronic and verbal interviews, health care provider statements, documentation showing ongoing communication of medical and lifestyle changes, and informed consent.
- Laboratory report of required blood tests.
- Indication of approval of applicant by two qualified individuals.
- Documentation of all raw milk deposits and their disposition.

Required Milk Processing Records

- Identification of donor deposits that comprise each batch.
- Batch information.
- Milk approval records.

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- Dispensation records, including rejected milk.
- Post-pasteurization microbiological test reports.
- Identification of the staff involved in the processing, from thawing to approvals.

Required Recipient Records

- Recipient's name and contact information.
- Dispensing date, batch numbers, number of bottles, and volume of milk dispensed.

Required Safety and Quality Assurance Records

Safety and quality assurance records include:

- Current Food Safety Plan (FSP)
- FSP team meeting agenda and minutes
- Freezer and refrigerator temperature records
- Calibration and maintenance records for all equipment
- Verification logs
- Customer complaint logs
- Pest control records
- Facility maintenance and inspection records
- Corrective action plans
- Accreditation audit results
- Recalls
- FDA food facility and other regulatory certification, site inspection materials

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Section 11. Donor Milk Depots and Distribution Site

Donor Milk Depot

A donor human milk depot is an agency contracted and trained with an accredited milk bank to receive and store donor milk from approved milk donors that is then transported to the milk bank for processing. The partnering milk bank is responsible for ensuring the screening, processing, distribution, and safety of the milk received from each depot.

Donor Milk Distribution Site

A donor milk distribution site, also referred to as a dispensary, is an agency contracted with an accredited milk bank to dispense donor milk to outpatients as needed. In both situations, the partnering milk bank is responsible for ensuring site compliance with HMBANA Standards for storage, dispensation, recordkeeping, and verification of compliance via an annual report or visit to each site.
Distribution sites provide families in their community with a readily available source of donor milk.

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Section 12. Resources

United States

- Center for Disease and Prevention: www.cdc.gov
    - Food safety
    - Cleaning a breast pump
    - Proper storage and preparation of breast milk
    - Specific pathogen screening algorithms (e.g., HIV, Hep B, Hep C, HTLV, syphilis)
    - Weekly morbidity and mortality report (MMWR) www.cdc.gov/mmwr/index.html
- Counsel of State and Territorial Epidemiologists: www.cste.org
- Dietary Guidelines for Americans: www.dietaryguidelines.gov
- Department of Health and Human Services, health information privacy: www.hhs.gov/hipaa/index.html
- Drugs and Lactation Database (LactMed®): www.ncbi.nlm.nih.gov/books/NBK501922
- Food and Drug Administration: www.fda.gov
    - Bacteriological Analytical Manual
    - Code of Federal Regulations, Title 21, Food for Human Consumption: www.ecfr.gov/current/title-21/chapter-I/subchapter-B
    - Current good manufacturing practice for blood and blood components
    - Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food
    - Employee Health and Personal Hygiene Handbook
    - Federal Food, Drug, and Cosmetic Act
    - Food allergies
    - Food Code 2025

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    - Food Safety Modernization Act (FSMA)
    - Guidance documents
    - Pasteurized Milk Ordinance
    - Recalls
    - Reportable registry for industry
- US Department of Agriculture, Food Safety and Inspection Service: www.fsis.usda.gov/food-safety

Canada

- Canadian Blood Services: www.blood.ca/en
- Canadian Food Inspection Industry (CFIA) (2026): inspection.canada.ca/en
- Canadian Institute of Food Safety: www.foodsafety.ca
- Canadian Pediatric Society: cps.ca/en
- Food safety for industry: inspection.canada.ca/en/food-safety-industry
- Government of Canada: www.canada.ca/en.html
- Office of the Privacy Commissioner of Canada: www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/02_05_d_15
- Public Health Industry of Canada: www.canada.ca/en/public-health.html
- Safe Food for Canadians Regulations: laws-lois.justice.gc.ca/eng/regulations/SOR-2018-108/page-1.html

Europe/Global

- European Directorate for the Quality of Medicines and Healthcare: www.edqm.eu/en/substances-of-human-origin
- International Society of Blood Transfusion: www.isbtweb.org

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Health Care

- Academy of Breastfeeding Medicine: www.bfmed.org
- American Academy of Pediatrics: www.aap.org
    a. AAP Red Book 2024–2027: Report of the Committee on Infectious Diseases: Committee on Infectious Diseases: publications.aap.org/redbook
    b. AAP Pediatric Nutrition, 9th ed.: www.aap.org/Pediatric-Nutrition-9th-Edition
    c. Pediatric Environmental Health, 4th ed.: publications.aap.org/aapbooks/book/524/Pediatric-Environmental-Health
- Association for the Advancement of Blood & Biotherapies: www.aabb.org
- The Council to Improve Foodborne Outbreak Response: cifor.us/products/industry
- Food Safety Preventative Controls Alliance: www.fspca.net
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- Mother to Baby: mothertobaby.org
- Mother to Baby LactRx App: mothertobaby.org/lactrx
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- Stop Foodborne Illness, stopfoodborneillness.org

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