Pennsylvania
Department of Agriculture

APPLICATION PACKET FOR PERMIT TO SELL MILK and/or MILK PRODUCTS

MILK PERMIT

Manufacturing, Processing, Transporting, Distributing, Warehousing, Raw Milk Producing

CONTENTS:

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Enclosed are the necessary forms and applications for obtaining a Permit from the Pennsylvania Department of Agriculture. Please be advised that according to **§ 59a.12.** (a) A person may not sell milk, milk products or manufactured dairy products within this Commonwealth without having a current, valid permit from the Secretary… (b). A separate permit shall be obtained for each milk plant, milk distributor, receiving station, transfer station, bulk tank unit and milk tank truck cleaning facility, and by every producer of raw milk in accordance with Subchapter F (relating to raw milk for human consumption). Additional permits or licenses may be required for milk haulers and weighers/samplers under regulations established and enforced by the PA Milk Board.

2301 N Cameron Street Suite 112 Harrisburg, PA 17110-9408
https://www.pa.gov/en/agencies/pda/food-safety.html
717.787.4315

MILK PERMIT APPLICATION AND PLAN REVIEW

APPLICATION FOR PERMIT TO SELL MILK AND/OR MILK PRODUCTS

SECTION 1:

PRODUCTION OPENING

Anticipated date to begin operations/open for production: _____

NAME OF ESTABLISHMENT (common public name)**:** _____

PHYSICAL ADDRESS:

_____
Facility street number and name | City | State | Zip code

_____ _____
County | Township/Borough

(_____)_____ (_____)_____
Facility phone number | Facility fax number

_____ (_____)_____
Facility email address | Facility cell number or alternate/emergency phone number

RESPONSIBLE OFFICIAL AT THE ESTABLISHMENT:

_____
Name | Title | Email address

MAILING ADDRESS (If Different Than Above):

_____
Street number and name | City | State | Zip code

_____
Contact Name | Title | Email address

SECTION 2:

PURPOSE OF THE APPLICATION

PART A: Select ALL boxes that indicate the type of permit you are applying for:

- ☐ Grade A Milk Plant (Plan to pasteurize Grade A milk/milk products)
- ☐ Non-Grade A Milk Plant (Plan to pasteurize Non-grade A milk/milk products)
- ☐ Milk Producer - Raw (Plan to sell raw milk, raw aged cheese and/or raw milk butter)
- ☐ Receiving Station _____ Grade A _____ Non-Grade A
- ☐ Transfer Station/Wash Station
- ☐ Milk Tanker
- ☐ Distributor
- ☐ Bulk Tank Unit (BTU) Number of Farms in Bulk Tank Unit (BTU):_____
- ☐ Single Service Container Manufacturer

MILK PERMIT APPLICATION AND PLAN REVIEW

PART B: Please select ALL product types that describe your operation:

Milk Plant Grade A and Non-Grade A

- ☐ Pasteurized Milk
- ☐ Ultra Pasteurized Milk
- ☐ Raw Milk for Pasteurization
- ☐ Cultured Milk/Milk Products
- ☐ Buttermilk
- ☐ Blended Dry Milk Products
- ☐ Lactose Reduced Products
- ☐ Sour Crean (& Dips)
- ☐ Pasteurized Ice Cream mix
- ☐ Concentrated Milk Products
- ☐ Pasteurized Cream
- ☐ Ice Cream Products
- ☐ Condensed Milk
- ☐ Cream Cheese
- ☐ Yogurt
- ☐ Nonfat Dry Milk
- ☐ Grade "A" Lactose
- ☐ Pasteurized cheese
- ☐ Eggnog
- ☐ Ultrafiltered Permeate (Milk/Whey)
- ☐ Low Sodium Milk/Milk Products
- ☐ Cottage Cheese
- ☐ Pasteurized Butter
- ☐ Whey/Whey Cream/Modified Whey
- ☐ Heat Treated Milk/Milk Products
- ☐ Other Manufactured Dairy Products
- ☐ Aseptically Processed and Packaged Products Ice Cream Products
- ☐ Milk and Milk Products with Safe and Suitable Microbial Organisms

Produce Raw Milk / Milk Products

- ☐ Raw Milk Bottled on premises
- ☐ Raw Milk Bottled off premises (Location: _____)
- ☐ Sales on premises -consumer container
- ☐ Sales on premises -facility container
- ☐ Sales off premises
- ☐ Raw Aged Cheese
- ☐ Raw Milk Butter

Milk Bulk Tank Unit (BTU)

- ☐ Grade A Milk for Pasteurization
- ☐ Manufacturing grade milk for Pasteurization

PART C: Species of milking animal:

☐ Cow ☐ Goat ☐ Sheep ☐ Other: _____

PART D: Processing Types

- ☐ Pasteurized
- ☐ Ultra-pasteurized
- ☐ Raw
- ☐ Organic
- ☐ Aseptically processed and packaged
- ☐ Single service container

PART E: DAYS & TIMES OF OPERATION: Check anticipated days and time the facility will be operational:

☐ Year Round ☐ Seasonal: From _____ To _____

- ☐ Monday Time _____
- ☐ Tuesday Time _____
- ☐ Wednesday Time _____
- ☐ Thursday Time _____
- ☐ Friday Time _____
- ☐ Saturday Time _____
- ☐ Sunday Time _____

PART F: FOOD SAFETY SYSTEMS AVAILABLE:
Check all applicable boxes to indicate the food safety system you will have implemented in the establishment:

☐ Pest Control (Company name): _____

☐ Third Party Audit (Company Name): _____

☐ FSMA Food Safety Plan ☐ Yes ☐ No ☐ Exempt – Attestation filing date: _____

☐ Process Controls ☐ Allergen Controls ☐ Sanitation Controls ☐ Supply-Chain Program ☐ Recall Plan

☐ Other Formal Food Safety Systems (Specify): _____

**NOTE: All labels used on Raw Milk and/or Raw Milk Products shall be submitted to the Department for review and approval before use in accordance with 7 Pa Code Chapter 59a.411. A copy of all labels and supporting documentation for claims (i.e. grass fed, non-GMO, A2A2, Kosher, etc.) shall be submitted to your assigned food inspector and approved by the Department prior to use of that label.

SECTION 3:

WATER, SEWER, WASTE INFORMATION

Issuance of a Milk Permit in no way implies that this operation is compliant with any other state or local rules relating to water, sewer, zoning or building codes of any kind. It is the applicant responsibility to assure they are compliant with all other state or local rules and regulations.

WATER:
You must contact the Department of Environmental Protection (DEP) to determine if your facility qualifies as a public water system (PWS). If DEP determines your facility qualifies as a public water system, then the water supply must be approved by DEP. **Written documentation** must be provided including your assigned Public Water System (PWS) ID# and **approval letter** from DEP. If DEP determines your facility does **NOT** qualify as a public water system, **written documentation** from DEP must be provided and **current water tests for Total Coliform**

The facility is using:

☐ A municipal (community) water supply.
Provide name of municipal water supplier: _____ (ex: PA American Water) **AND a copy of the water bill.**

☐ A non-community water supply that is not owned/operated by the facility.
Provide name of the regulated water supplier and its Public Water System ID#: _____
(ex: The Shopping Plaza, Public Water System ID# 1111111)

☐ A non-community public water supply Regulated by the Department of Environmental Protection (DEP). Provide its Public Water System (PWS) ID#: _____ **AND DEP Approval Letter (or other written proof of operation from DEP).**

☐ Other / Private water supply (ex: well water). **Provide written verification from DEP AND water supply test results**.

SEWER: The Establishment is using:

☐ A municipal/public sewage disposal system. Name of Sewage Authority: _____

☐ A non-public sewage disposal system (examples; Sand mounds, holding tanks, septic). For on-lot sewage disposal systems, please contact the certified Sewage Enforcement Officer for your municipality and discuss if the current sewage disposal system is appropriate for your operation.

WASTE: All types of waste must be contained and disposed of properly according to Milk Sanitation Ch59a and The Grade A Pasteurized Milk Ordinance (PMO).

Name of Waste Hauler: _____

ZONING AND OTHER CODES

Issuance of a Milk Permit in no way implies that this Establishment is compliant with any other state or local rules relating to water, sewer, zoning or building codes of any kind. It is the applicant responsibility to assure they are compliant with all other state or local rules and regulations.

☐ I have verified that the Establishment is compliant with all Local Zoning and all Building Codes as required. If you will be operating in a County Health Department, all applicable licenses/registrations issued by the County must be obtained **BEFORE** obtaining a PDA permit.

☐ A license to collect PA State sales tax has been obtained or applied for. For information on applying for a PA State sales tax license, contact the Pennsylvania Department of Revenue - (888) PATAXES or https://mypath.pa.gov/_/
OR

☐ According to the PA Department of Revenue rules and regulations, I have determined that my business is exempt from collection of sales tax.

SECTION 4:

PLAN REVIEW: Properly prepared plans for all milkhouses, milking barns, stables and parlors, milk tank truck washing facilities, milk plants, receiving stations and transfer stations which are constructed, reconstructed or extensively altered shall be submitted to the Department for written approval before work begins. Plans must likewise be approved before construction or extensive modification of a manure storage system; installation of a bulk milk storage tank; installation of a milk transfer system on a dairy farm; or installation of milk handling equipment in a transfer station, receiving station, or milk plant (7 Pa. Code Chapter 59a.26).

Additional Applications may be necessary and can be found at: https://www.pa.gov/en/agencies/pda/food-safety/dairy-and-dairy-product-manufacturing.html

- ☐ Application to Install or Modify Dairy Processing Equipment (Full Dairy Plant Installation-Modification Application)
- ☐ Application to Install or Modify Milk Handling Equipment on a Dairy Farm. (Full Dairy Farm Equipment Application)
- ☐ Application for Appendix N Variance
- ☐ Milk Shared Facility and or Equipment Agreement
- ☐ FDA Food Facility Registration - https://www.fda.gov/food/registration-food-facilities-and-other-submissions/online-registration-food-facilities

SECTION 5: ALL APPLICANTS READ AND SIGN

The Applicant understands and agrees that this document is an application to obtain a milk permit in accordance with Chapter 59a.12 Permit. The holder of this permit, permitholder, understands that all milk and/or milk products are subject to the Pennsylvania Milk Sanitation Law and all other applicable regulations. By signature on this application, the applicant verifies that all statements and information in this application is true and correct to the best of the applicant's knowledge, information and belief; and makes these statements subject to the penalties of 18 Pa.C.S.A. § 4904, relating to unsworn falsification toauthorities.

☐ INDIVIDUAL PERSON:

Signature

Legibly Print Name

Date _____ Date of Birth _____

☐ PARTNERSHIP:

Signature – General Partner _____ Signature – General Partner _____

Legibly Print Name _____ Legibly Print Name _____

Date _____ Date of Birth _____ Date _____ Date of Birth _____

☐ CORPORATION OR ASSOCIATION / NON-PROFIT ENTITY:

Name of Corporation or Non-profit Entity

Name of current CEO/President/or Similar _____ Official Title _____ Date of Birth of CEO/President/or Similar _____

Signature of Corporate / Association / Non-Profit Official _____ Official Title of Signatory _____

Legibly Print Name _____ Date _____

☐ LIMITED LIABILITY COMPANY (LLC), LIMITED LIABILITY PARTNERSHIP (LLP):

Name of LLC or LLP

Name of Senior Official/General Partner, or Similar _____ Official Title _____ Date of Birth of Senior Official/General Partner, or Similar _____

Signature – Member _____ Date _____ Signature – Member _____ Date _____

Legibly Print Name _____ Legibly Print Name _____

MILK PERMIT APPLICATION AND PLAN REVIEW

LEGAL BUSINESS NAME (if different than establishment name)**:** _____

LEGAL OWNER MAILING ADDRESS (if different than above mailing address):

_____

Owner street number and name City State Zip code

(_____)_____ (_____)_____ _____

Owner phone number Owner fax number Owner e-mail address

All material must be submitted at least **60 days prior** to **construction, remodeling, alteration of a facility, change in type of operation, new ownership AND at LEAST 60 days prior to opening.** Failure to provide all required information could delay your plan review and permit.

Please check and sign you have included all required supporting documentation along with submission of the completed application.

I have attached the following supporting documents where applicable.

- ☐ Proof of municipal water supply (ex. A copy of a water bill) or a copy of Laboratory results for a private well
- ☐ A copy of Laboratory results for recirculated cooling water
- ☐ Animal Herd Health Veterinarian certification
- ☐ Tuberculosis and Brucellosis test date/results
- ☐ Negative Pathogen test and passing lab reports for 3 consecutive samples for raw milk permits
- ☐ Appendix N Variance
- ☐ Supporting Documentation for claims (Grass Fed, Kosher, Organic, A2A2, etc..)
- ☐ Plan review applications

I have attached all required documentation for each section outlined above that are applicable to this plan review and application. I have signed all applicable individual sections within the application. **Failure to provide documentation or sign all sections will result in a delay of processing and/or the application may be denied.**

Applicant Signature:_____

The Department of Agriculture will review the plans and notify you of its approval/ disapproval. Please allow **4 – 6 weeks** for processing. Once you receive your approval, notify your Food Inspector or regional office at least **ten (10) days prior** to production to arrange an inspection. Inquiries regarding your application status should be directed to 717-787-4315.

All material **must be fully completed** and returned with any necessary accompanying documentation to:

RA-AGPLANREVIEW@PA.GOV

or mail / fax to:

Pennsylvania Department of Agriculture
Bureau of Food Safety and Laboratory Services
Attn: Plan Review
2301 N. Cameron St, Room 112
Harrisburg, PA 17110
Fax: 717-787-1873

APPLICATION INSTRUCTIONS FOR Permit to sell Milk and/or Milk Products

Transporting, Processing, Manufacturing, Warehousing, Selling, Distribution,

PREPLANNING

1. Review thoroughly a copy of the rules and regulations pertaining to the Pennsylvania Milk Sanitation Laws prior to and during preparation of plans. Applicable laws are Chapter 59a, Grade A Pasteurized Milk Ordinance (PMO), Pennsylvania Milk Sanitation Law,
2. For information regarding Pennsylvania Milk and Dairy Product permitting, please visit: https://www.pa.gov/en/agencies/pda/food-safety/dairy-and-dairy-product-manufacturing.html
3. Discuss any unanswered questions regarding permits and requirements for plan review with the Milk Program Specialist.
4. **Complete an application for "Permit to sell milk and/or milk products"** which is to be submitted at **least 60 days** prior to opening.
5. DO NOT begin construction, remodel or conversion of the facility prior to submitting acceptable plans and prior to receiving approval of the submitted plans from the Department. Equipment must meet 3-A sanitary standards and obtain approval before installation. New owners and change of ownerships are required to apply for a registration and gain approval *prior to* beginning operations. Attach appropriate copy of the completed Installation/Modification Application for the processes conducted.
6. All local planning, zoning, building, fire etc., codes must be considered as well as requirements of the Department of Labor and Industry and the Department of Environmental Protection, if the establishment will also be regulated by these agencies. Issuance of a Milk Permit in no way implies that the Establishment is compliant with any other state or local rules relating to water, sewer, zoning or building codes of any kind. It is the applicant's responsibility to assure they are compliant with all other state or local rules and regulations.

SECTION 1:

This section will capture information about your establishment. Please fill this section out completely. The physical address must be the 911 address. PO boxes cannot be used as a physical address but can be used as the mailing address. Enter the Date the Establishment is anticipating opening or beginning production or when the legal change of ownership will occur.

SECTION 2:

PART A: Please select in this section all boxes which best describes the type(s) of permit you are applying for.

PART B: Please select all boxes that describe your operation type and the products you intend to produce, transport, manufacture, sell or store.

PART C: Select the species of milking animal(s).

PART D: Select the applicable processing types for your facility. Please be aware that documentation of organic status will have to be resubmitted to the department annually or biennially depending on the certification. It is your responsibility to ensure the Department receives the updated information.

PART E: Please indicate if this is a year-round or seasonal operation and your planned operating days/hours. List as best as possible your operating days. If your operation times vary or fluctuate greatly, please make a best guess as which days of the weeks and times you plan on operating/processing.

PART F: Select any Food Safety Systems you will have implemented in the establishment.

SECTION 3: Water, Sewer, Waste Information

This section will capture the information about the water supply you are using, your wastewater disposal and your trash collection.

Water Supply: Please select the type of water supply you are using at the establishment. Building owners/operators may need to supply you this information if you are using their water supply. All water supplies are either PUBLIC or NON-PUBLIC.

Public or Municipal Water Supplies:

Public supplies are those regulated by DEP. Some ''wells'' and/or non-municipal water supplies are additionally regulated by DEP as Public Supplies. ***You must contact DEP*** (717-783-2300) ***to determine if your water supply should be regulated by that Agency.*** You may obtain your water from any DEP regulated water supply.

For Municipal- Public water sources, please list the name of the Public Water Supplier. For example: Pennsylvania American Water.

For Non-Municipal Public water supplies, please provide proof from DEP that you water supply has been approved as a Public supply, such as your assigned Public Water Supply (PWS) number.

Non-Public Water Supply:
If it has been determined that you are utilizing a Non-Public, Non-DEP regulated water supply, you shall then conform to the construction, maintenance, and operation requirements established for a Non-Public water system as defined in Chapter 59a and the Pasteurized Milk Ordinance (PMO) Appendix D. ***Those water systems will need to submit initial testing of the water supply to include, Total Coliform/E. Coli Testing to PDA prior to permitting.*** Ongoing testing of the water supply for non-public sources, shall continue to be performed at a frequency Outlined in Ch. 59a and the PMO.

Sewage Disposal: On the application, please check which applies**.**
If your operation is utilizing a municipal sewage system, you need only supply the name of the sewage enforcement municipality.
For operations NOT using a municipal/public sewer, please check the non-public sewage disposal system box.

Refuse, Recyclables & Returnable:
Please list the name of the collector or location of disposal site if you self-haul.

Zoning and other Codes: Please select whichever box(es) may apply.
Zoning and Building Code information may need verified with the property or building owners. By signature on this application, you are confirming that you have contacted local authorities to review compliance with the applicable local codes.
Sales Tax License information can be obtained with the PA Department of Revenue at (888) PATAXES or https://mypath.pa.gov/_/ Please check which box best describes your tax situation.

SECTION 4: Plan Review

Plan Review: Although not required by Law, it is in your best interest for the Department to review and provide comments on plans for layout and/or a listing of proposed equipment. All equipment must have verification meeting 3-A Sanitary standards and the facility must prove compliance with all Pennsylvania Milk Sanitation laws before operations can begin. **NOTE:** 3-A Sanitary Standards and Accepted Practices for dairy equipment are developed by 3-A SSI. 3-A SSI is comprised of equipment fabricators, processors, and regulatory sanitarians, which include State milk regulatory officials, USDA Agricultural Marketing Service Dairy Programs, the USPHS/FDA CFSAN/MST, academic representatives, and others. Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this *Ordinance*. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices may be used by Regulatory Agencies as guidance in determining compliance with this Section. Please visit https://gams.fda.gov Grade A Milk Search (GAMS) (fda.gov) for a list of FDA M-b documentation.

SECTION 5: Read and Sign

In this section you will check the box for business type, fill in required information and sign. Indicate the Legal Business Name and Legal Owner Mailing Address.

REFERENCES

- To visit the PA Department of Agriculture's Milk and Dairy Product Manufacturing webpage:
  https://www.pa.gov/en/agencies/pda/food-safety/dairy-and-dairy-product-manufacturing.html

- To find information located in the 2023 Grade A Pasteurized Milk Ordinance:
  https://www.fda.gov/media/180975/download?attachment

- To visit the webpage of the Pennsylvania Consolidated Statutes:
  http://www.legis.state.pa.us/cfdocs/legis/LI/Public/cons_index.cfm
  (The Food Safety Act (*known as Act 106*) can be found in Title 3 (*Agriculture*), Chapter 57 (*Food Protection*), Subchapter C (*Milk SELL-BY DATE AND BEST-BY DATE LABELING*) §§ 5741 – 5747).

- To Visit webpage with the Milk Sanitation Laws:
  0210..PDF (state.pa.us) https://www.legis.state.pa.us/WU01/LI/LI/US/PDF/1935/0/0210..PDF

- To find the Code of Federal Regulations related to FSMA's new Preventive Controls for Human Food Final Rule (21 CFR 117--cGMPs, Hazards Analysis, and Risk-Based Preventive Controls for Human Food):
  http://www.ecfr.gov/cgi-bin/searchECFR?idno=21&q1=117&rgn1=PARTNBR&op2=and&q2=&rgn2=Part

- To find resources and information about the Food Safety Modernization Act (FSMA) of 2011,
  https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma
  - Food Safety Plan Builder: https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder
  - and how Penn State Extension is responding and assisting industry:
    http://extension.psu.edu/fsma

- To Visit web page with the USDA Regulations: General Specifications for Dairy Plants:
  Subpart B -- General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service
  eCFR :: 7 CFR Part 58 Subpart B -- General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service

- To find resources and information about the regulations pertaining to specific milk and or milk products and their standards:
  eCFR :: 21 CFR Part 131 -- Milk and Cream eCFR :: 21 CFR Part 133 -- Cheeses and Related Cheese Products
  eCFR :: 21 CFR Part 135 -- Frozen Desserts eCFR :: 7 CFR 58.345 -- Butter.

OTHER GUIDELINES AND REQUIREMENTS FOR MILK PERMITTED OPERATONS

Raw Milk Permit Sampling and Testing.

- **Note:** This section only applies to testing of the raw milk. Please refer to Ch. 59a subchapter F for complete start up requirements

It is the responsibility of the raw milk permitholder to arrange for the regular sampling and testing required with respect to the raw milk permit, and to pay for this testing. An approved sampler must draw the samples and they shall be submitted to a Pennsylvania-approved dairy laboratory for analysis.

Raw Milk Permit Initial Testing:
An applicant for a new raw milk permit shall demonstrate its ability to produce safe raw milk for human consumption through the following process:

- An approved sampler must draw three separate samples of commingled milk from the bulk tank. The samples shall be drawn at least 7 days apart and be taken on an unannounced basis.
- If any of the three analyzed samples violates or exceeds a standard, the three-sample process shall repeat itself until three successive samples are in compliance.
- If the first of the three required samples is tested and concludes that no pathogenic bacteria are present, the second and third samples need not be tested for the presence of pathogenic bacteria. If a sample test concludes that pathogenic bacteria are present, a raw milk permit will not be issued until two separate consecutive tests, from samples drawn at least 7 days apart, conclude that no pathogenic bacteria are present.

Regular testing of raw milk for human consumption.

- Raw milk for human consumption must be tested twice a month for bacterial count, coliform count, somatic cell count and growth inhibitors and once every 6 months for pathogens.
- The raw milk samples must meet the following standards: Bacterial Count <20,000, Coliform Count <10, Somatic Cell Count <500,000, Growth Inhibitors not found and Pathogens Negative

Updated Current Good Manufacturing Practices (cGMPs)

The FDA Current Good Manufacturing Practice (GMP) requirements found in 21 CFR 110 has been revised as part of the FSMA new Preventive Controls rule and are now replaced by 21 CFR 117, Subpart B. The new updates include:

- *Clarifications on protections against cross-contact of food by allergens,*
- *Deletion of certain nonbinding provisions (language containing recommendations).*
- *Some previously nonbinding provisions are now modified to be binding provisions. One example is education/ training, in which management is now required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties.*

A business that meets the definition of a "qualified facility" is subject to modified requirements of the preventive controls rules. These modified requirements can be met by submitting a form to FDA, attesting to the business's status as a qualified facility and attesting that the facility is implementing preventive controls to address hazards associated with its food or is in compliance with non-Federal food safety laws and regulations.
The guidance, "Determination of Status as a Qualified Facility: Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 5.Q.7: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" explains how to determine whether a business meets the definition of "qualified facility" and how to submit the FDA form attesting to its status as a qualified facility. The two forms, Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food) should be used to submit attestations.
Since October 1, 2018, facilities have been able to submit the qualified facility attestation forms electronically at https://www.access.fda.gov/ via the Qualified Facility Attestation Module.

Please note that facilities must have a valid food facility registration to submit their attestation.
FDA Food Facility Registration Site: https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions

For additional Information:

- Guidance for Industry: Determination of Status as a Qualified Facility under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals
- Instructions for Submitting Your Attestation: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)
- Form FDA 3942a (Human Food)

COMBINING REGULATIONS FOR INSPECTIONS GUIDANCE: CH. 59a, Pasteurized Milk Ordinance (PMO) and Current Good Manufacturing Practices (cGMP's)

The section of the document will address the general construction, equipment, processes and controls, and sanitation requirements as per Ch. 59a, the PMO and cGMP's, and serve as guidelines to help the industry be compliant with the regulations in order to ensure that milk and/or milk products are manufactured/processed and or stored under sanitary conditions.

❖ FLOORS

Key Points: smooth, impervious, trapped drains, no pooled water, sloped to drain as applicable.

The floors of all rooms in which milk or milk products are handled, processed, packaged, or stored; or in which containers, utensils and/or equipment are washed, shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped so that there are no pools of standing water after flushing, and the joints between the floor and the walls are impervious, and shall be provided with trapped drains and kept in good repair.

Regulations on this area can be found in: 21 CFR 117.20(b)(4), 117.37(b)(4), 117.37(c), CH. 59a.202, CH 59a.302(d), PMO 2r, 5r, 1p

❖ WALLS AND CEILINGS

Key Points: smooth, washable, light colored, impervious, good repair.

Walls and ceilings of rooms in which milk or milk products are handled, processed, packaged, or stored; or in which containers, utensils and/or equipment are washed, shall be of a durable, smooth, non-absorbent, washable, light-colored surface and be in good repair.

Regulations on this area can be found in: 21 CFR 117.20(b), 117.20(b)(4), CH 59a.205(b), CH 59a.302(c), PMO 2r, 5r, 2p

❖ DOORS AND WINDOWS

Key Points: outer openings protected against entry of flies and rodents, Outer doors self-closing; screen doors open outward.

Effective means shall be provided to prevent the access of insects and rodents. All openings to the outside shall be equipped with tight-fitting, self-closing, solid doors or glazed windows, which shall be closed during dusty weather. All openings to the outer air shall be effectively protected by any method to the extent to prevent the entry of insects, rodents and other pests (e.g. screening, air curtains, self-closing doors, etc.).

Regulations on this area can be found in: 21 CFR 117.20(b), 117.20(b)(7), CH 59a.302(b), PMO 2r, 5r, 3p

❖ LIGHTING AND VENTILATION

Key Points: adequate lighting/ventilation, well-ventilated to preclude odors and condensation; filtered air with pressure systems.

All rooms in which milk or milk products are handled, processed, packaged, or stored; or in which containers, utensils and/or equipment are washed shall be well lighted and well ventilated. Ample light (natural or artificial) promotes cleanliness. Proper ventilation reduces odors, vapors and prevents condensation upon interior surfaces.

Safety type light bulbs, fixtures, skylights, or other glass suspended over exposed product or product contact surfaces in any step of preparation shall be provided or any other means to protect against contamination from glass breakage (ex. use of plastic shields, plastic sleeves with end caps, shatterproof bulbs, etc.).

Fans and other air blowing equipment must be located in a manner that minimizes potential for contaminating milk, milk products, product contact surfaces and packaging.

Regulations on this area can be found in: 21 CFR 117.20(b)(5)-(6), CH 59a.302(e), PMO 2r, 5r, 4p

❖ SEPARATE ROOMS

Key Points: separate rooms when required, adequate size for intended use, no direct opening into living quarters.

There shall be separate rooms for:

1. The pasteurizing, processing, cooling, reconstitution, condensing, drying and packaging of milk and milk products.
2. Packaging of dry milk and milk products.
3. The cleaning of milk cans and containers, bottles, cases and dry milk or milk product containers.
4. The fabrication of containers and closures for milk and milk products.
5. Cleaning and sanitizing facilities for milk tank trucks in milk plants receiving milk or whey in such tanks.
6. Receiving cans of milk and milk products in milk plants receiving such cans.

Rooms in which milk or milk products are handled, processed, stored, condensed, dried and packaged, or in which containers, utensils and/or equipment are washed or stored, shall not open directly into any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

Designated areas or rooms shall be provided for the receiving, handling and storage of returned milk and milk products.

Regulations on this area can be found in: 21 CFR 117.20(b), 117.20(b)(1)-(2) CH 59a.302(f), PMO 5p

❖ TOILET-SEWAGE DISPOSAL FACILITIES

Key Points: no direct openings into process rooms, self-closing doors, clean, ventilated, adequate lighting, properly equipped, sewage / other wastes disposed of in sanitary manner.

Every Dairy Farm or Milk Plant shall be provided with toilet facilities conforming to the regulations of the appropriate regulatory agency.

Toilet rooms shall not open directly into any room in which milk or milk products are processed except where alternate means have been taken to protect against such contamination (such as double doors or positive air- flow systems).
Toilet rooms shall be completely enclosed and shall have tight-fitting, self- closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner so as not to contaminate containers, utensils or equipment, or any water supply.

Regulations on this area can be found in: ***21 CFR 117.37(b), (c), (d) CH 59a.302(f(4)), PMO 7r, 6p***

❖ WATER SUPPLY & SAFETY

Key Points: constructed properly, no direct/indirect connections between potable/non potable water, complies with appropriate bacteriological standards.

Water for dairy farm or milk plant purposes shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.
Running water at a suitable temperature, under pressure as needed, shall be provided in all areas where required.
Private water sources shall comply with the specification outlined in the EPA ground water manual and the Bacteriological Standards outlined herein.
Plumbing shall be of adequate size and design and adequately installed and maintained.
No cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated.

Regulations on this area can be found in: ***21 CFR 117.37(a), 117.37(b) (1)-(5), 117.80(b)(1), 117.80(c)(16) CH 59a.303(a), 404(d), 407, PMO 8r, 7p***

❖ HANDWASHING FACILITIES

Key Points: located, properly equipped, clean, good repair, only hand sinks used for hand washing.

Convenient hand washing facilities shall be provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices. Hand washing facilities shall be kept in a clean condition and in good repair. Hand washing facilities shall be convenient to all toilets and to all rooms in which milk operations are conducted.

Regulations on this area can be found in: ***21 CFR 117.37, 117.37(e), 117.10 (b)(3) CH 59a.303, PMO 17r, 8p***

❖ PLANT CLEANLINESS

Key Points: no unnecessary equipment, neat, clean, trash properly handled, no evidence of insects/ pests.

All rooms in which food and food products are handled, processed or stored; or in which containers, utensils and/or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations, or the handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk food or packaged food product storage rooms.

Regulations on this area can be found in: ***21 CFR 117.40(a)-(d), 117.35(c)-(d), 117.80(c)(6), 117.37(f), 117.20(b)(6) CH 59a.405, PMO 3r, 6r, 9p***

❖ SANITARY PIPING

Key Points: Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials, good repair, accessible during inspection; mechanically cleaned lines meet regulations; pasteurized products conducted in sanitary piping.

All sanitary piping, fittings and connections which are exposed to milk and milk products or from which liquids may drip, drain or be drawn into milk and milk products shall consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material, which is approved for milk product-contact surfaces. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.

Regulations on this area can be found in: ***CH 59a.304, 311, PMO 5r, 10p***

❖ CONSTRUCTION, AND REPAIR OF UTENSILS, CONTAINERS AND EQUIPMENT

Key Points: Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials, good repair, accessible during inspection; self-draining, strainers of approved design; approved single-service articles not re-used.

All multi-use containers and equipment that milk and milk products come into contact with shall be of smooth, impervious, corrosion-resistant, non-toxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets and other articles that milk and milk products come in contact with shall be non-toxic and shall have been manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

Regulations on this area can be found in: CH 59a.206, 304(a), PMO 9r, 11p

❖ CLEANING AND SANITIZING OF UTENSILS, CONTAINERS AND EQUIPMENT

Key Points: containers, utensils and equipment effectively cleaned; mechanically cleaned lines meet regulations, records complete; approved sanitization process applied prior to use on food-contact surfaces; required efficiency tests in compliance; multi-use plastic containers in compliance; aseptic systems sterilized.

The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use. Provided that cloth-collector systems used on dryers shall be cleaned and sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency.

Regulations on this area can be found in: CH 59a.116(e), 206, 311, PMO 10r, 11r, 12p

❖ STORAGE OF CLEANED CONTAINERS AND EQUIPMENT

Key Points: stored to assure drainage, protected from contamination.

After cleaning, all multi-use food or food product containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.
Containers shall be stored inverted, if practicable, on racks or in cases constructed of relatively nonabsorbent, impervious, food-grade, corrosion-resistant, non-toxic materials, or otherwise protected from contamination.

Regulations on this area can be found in: 21 CFR 117.35(f) CH 59a.410(c), PMO 12r, 13p

❖ STORAGE OF SINGLE- SERVICE CONTAINERS, UTENSILS

Key Points: received, stored, handled in sanitary manner, single service articles not reused.

Single-service caps, cap stock, parchment paper, containers, gaskets, liners, bags and other single-service articles for use in contact with food and food products shall be purchased and stored in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

Regulations on this area can be found in: 21 CFR 117.35(d)(3) CH 59a.302(e), PMO 2r, 5r, 4p

❖ PROPER LABELING, STORAGE & USE OF CHEMICALS, TOXIC COMPOUNDS AND ON-FARM DRUGS

Key Points: only approved cleaners, sanitizers, pesticides and on-farm drugs properly used, properly identified, properly stored.

Chemicals, poisonous and toxic materials shall be identified, held and stored in a manner to preclude the contamination of milk and milk products, or the product- contact surfaces of all containers, utensils and equipment.
Use of pesticides is permitted only under precautions and restrictions that will protect against contamination of milk, milk products, food-contact surfaces or packaging materials. Cleaners and sanitizers shall be stored in properly identified, dedicated end-use containers. Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination. Animal drugs shall be properly labeled and segregated, lactating from non-lactating. Unapproved drugs shall not be used. For the purpose of this Item, drugs intended for use in dry dairy animals shall be stored with the "Non-lactating Drugs". Therefore, drugs intended for use in dairy calves, dairy heifers, dairy bulls and dry dairy cows shall be

segregated from drugs for cows that are currently being milked. This required storage system shall also be followed for drugs intended for use in goats, sheep and other dairy animals. The only drugs that shall be stored with the "Lactating Drugs" are drugs that are specifically indicated on the drug label or on a veterinarian's label for extra-label drug use to be used in a specific class/species of lactating dairy animals. For the purpose of complying with this Item "lactating dairy animals" shall mean those dairy animals that are currently producing milk.

Regulations on this area can be found in: ***21 CFR 117.35(b)(2), 117.35(c) CH 59a.205(e), 311, PMO 15r, 19r, 15p***

❖ PROTECTION FROM CONTAMINATION (ADULTERATION)

Key Points: operations conducted/located to preclude milk/milk products/containers/ingredients/equipment/utensils; air and steam used to process products in compliance, No direct connections between pasteurized and raw milk/milk products; overflow, spilled and leaked products or ingredients discarded; no direct connections between milk/milk products and cleaning/sanitizing solutions.

Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, containers, utensils and equipment. All milk or milk products or ingredients that have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than Grade "A" milk or milk products in the milk plant shall be performed to preclude the contamination of such Grade "A" milk and milk products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products, or the product-contact surfaces of all containers, utensils and equipment. Milk plant operations that handle nondairy food allergens shall have a written food allergen control plan to protect milk and/or milk products from food allergen cross-contact, including during storage and use, and to ensure proper declaration of food allergens on product labeling. Human food by-products held for distribution as animal food without additional manufacturing or processing by the milk plant shall be accurately identified, labeled by the common or usual name and held under conditions that will protect against contamination. Milking and milkhouse operations, equipment and facilities shall be located and conducted to prevent any contamination of milk, containers, utensils and equipment. Milk shall not be strained, poured, transferred or stored unless it is properly protected from contamination. After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent the contamination of any milk product-contact surface. Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station shall be constructed and operated to protect their contents from sun, freezing and contamination. Such vehicles shall be kept clean, inside and out, and any substance capable of contaminating the milk shall not be transported with the milk.

Regulations on this area can be found in: 21 CFR 117.20(b)(4), 117.35(a), 117.40(a)(1)-(6), 117.80(a)(1)-(6), 117.80(b)(5), 117.80(b)(7), 117.80(c)(5), 117.80(c)(7), 117.80(c)(10), 117.80(c)(12), 117.80(c)(13), 117.93. CH 59a.349, PMO 14r, 15p

❖ TRANSPORTATION, STORAGE & DISTRIBUTION

Key Points: adequate storage, capable of protecting milk/milk products in transit and during storage, capable of maintaining food temperature as appropriate, clean, no toxics transported.

Adequate and suitable floor space shall be provided for the storage of milk/milk products, ingredients and or finished products. Storage and transportation of finished food shall be under conditions that will protect against physical, chemical, and microbial (including radiological) contamination as well as against deterioration of the food and the container.

All vehicles used for the transportation of milk/milk products shall be constructed and operated so that the milk or milk product is maintained at the appropriate temperature and to protect from contamination. Vehicles may not be used to transport or contain any substances that may be toxic or harmful to humans.

Regulations on this area can be found in: ***21 CFR 117.93 CH 59a.307(b), 371(f), PMO 21p, Appendix B***

❖ SURROUNDINGS

Key Points: neat, clean, no harborages, no pooled water, approved pesticides used properly.

Surroundings shall be kept neat, clean and free of pooled water and harborages and breeding areas that might attract flies, other insects and rodents. Tank unloading areas properly constructed. Waste material shall be stored in suitable covered containers.

No accumulation of trash, garbage or similar waste in areas adjacent to the food plant. This includes properly storing equipment, removing waste and trash, cutting weed/grass/other vegetation in the immediate vicinity of the plant buildings and structures that may constitute harborage areas for pests. Only insecticides and rodenticides approved for use by the Regulatory Agency and/or registered with EPA shall be used for insect and rodent control.

Regulations on this area can be found in: ***21 CFR 117.20(a) (1)-(4), 117.35(b) (2) CH 59a.301, PMO 19r, 22p***

❖ COOLING OF MILK

Key Points: Raw milk maintained at 45º or less until processed; Pasteurized milk/milk products (except those to be cultured) cooled immediately to 45º or less in approved equipment and stored until delivered or further processed. Approved thermometer or recording device located in all refrigeration rooms and storage tanks; recirculated cooling water from a safe supply.

Raw milk shall be cooled to 10ºC (50ºF) or less within four (4) hours after starting the milking operation. The milk shall then be cooled within two (2) more hours to 7ºC (45ºF) or less. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF). All raw milk and milk products shall be maintained at 7ºC (45ºF) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of 7oC (45oF) or less; or 57°C (135°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements.
All pasteurized milk and milk products shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7ºC (45ºF) or less, unless drying is commenced immediately after condensing:

Regulations on this area can be found in: ***CH 59a.204, PMO 18r, 17p***

❖ PERSONNEL – CLEANLINESS & HEALTH

Key Points: hand washing, clean outer garments, hair restraints, tobacco/gum use, no jewelry, proper clothing storage, disease management, exclusion and restriction of sick/suspect employees.

Hands shall be thoroughly washed before milking or performing milkhouse or plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing their hands. All persons, while engaged in the handling, processing, pasteurization, storage, transportation, or packaging of milk and/or milk products, containers, utensils and equipment shall wear clean outer garments. All persons, while engaged in the processing of milk or milk products, shall wear adequate hair coverings and shall not use tobacco.

Any person who by medical examination, or supervisory observation is shown to have or appears to have an open lesion, cuts, boils, sores, open wounds and like items; illness, or other source of microbial contamination whereby there is a reasonable chance to contaminate milk, milk products, product contact surfaces, or packaging shall be excluded. No persons affected with any disease capable of being transmitted to others through the contamination of milk, milk products or ingredients shall work at a facility in any capacity which brings them into direct contact with milk or milk products or product-contact surfaces.

Regulations on this area can be found in: ***21 CFR 117.10(a), 117.10(b)(1)-(9) CH 59a.305, PMO 17r, 20p***

TRAINING OPPORTUNITIES

For establishments/manufacturers that are subject to the full Preventive Controls requirements, the regulation requires that certain activities must be completed by a Preventive Controls Qualified Individual (PCQI) who has successfully completed training in the development and application of risk-based preventive controls. FSPCA has developed a standardized curriculum recognized by FDA; and successfully completing this course is one way to meet the requirements for a PCQI.

These courses are taught by Lead Instructors trained by the FSPCA, who have been instructed in how to teach the FDA-recognized standardized curriculum.

List of upcoming courses and registration information can be accessed at:
https://fspca.force.com/FSPCA/s/course_registration/Course_Registration__c/00B36000007edjpEAA?language=en_US

For more information about FSPCA Alliance Training opportunities, visit:

https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food

A copy of the FSPCA PC for Human Food Participant manual can found at:
https://ifpti.absorbtraining.com/Files/Instructor%20Resource%20Portal/FSPCA%20PC%20Course%20Participant%20Manual_V1.2_2016.02.23.pdf

Other training opportunities can be found on the Penn State Department of Food Science web site:
https://foodscience.psu.edu/workshops