Starting and Operating a Small Dairy Processing Plant

DEPARTMENT OF AGRICULTURE

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Introduction

This document is an educational resource providing a starting point for meeting the regulations that apply to dairy processing plants. It includes an overview of key considerations as you plan and operate your plant. It does not cover every possible situation, so you will need to consult other resources in addition to this manual. It is also important to work with your local Minnesota Department of Agriculture (MDA) dairy inspector or other Dairy Inspection Program personnel to be confident you've completed all the necessary steps before you get started.

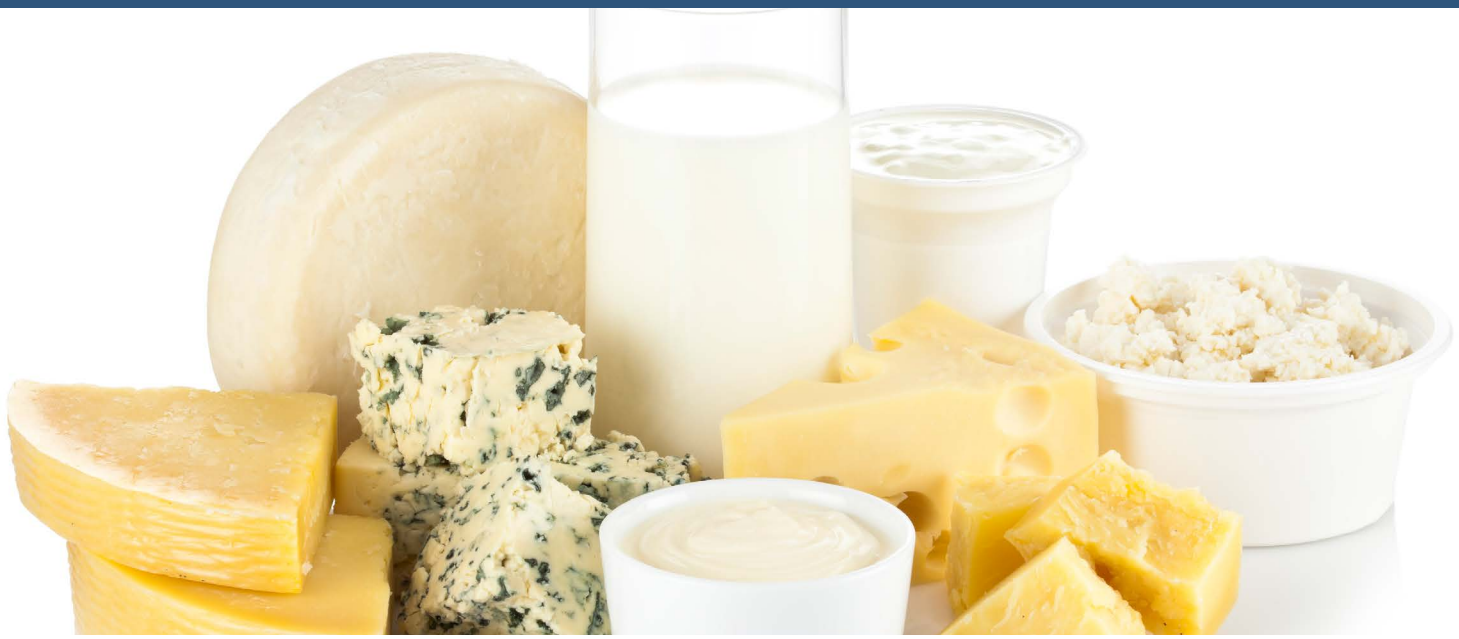
Checklist for Getting Started

Appendix A outlines first steps and questions to consider before you do any processing of milk and dairy products. Use this as a tool to help you with the initial planning of your dairy processing plant.

Disclaimer

The information contained in this manual is current as of the date of publication. Because laws can change, it is important to check if there have been any changes or updates to applicable laws and regulations.

Section 1: Overview of the Regulatory Requirements



All dairy plants must be approved and permitted before beginning operations. It is very important to consult with staff from the MDA Dairy Inspection Program as you make plans to start a dairy processing operation.

Dairy products fall under two separate and distinct sets of regulations. Grade A dairy products are products such as fluid/bottled milk, yogurt, and cottage cheese and are regulated by the Pasteurized Milk Ordinance (PMO). Products which can be made from manufacturing grade milk (also called Grade B) include ice cream, butter, and cheese, among others. These products fall under the Federal Code of Regulations (7 CFR 58) and the USDA Guidelines for Milk for Manufacturing Purposes and its Production and Processing. Additional regulatory requirements for dairy products are listed in the Minnesota State Statutes, with Chapter 32D specifically addressing dairy products. The MDA Dairy and Meat Inspection Division (DMID) administers and enforces these dairy laws and regulations designed to protect the public.

Dairy Plants

All dairy plants are required to be licensed and inspected by the MDA Dairy Inspection Program, regardless of size. Below are definitions of a few specific categories of dairy processing plants.

On-Farm Dairy Processing Plant

An on-farm processing plant is a dairy plant at the same location as the farm producing the milk used to process dairy products. These plants may also take in milk from other farms.

Small Dairy Processing Plant

A small dairy processing plant is a dairy plant which is not located on a farm and which processes less than 700,000 pounds of milk a year.

Farmstead Cheese Plant

A farmstead cheese plant produces all the milk used in its processing and does not purchase milk from any other farms.

Grade A Versus Manufacturing Grade

Dairy plants fall under different regulatory requirements according to the products that they produce. It is important to understand how the products you intend to produce are categorized so that you can ensure you are meeting the regulatory requirements for that type of product. The following table shows how the dairy products are split into different categories. If you want to produce a product that does not appear in the table but is made primarily from a dairy product, check with the MDA Dairy Inspection Program to determine which dairy regulatory requirements will apply.

Table 1: Grade A Versus Manufacturing Grade Product Differentiation

Grade A
Fluid milk and milk products (e.g., whole milk, low-fat milk, skim milk)
Cream (heavy, light, whipping)
Half and half
Yogurt
Cottage cheese
Cultured or acidified milk
Sour cream and dips
Some dry milk products
Buttermilk
Eggnog
Other similar type products

Manufacturing Grade
Cheeses
Butter, ghee, butter oil, anhydrous milk fat
Ice cream
Ice cream mix
Ice cream products
Evaporated milk
Some dry products
Other food products whose primary ingredients are dairy or milk

Grade A

Grade A dairy facilities and processing plants are held to the strictest standards, including:

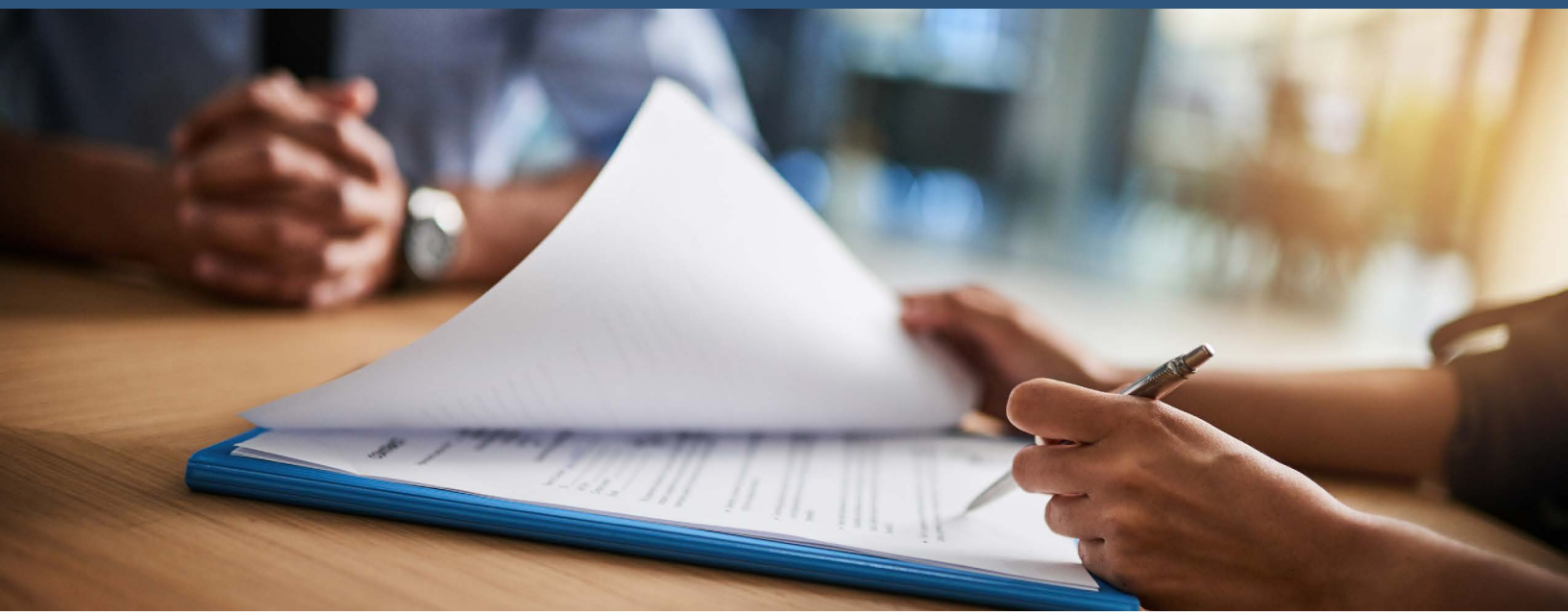
- Compliance with all requirements of the PMO and Minnesota State Statutes
- Inspected a minimum of four times per year with products typically sampled monthly by the dairy inspector
- Using only milk from Grade A dairy farms for Grade A products
- Pasteurizing the milk used to make Grade A products at the place of production (i.e., if a plant buys pasteurized milk from another Grade A dairy facility, the milk must be re-pasteurized at the plant where the Grade A product is being made)

Manufacturing Grade

Manufacturing grade dairy facilities and processing plants must meet specific requirements as well, including:

- Compliance with the Code of Federal Regulations, USDA's Milk for Manufacturing Purposes, and Minnesota State Statutes
- Inspected a minimum of two times per year with products typically sampled yearly by the dairy inspector
- Using milk from either Grade A or manufacturing grade farms for manufacturing grade dairy products
- Depending on the situation, milk may need to be pasteurized at the place of production of the manufacturing grade product

Section 2: Licensing, Permitting, Fees, & Other Considerations



A dairy processing facility must get the appropriate license and/or certification and pay the required fees before starting operations.

Licensing

Almost all dairy processing plants will need some sort of license. Licensing is based on the physical facilities and the type of business activities conducted inside and outside of those facilities.

Licensing the Plant/Operation

The type of license you need will be based on the type of activities you do. For example, if you are primarily a manufacturer, you will need a wholesale manufacturer/processor license. The owner of the plant or operation is required to have only one processing license per physical location (i.e., per unique address). If you are conducting mobile activities, such as selling products at a farmers' market or festival, you will also need a mobile food handler license. There are many different licensing scenarios; your dairy inspector can help you determine how your operation fits into licensing categories.

Other Types of Licenses

Individuals working in the operation may be required to obtain additional licenses or certifications to perform specific activities such as:

- Bulk hauler license – for individuals collecting monthly farm milk qualities samples
- Certified food protection manager (CFPM) may be required for plants operating a retail store
- Appendix N certifications – for individuals conducting drug testing on raw milk samples

Permitting

Permits are separate from licenses, and dairy plants must have both a license and a permit. There is no fee for the initial permit, but there is an inspection fee that accompanies the permit. All dairy plants are required to have a dairy plant permit represented by a certificate and assigned dairy plant number.

Dairy Plant Permit Numbers

- Are individually assigned to each plant by MDA Dairy Inspection Program personnel
- Start with a state-specific prefix (each state has an assigned prefix; the Minnesota prefix is 27)
- Are formatted "27-XXX" with the "XXX" representing a 3-number sequence unique to that plant
- Must be put on all dairy products produced at the facility to provide a means to trace the product back to the production facility

Permits

Permits and approval for operations to begin are granted upon the completion of the final inspection of a dairy plant found to be in substantial compliance to applicable regulations. Permits are non-transferrable to other people or locations. However, a permit number may be transferable if the previous owner does not have any ties to the permit number and gives it up upon transfer to a new owner.

Fees

Dairy plants are required to pay certain fees that fund MDA Dairy Inspection Program activities. For an individual dairy plant, the fees required are dependent on the type of operation, the products that are produced and where they are produced, and where and how those products are sold. Specifically, plants may be subject to the following:

- Plant inspection fees
- Pasteurizer testing fees
- Fees for approval of equipment plan reviews, plant reviews, and inspections or special approvals (approval services fees)
- Reinspection fees
- Farm inspection fees
- Laboratory evaluation fees
- Processor assessment fees
- Milk procurement fees

Tables of the fees charged by the inspection program are found in Appendix C: Fees for Dairy Processors.

Other Considerations

Interstate Shipment

If you will be shipping Grade A products across state lines, your plant will need to be surveyed as an Interstate Milk Shipment (IMS) plant. The plant must meet all Grade A regulatory requirements for shipment of Grade A product into other states. There are no additional fees associated with IMS certification. Associated dairy farms will also need to be IMS inspected.

The Grade A Interstate Milk Shipment requirements do not apply to manufacturing grade dairy products. These products may be shipped across state lines without meeting any additional inspection requirements.

Federal Milk Marketing Order Requirements

Minnesota is part of the Upper Midwest Marketing Area, Federal Order 30. Only on-farm plant operations that bottle Class I milk products are required to file reports with the Federal Order. Small on-farm processors may qualify for exemptions. There are no cost obligations or fees required if the dairy herd and the plant are owned by the same, single entity.

Other on-farm plant operations that manufacture dairy products, other than bottled milk products, do not have any reporting obligations to the Federal Order, but they may be responsible for National Dairy Promotion and Research Board (NDPR) checkoff fees which are subject to Federal Order field audits.

All on-farm processors should contact the Federal Order 30 Minneapolis Office for guidance as it applies to their specific operations.

Label Requirements

Your dairy products will need to be labeled with certain required information established by federal and state laws. It's a good idea to work on the product labels and submit them for review well in advance of the final inspection. This allows time to work out any issues with the labels before receiving your license and permit and beginning production. The following label components are required on dairy products sold in Minnesota:

- Product identity
- Net weight
- Ingredient list
- Business name and address
- Plant number

Additional labeling requirements may apply depending on the type of dairy product or how the product is sold. More information is available on the MDA website at Dairy Product Labeling. Dairy product labels must be submitted for review using the designated form found in Appendix B: Dairy Inspection Forms.

Section 3: Inspections

Routine inspections of dairy plants are conducted by MDA dairy inspectors to ensure regulatory requirements are met and that food safety issues are addressed. Additional inspections may be conducted by the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA), depending on the type and distribution of the product being produced. The inspection process starts prior to operations with plan reviews and site visits. Examples of inspection documents are included in Appendix B: Dairy Inspection Forms.

Prior to Processing

All dairy plants must be approved by the MDA Dairy Inspection Program prior to operation. Before and during construction, the dairy inspector will work closely with the processor, making visits to the facility when needed. Working with the inspector during this phase helps ensure you are meeting the regulatory requirements and won't need to make major changes after you've finished construction and equipment installation.

A start-up processor should expect to incur some expenses for approval of their plant, though these costs will vary depending on the operator's experience, need for assistance, and overall plan for implementation. There is an hourly charge for plan reviews and on-site inspection work that takes place to help get the dairy plant approved (i.e., approval services). The initial on-site inspection and any subsequent contact or visits initiated by the inspector will not be billed to the plant. However, inspections or work initiated by the processor will be billed. More details about the plan review process can be found in Appendix A: Getting Started.

After You've Started

After start-up, your local dairy inspector will routinely inspect your plant. During these inspections, the inspector will observe the production process, review equipment to ensure it is clean, assess the overall plant environment, review records, and perform other activities to verify that the regulatory requirements are being met.

Inspections are:

- Conducted at least four times per year for Grade A plants
- Conducted at least two times per year for manufacturing grade plants
- Unannounced

- In some special cases, like intermittent operators, inspections may be scheduled to ensure the inspector has an opportunity to observe actual production
- Anytime the plant is open and operating, an inspection may be conducted

The Inspection Process

Notice of Inspection

A notice of inspection is delivered at the beginning of an inspection. The document states the reason for inspection and includes a statement that discusses how the data collected during the inspection are handled. Specifically, the notice includes the following statements:

"The data provided is not public and will be protected; available only to those whose access is authorized by law, department employees whose job reasonably requires access or by court order. When the Department of Agriculture determines no action is to be taken or the inspection or investigation becomes inactive; data will become public unless otherwise protected by law."

This provision requires the MDA to keep the results and documentation associated with an inspection or investigation private until that action is officially closed. This means that the MDA cannot release copies of the inspection reports, lab results, or any other information from an inspection or investigation until that action has been concluded or resolved. Once the investigation or inspection is closed, these documents will become public. If a member of the public requests copies of these documents, the MDA will have to release the information.

During the Inspection

The inspector will do several different things during the inspection process, including, but not limited to, the following:

- Hold an entrance meeting at the beginning of the inspection to review their plans for the inspection
- Perform a visual inspection of the plant facility, equipment, and surroundings
- Examine equipment and utensils to ensure that they are clean and in good repair
- Observe the facility and operators during production for compliance with good manufacturing practices (GMPs)
- Review labels and containers for any chemicals used in the production process or for cleaning
- Perform pasteurizer tests on pasteurization equipment at least once every three months at Grade A plants and once every six months at manufacturing grade plants
- Review pasteurization charts, cleaning records, recording charts, production records, and the facility Food Safety Plan to ensure legal pasteurization temperatures and holding times are being met, antibiotic screening is being properly completed and documented, and other production parameters are in compliance and adequately documented
- Review product labels to ensure they meet the regulatory requirements
- Hold a closing meeting to go over their findings and any violations found or items that must be completed by the next inspection

Documentation of Inspections

Inspections are documented using a standard inspection report form. When an inspector documents their findings, they will:

- Complete a standardized inspection form that will mark the items found to be in violation with an X
- Complete a written narrative report with written orders that include:
  - A description of the things observed to be in violation
  - Details on violations and required repairs
  - A compliance date (a deadline for when the item must be corrected)
- Create a signature document for the plant owner or representative to sign, indicating receipt of the documentation
- Provide the plant with a copy of all inspection documentation after the on-site inspection is concluded

Violations

When the inspector identifies something out of compliance with the regulatory requirements, they will document this finding as a violation. While all violations are important, some violations are more critical than others. Critical violations are violations that have a significant potential to directly affect the safety of the product. More minor violations may not have as much potential to directly affect the safety of the product, but taken with other findings, minor violations may affect product or the sanitary condition of the environment.

Since pasteurization is critical to the production of safe milk, all violations found during pasteurizer testing need to be corrected immediately to continue processing milk. If the violation is serious, the inspector may order a recall of products processed in a determined time span. When other critical violations are found, the inspector may issue a “Notice of Intent to Suspend” document which provides warning that the inspector will be returning for a reinspection. The violations will need to be corrected at that time or a plant’s permit will be suspended. There is also a fee charged to the plant when there is a reinspection.

Violations that are noted on an inspection need to be corrected as soon as possible. Inspectors will usually note violations have been corrected during documentation of subsequent inspections. Correcting violations in a timely manner is an opportunity to demonstrate cooperation and a willingness to address food safety issues in your facility. Failure to correct violations may result in reinspection (with fees), a regulatory hearing, a permit suspension, or other enforcement action.

Section 4: The Production Process

The following is an overview of the requirements at different steps in the production process.

Transporting Milk

The following information applies to both Grade A and manufacturing grade dairy facilities. The type of vehicle or transportation method you need will depend on the setup of your operation.

- An on-farm processer may transport milk through a pipeline from the farm bulk tank to the plant.
- A small dairy plant may need a small bulk milk pick-up truck and tank to travel to their producers and pick up purchased milk.

Work with your dairy inspector to determine the best way to meet your transportation needs. In some cases, additional permits or licenses will be required for milk transportation vehicles. Keeping milk cold and using clean equipment to transport the milk are both very important to food safety during transportation.

Fluid Milk Products

Vitamin Addition

Vitamins A and D are fat soluble and must be added to all reduced fat Grade A dairy products to replace the amounts lost during fat removal. The addition of these vitamins back into the dairy products ensures the standard of identity is maintained and nutritional deficiencies are prevented.

- **Vitamin A** does not have to be added to whole milk because whole milk contains fat.
- **Vitamin D** is naturally present at low levels in milk. However, because it promotes the absorption of calcium by the intestine, historically regulations have required the addition of this vitamin to prevent rickets in children as well as other health concerns, such as osteoporosis.

Annual testing of products that require the addition of vitamins is necessary to confirm proper amounts are being added. The processor is responsible for the costs associated with annual vitamin testing.

If you are producing reduced fat Grade A dairy products, refer to Appendix O of the PMO to help you formulate a plan and answer the following questions:

- Where will you source your vitamins?
- Will the vitamins be added manually, or will they be metered into your process with a pump?
- When and where in your process will they be added?
- What are the minimum and maximum levels required?
- How will you document the amount and type of vitamins used?
- Where will you have your product tested to validate the adequacy of vitamin addition?

Packaging and Capping

The requirements for bottling, packaging, and capping (of bottled products) vary by product type. Some of the general requirements for this step in processing include:

- All bottling and packaging of Grade A milk and milk products must be done at the plant where the product was pasteurized. It must be completed in a sanitary manner with approved mechanical equipment. Capping and/or closure of the containers must be done in a sanitary manner by approved mechanical capping and/or closing equipment (i.e., capping bottles by hand is not allowed).
- All packaging materials and containers must be made of food grade materials. In some cases, single service packaging materials (e.g., plastic milk jugs) must be obtained from an approved source on the Interstate Milk Shippers List.
- The cap or closure for bottles must be "tamper proof" so that it cannot be removed without breaking a seal.

All Grade A and Manufacturing Grade Dairy Products

Pasteurization

In Minnesota, all Grade A dairy products must be made from pasteurized milk. This requirement comes directly from Minnesota Statute 32D.20 which states, "No milk or fluid milk products shall be sold, offered or exposed for sale or held in possession for sale for the purpose of human consumption in fluid form in this state unless the milk or fluid milk product has been pasteurized and cooled."

This statute also addresses milk used for all other dairy products, not just Grade A. The exception to the pasteurization requirement is for milk that is used to make raw milk cheese. In this case, cheese must be aged no less than 60 days prior to consumption. Refer to the information on raw milk cheeses at the end of this section.

What is Pasteurization?

Pasteurization is the process of heating every particle of milk to a temperature designed to kill bacteria that can cause human illness. The milk must be held at that temperature for the designated period of time to ensure the bacteria are killed. The following chart lists legally allowed pasteurization holding times and temperatures.

Table 2: Pasteurization Specifications: Minimum temperature and holding time varies by the type of product and the pasteurization method. Vat pasteurization works by heating one batch at a time in an approved tank. "High temperature short time (HTST)" pasteurization involves a continuous flow system. There are no time and temperature combinations outside the options listed below that comply with regulatory requirements.

Type of Product	Type of Pasteurization	Minimum Temperature	Minimum Holding Time
Regular milk products	Vat	145º F	30 minutes
	HTST	161º F	15 seconds
Milk products with added sweeteners, fat content > 10%, and total solids > 18%	Vat	150º F	30 minutes
	HTST	166º F	15 seconds
Ice cream mix (frozen dessert mix)	Vat	155º F	30 minutes
	HTST	175º F/180º F	25 seconds/15 seconds
Eggnog	Vat	155º F	30 minutes
	HTST	175º F/180º F	25 seconds/15 seconds
Cream for butter	Vat	165º F	30 minutes
	HTST	185º F	15 seconds

Other Important Facts About Pasteurization

Because pasteurization is a very important public health control, there are additional requirements for the pasteurization process. Specifically, the following are important things to consider as you design your process:

- Typically, raw products must be added before pasteurization begins. After pasteurization has occurred, the addition of ingredients introduces an additional potential hazard into the product.
- Cross-connections between raw and pasteurized products are not allowed. These occur when common piping or valves are used for both raw and pasteurized product or have a common opening which could allow raw and pasteurized product to intermix. A dairy equipment specialist can help you determine an acceptable set-up for your equipment.
- Equipment used for pasteurization must be approved and tested by the MDA Dairy Inspection Program on a routine basis. Various controls on the pasteurization units are sealed by the dairy inspector so that temperatures, timing, and pressures cannot be changed after they are tested.

Table 3: Pasteurization Equipment Testing Frequency

Type of Production/Plant	Testing Frequency
Grade A	Quarterly (4 times per year)
Manufacturing grade	Semi-annually (2 times per year)

Cooling

Proper cooling is required for all Grade A and manufacturing grade dairy products. By keeping the product cool, the temperature of the product stays in a range that helps limit or prevent the growth of bacteria. Milk products must be maintained at 45°F or less at all stages during processing (except when intentionally heated for pasteurization or processing). This includes, but is not limited to the following processing steps:

- The holding of raw milk or milk products in storage tanks prior to processing
- Cooling of the milk or milk products as soon after pasteurization as possible
- Storage of all milk or milk products after they have been processed, bottled, or packaged
- Any other step in the process where milk or milk products are being held

All coolers (or rooms), cooling units, or storage tanks used for cooling or storage must have an appropriately designed, calibrated, and operating thermometer.

Warehousing

The following information applies to all Grade A and manufacturing grade dairy facilities. Sanitary storage of finished product, ingredients, packaging materials, containers, single service items, filters, chemicals, and other items is important. All these items must be stored in a way that they do not become contaminated by harmful substances. For most products, this means they need to be stored in a clean, dry place above the ground, away from wet walls. Products and ingredients containing allergens must not be stored above products they could potentially leak onto and contaminate.

Rodent and pest control is very important in these areas as well. Routine cleaning, good storage and organization, and frequent maintenance of the building and exterior surrounding areas is important to prevent introduction of unwanted pests.

Raw Milk Cheeses

Cheeses aged for a minimum of 60 days are the only products that are currently acceptable to be made with raw milk. Raw milk cheeses must be aged for a specific length of time. When properly done, it reduces the quantity of harmful microorganisms present in raw milk. For all cheeses, at least one of the following requirements must be met, per Minnesota Statutes Chapter 32D.22:

- Cheese is manufactured from milk or milk products which have been properly pasteurized.
- If the milk hasn't been pasteurized, the milk used to produce cheese is subjected to a heat treatment equivalent to pasteurization during manufacturing or processing.
- Cheese made with raw milk is subjected to an aging process whereby it has been kept for at least 60 days after its manufactured at a temperature not lower than 35°F.

Raw milk cheeses must be labeled as such. The label must also contain the true date of manufacture. If the cheese is repackaged, handled, or processed in any way that removes the date of manufacture, it must be relabeled to show the true date of manufacture or labeled with a statement that indicates that it is more than 60 days of age.

Section 5: Milk Quality, Sampling, and Testing

Dairy Inspection Program Sampling

Milk and milk products are sampled and tested by the regulatory agency on a regular basis to ensure the quality, safety, and labeling compliance of the product. For Grade A, the sampling frequencies for different products are described in the PMO. Manufacturing grade products are sampled on a more intermittent basis; however, they are tested for specific pathogens when a sample is collected.

Sample results are compared against the regulatory requirements to determine whether the product is in compliance. If specific disease-causing bacteria (pathogens) are found in a sample or the sample isn't in full compliance with the requirements, a product recall or other regulatory action may be conducted.

Raw Milk from the Farm

Section 6 of the PMO requires that all plants submit official dairy qualities samples for each of their active producers at least four out of every six months. Raw milk samples, known as monthly qualities samples, are collected from the farm bulk tank by a licensed sampler and sent to an approved laboratory to be analyzed for compliance with the regulations for standard plate count bacteria (SPC), somatic cell count (SCC), temperature, and antibiotic residues. Your dairy inspector can provide more information about how these samples are collected. Sampling plans must be in place before a permit will be issued. Qualities samples are required from all raw milk sources used by the plant. It's the plant's responsibility to ensure all qualities samples are:

- Representative of the entire herd's milk
- Collected monthly by a licensed bulk hauler or sampler
- Submitted to an approved laboratory for qualities testing (SPC, SCC, temperature, and antibiotics)
- Results reported monthly to the MDA Dairy Inspection Program

Monthly qualities sample results must be submitted to the MDA Dairy Inspection Program through the electronic qualities email system by an approved laboratory. Your inspector will help you get signed up to use this system. Upon receipt of the results, inspection program personnel will determine if they meet the regulatory requirements. The following table details the regulatory requirements for these samples. On-farm processors must demonstrate they have planned for collecting and testing monthly raw milk samples as part of the permitting process. A permit will not be issued unless this is in place.

Table 4: Regulatory Standards for Raw Milk from Farms

Standards for Raw Milk	Grade A	Manufacturing Grade
Bacteria (Standard Plate Count)	<100,000	<500,000
Somatic Cell Count (Sheep & Cows)	<750,000	<750,000
Somatic Cell Count (Goats)	<1,000,000	<1,000,000
Temperature	<45°F	<45°F
Drug Residues	Not Found (Negative)	Not Found (Negative)

Enforcement of Raw Milk Farm Sampling Results

Monthly qualities sample results are recorded and kept electronically by the MDA Dairy Inspection Program as part of farm and plant official qualities status. The electronic system monitors the number of violative results received in the last four out of five samples.

- One count above the legal standard, except for antibiotic results, does not result in regulatory action.
- Whenever two of the last four consecutive quality counts exceed the standard, a written "Notice of Intent to Suspend" letter will be issued. Within 21 days of the letter, but not before the lapse of three days, an additional sample must be taken.
- Whenever the standard is violated by three of the last five quality counts, immediate suspension of permit or product will occur. Regulatory action will also be taken if the farm fails to submit counts in at least four out of every six months.
- Any positive antibiotic test will trigger the adulterated milk enforcement process and be counted as a violation.
- Failure to submit regular raw milk samples can affect tracking of qualities and may result in permit suspension if samples are not collected and submitted monthly.

Raw Milk at the Plant

All milk that is used for processing or manufacturing dairy products must be tested for animal drug residues (beta-lactam antibiotics) per the requirements of Appendix N of the PMO and Minnesota Statutes Chapter 32D.19. Proper certification is required to run this test in a processing plant setting. Refer to Section 7 in the PMO on Appendix N Testing. Results of these tests are recorded and kept by the plant for review by the dairy inspector and laboratory evaluation program staff. A raw milk sample is also taken monthly by the dairy inspector at Grade A plants. This may be from a raw milk tank or commingled milk if milk is being accepted from multiple farms.

Product Samples

Sampling Frequency

Grade A product samples are collected monthly. At least one sample of each type of product that is produced is sampled each month. Samples of manufacturing grade products are collected at an intermittent frequency. Higher risk products are typically sampled more frequently than lower risk products. At start up, more samples may be taken to ensure there are no pathogens prevalent.

Types of Samples

Samples of all different types of finished products are collected. For example, any of the following might be sampled by your dairy inspector:

- Bottled milk products
- Yogurt in its final packaged form
- Cheese that is ready for sale or at a retail outlet
- Packaged ice cream
- Ice cream mix
- Bulk packaged dry milk products

Sample Analysis

Samples are analyzed for different types of food safety hazards or to ensure they meet specific regulatory requirements. Examples of the types of testing include:

- General bacteria levels
- Drug residues
- Coliforms
- Phosphatase
- Pathogens (Salmonella, E. coli, Listeria, Staphylococcus, etc.)

Other non-food safety testing, such as fat or protein levels, may be completed in specific cases but is not routinely done.

Sample Results

MDA Dairy Inspection Program personnel will send the results of any sampling as soon as lab results are available. Keep in mind that sample analysis takes time, sometimes up to two weeks, so it is important to conduct your own testing to achieve more timely information on your products.

If the results of sampling indicate there is a food safety concern, inspection program personnel will work with you to determine the appropriate response. In some cases, such as when a pathogen like Salmonella is present, the response may be to recall the affected product. Implementing and managing the product recall is the plant's responsibility.

Internal Testing and Quality Assurance

The sampling that is conducted by the MDA Dairy Inspection Program is designed to periodically check if your product results are meeting regulatory requirements. This testing can be used as a supplement to your quality assurance program but is not designed to be your quality assurance program.

Each plant is responsible for implementing their own quality assurance program specific to their food safety plan. This may consist of product sampling to assess whether the production process is consistently meeting the desired standards, product specifications, as well as food safety-based requirements.

The number of samples that are tested, and what they are tested for, depends on many factors, such as:

- The type of product and the food safety risks associated with it
- The product hazard analysis you completed for your food safety plan
- The plant's product history
- The complexity of your production system

You may need to test more samples of your product during the start-up phase of your production to develop a good baseline for your process. It is important to ensure the products you produce are meeting the quality results you expect and are safe for your customers to consume.

Section 6: PMO Appendix N Testing & Adulterated Milk Enforcement

Penicillin-type drug residues, also called beta-lactams, are a major food safety concern. People with antibiotic allergies can experience life-threatening reactions to dairy products contaminated with antibiotic residues.

Appendix N Testing

Appendix N drug residue testing is a portion of the PMO that applies to all Grade A and manufacturing grade dairy farms and processing plants. The Appendix N requires the screening of all raw milk sources for beta-lactam drug residues prior to processing. This testing must be done in a certified Appendix N screening laboratory by approved methods. Screening milk in a non-certified laboratory by unapproved methods will not satisfy this requirement. Most dairy processing firms have on-site certified Appendix N screening laboratories for this purpose, but in some cases, milk may be screened at an off-site certified laboratory. Your dairy inspector can help you determine your best option for meeting these requirements.

MDA Laboratory Evaluation Officers (LEOs) are responsible for analyst training and laboratory certification and can provide this service to any facility seeking to become a certified Appendix N screening laboratory. Laboratory certification will include, but is not limited to:

- Training of all laboratory analysts on methods and procedures
- Evaluation of laboratory methods
- On-site inspection of the laboratory facility
- Annual proficiency testing

The LEO will assist in selecting an approved test method for the species of raw milk and will be available for questions and scheduling of laboratory certifications. Separate fees apply. More information and contacts can be found at State Laboratory Evaluation Program.

Producer Enforcement Actions and Penalties

When a positive is found on Appendix N testing, the producer will be required to discard the contaminated milk, and the positive result is reported to the state. A dairy farm inspector will meet with the producer to discuss the cause of the adulteration, and the producer will need to follow the actions in the chart below.

Table 5: Adulterated Milk Violation Actions and Penalties

Violation Number (within past 12 months)	Actions and Penalty
1	Any contaminated milk needs to be discarded
	A meeting with the inspector to discuss the potential causes of the residue
	Completion of the "Milk and Dairy Beef Residue Prevention Education"
2	Any contaminated milk needs to be discarded
	A meeting with the inspector to discuss the potential causes of the residue
	Completion of the "Milk and Dairy Beef Residue Prevention Education"
3	Any contaminated milk needs to be discarded. An administrative meeting with the MDA Dairy Inspection Program will be held to discuss the potential causes of the residues and the corrective actions that have occurred. Depending on the nature of the violation and the corrective actions taken, the MDA may suspend the permit or certification up to 30 days, or assess, in lieu of suspension, an administrative penalty up to $1,000 or value of milk sold during the intended suspension period.

Section 7: Resources and References

Minnesota Statutes and Rules

- **Minnesota Statutes Chapter 28A, Licensing of Food Handlers:** www.revisor.mn.gov/statutes/cite/28A)
- **Minnesota Statutes Chapter 32D, Dairy Law:** www.revisor.mn.gov/statutes/cite/32D

Federal Regulations

- **Code of Federal Regulations (CFR), Title 7, Part 58 – Grading and Inspection, General Specifications for Approved Plants and Standards for Grades of Dairy Products:** www.ecfr.gov/current/title-7/subtitle-B/chapter-I/subchapter-C/part-58
- **Code of Federal Regulations (CFR) Title 21, Chapter 1, Subchapter B, Part 117:** https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117

  This is the CFR for current good manufacturing practices, hazard analysis, and risk-based preventive controls for human food. It establishes requirements for facilities that manufacture, process, pack or hold food for consumption.
- **Grade A Pasteurized Milk Ordinance (PMO):** www.fda.gov/media/140394/download
- **Milk for Manufacturing Purposes and its Production and Processing:** www.ams.usda.gov/publications/content/milk-manufacturing-purposes-and-its-production-and-processing

Food Safety

Food Safety Modernization Act (FSMA)

- **FDA Food Safety Modernization Act (FSMA):** www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma

  A set of federal laws passed to create consistent, science-based food safety standards across the entire food system by shifting the focus from responding to foodborne illness to preventing it. Full text: www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma

  - **FSMA Final Rule for Preventive Controls for Human Food:** www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food

    Overview of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; includes key requirements, frequently-asked questions, industry guidance, FSMA training resources, and FSMA Technical Assistance Network (TAN).

    - **Food Safety Plan Builder to Help You Develop a Food Safety Plan:** https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder
    - **Small Entity Compliance Guide:** www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-what-you-need-know-about-current-good-manufacturing-practice-hazard
    - **Qualified Facility Attestation:** www.fda.gov/food/registration-food-facilities-and-other-submissions/qualified-facility-attestation

- **Food Facility Registration Guidance:** www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions

  Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S. are required to register the facility with the FDA.

- **Food Safety Preventive Controls Alliance (FSPCA):** www.ifsh.iit.edu/fspca

  A public private alliance consisting of industry, academic, and government stakeholders whose mission is to develop curricula and training and outreach programs to support compliance with FSMA.

- **Preventive Controls for Human Food:** www.mda.state.mn.us/food-feed/preventive-controls-human-food

  List of FSMA fact sheets and external resources compiled by the MDA.

Other Food Safety Resources

- **Food Safety Basics for Ice Cream Makers Online Training:** units.cals.ncsu.edu/foodsafety/food-safety-basics-for-ice-cream-makers/

  Online training course providing practical guidance and tools for ice cream manufacturers to develop their food safety programs and enhance the safety of their products.

- **Milk & Dairy Beef Drug Residue Prevention Manual:** nationaldairyfarm.com/wp-content/uploads/2019/06/DRM2019-Web.pdf

  An educational tool and resource guide promoting best management practices for administering treatment to dairy cattle.

- **What is Raw Milk?:** www.mda.state.mn.us/food-feed/what-raw-milk
  Basic facts and frequently asked questions about raw milk in Minnesota.

Business Assistance

- **MDA Agricultural Growth, Research, and Innovation Program (AGRI):** www.mda.state.mn.us/grants/agri
  The AGRI Program supports the advancement of Minnesota's agricultural and renewable energy industries through grants and scholarships.
- **MDA Data Access Procedures:** Public Data: www.mda.state.mn.us/home/data-access-procedures-public-data
  Overview of the Government Data Practices Act (Minnesota Statutes, Chapter 13) and brief instructions on how to request public data.
- **MDA Plan Review – Retail Food Establishments:** www.mda.state.mn.us/planreview
  Plan review for Minnesota retail food establishments.
- **MDA Starting a Food Business Roadmap:** www.mda.state.mn.us/business-dev-loans-grants/starting-food-business-roadmap

  A tool and reference guide developed by the MDA and partners from across the Minnesota food community to help prospective business owners navigate the different steps of starting a Minnesota food business.
- **Minnesota Department of Administration – Requesting Data and Info:** mn.gov/admin/data-practices/data/requests/

  General information on requesting public data from a Minnesota government entity.
- **Minnesota Department of Employment and Economic Development (DEED) - Starting a Business:** www.mn.gov/deed/business/starting-business/

  Resource guide for prospective business owners with information about business organizing, planning, accounting, financing, and more.
- **Minnesota Department of Health (MDH) Well Management Program:** www.health.state.mn.us/communities/environment/water/wells/waterquality/test.html

  An owner's guide to wells, describing responsibilities of licensed well contractors and well owners.
- **Minnesota Department of Labor and Industry (DLI) Plumbing:** www.dli.mn.gov/business/get-licenses-and-permits/plumbing

  Describes the plumbing plan review process in Minnesota, including plumbing code information and links to apply for plan review or inspections.
- **Minnesota USDA Rural Development:** www.rd.usda.gov/mn

  Home page for the Minnesota USDA Rural Development office, with contact information and links to key programs and news.
- **Types of Minnesota businesses:** www.sos.state.mn.us/business-liens/start-a-business/types-of-minnesota-businesses/

  Overview of the main types of business structures from the Office of the Minnesota Secretary of State.
- **USDA Business and Industry Loan Guarantee Program:** www.rd.usda.gov/programs-services/business-industry-loan-guarantees/mn)

  A USDA program that offers loan guarantees to lenders for their loans to rural businesses.

Facilities and Equipment

- **3-A Sanitary Standards for construction of dairy equipment:** www.3-a.org/

  Standards that determine the criteria for the design, fabrication, and cleanability of equipment intended for contact with food, including dairy processing equipment. These standards are developed by a not-for-profit corporation dedicated to advancing food safety through hygienic equipment design.

Product Development

- **Agricultural Utilization Research Institute (AURI):** https://auri.org/

  Supports development of value-added agricultural products to foster long-term economic benefit for Minnesota; assists business owners with process and product development.

- **Dairy Business Innovation Alliance (DBIA):** www.cdr.wisc.edu/dbia

  A partnership between the Center for Dairy Research (CDR) and the Wisconsin Cheese Makers Association (WCMA) that develops and administers programs providing technical assistance as well as grants to dairy farms and businesses in Illinois, Iowa, Minnesota, South Dakota, and Wisconsin.

Appendix A: Getting Started

Introduction

As with most businesses, starting a dairy processing plant takes a lot of time and planning. While many requirements for dairy processing are state or federally based, local authorities also have regulations which can impact new processors, such as zoning, water sources, plumbing, and septic or waste disposal systems. Some local regulations must be addressed first or at the same time as the MDA Dairy Inspection Program requirements. As you plan your operation, you may also find it beneficial to consult experts in industry or academia for technical advice or assistance with business planning and marketing.

Initial Considerations

Before you get started, it's a good idea to do product and market research and develop a business plan. The Minnesota Department of Employment and Economic Development (DEED) has a resource guide to help new business owners in this process, and the MDA Starting a Food Business Roadmap can also be useful. Additionally, being able to answer the below questions can help you determine whether you are ready to get started or need to do more research and planning:

- Have you decided what dairy products you want to produce, both initially and long-term?
- Do you have the skills and expertise necessary to make these products?
- What do you know about the market for the products? Who will your customers be?
- Are you prepared to hire additional help if needed?
- How will you finance your operation?

You may be able to find grant or loan opportunities to help offset costs of building or renovating a facility to start your business. These include the USDA Business and Industry Loan Guarantee Program through Minnesota USDA Rural Development and the MDA Agricultural Growth, Research, and Innovation (AGRI) Program. Contact the MDA Agricultural Marketing and Development Division at 651-201-6012 for information on current opportunities through the state of Minnesota. There are many educational resources available to help you further your knowledge or learn the skills required to process dairy products. Check out Section 7: Resources and References for a few ideas.

Almost all businesses in Minnesota must register with the Office of the Minnesota Secretary of State (SOS). Before registering your business, you will need to decide on the structure (e.g., Corporation, LLC, Sole Proprietorship). For more information about business structures, refer to Types of Minnesota Businesses. When registering with the SOS, you may be asked to provide personal information and other details about your business. Be prepared to provide your Minnesota Tax ID number or Social Security Number. Additionally, you will need to determine if workers' compensation insurance is needed for any employees you plan to hire.

Action Items

- ☐ Research your products and market
- ☐ Develop a business plan
- ☐ Register with the Secretary of State

Planning Your Facility

Food Safety Modernization Act (FSMA) and Current Good Manufacturing Practices (GMPs)

The Food Safety Modernization Act (FSMA) is a federal law that shifts the focus from responding to foodborne illnesses to preventing them through the establishment of a risk-based approach to food safety. The FSMA rules are published in the Code of Federal Regulations (CFR). Dairy foods are subject to the FSMA Preventive Controls for Human Food, Title 21 CFR 117 subparts A, B, C, G and F. The U.S Food and Drug Administration (FDA) has developed a small entity compliance guide with an overview of everything you need to know to comply with FSMA.

A facility that makes, packs, or holds food for human or animal consumption must register with the FDA, unless exempt from the requirement to register. Guidance on this process can be found at Registration of Food Facilities and Other Submissions.

Food facilities that qualify as "very small businesses" are eligible for "modified requirements," meaning they are exempt from the requirement to develop and maintain a food safety plan but may still do so if they choose. If your facility is eligible for a modified requirement, you will need to file an attestation with the FDA to obtain this exemption.

All registered facilities are required to comply with 21 CFR 117 subpart B, Current Good Manufacturing Practices (GMPs), even if eligible for a modified requirement. GMPs are industry-specific practices that help ensure the products you produce are safe. They serve as the basis for all food safety programs.

The GMPs specifically address:

- Facility requirements
- Employee requirements
- Equipment requirements
- Cleaning requirements
- Warehousing and distribution requirements

As a best practice for **on-farm processing plants,** livestock workers as well as other farm employees should not enter the processing plant without showering and changing clothes. In cases where showering is not easily accomplished, people should complete their work in the processing plant first and then move into the less sanitary zoned farm areas. This reduces the chance that undesirable microorganisms such as pathogens are moved from the farm into the dairy plant.

- Foot traffic control policies need to be maintained to prevent the spread of pathogenic bacteria commonly found on a farm from getting into the plant. These bacteria (Listeria monocytogenes, Salmonella, Coliforms, Campylobacter, and others) are serious public health threats, and every effort must be taken to minimize the entrance of such pathogens into a dairy plant.
- Sanitizing foot baths or foamers are recommended for each entrance to the plant as well as between rooms or work areas in processing plants.
- Adequate hair and beard covering, and clean clothes and footwear are required for anyone present at the plant.
- Hands must be thoroughly washed before beginning plant functions and as often as required to remove soil and contamination. Hand washing is required after visiting the toilet room before returning to work. Hand-washing signage must be posted in all toilet facilities.
- Use of tobacco in a dairy facility is prohibited.
- Persons working in the plant must maintain good clean working habits and conduct themselves in such a manner as to not contaminate the milk products or equipment.

For more GMP guidance, refer to the FDA Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR, Part 117) Small Entity Compliance Guide.

Building, Buying, or Renting

Determining whether you should build a new facility, buy, rent an existing facility, or use a community kitchen may be one of the first major decisions you make. If buying an existing facility, you'll need to make sure the facility meets the requirements and that you've fully assessed the necessary permitting and costs for any major renovations needed. Some specific things to consider when deciding whether to build or buy include:

- Location and site
- Changes needed to meet regulatory requirements in an existing facility
- Existing business operations, and whether other regulatory programs will need to be involved
- Building codes and changes needed in the plumbing and water systems

Location and Site

Review zoning and building code requirements with your local authorities (township/city/county/state) before purchasing land or beginning any construction. Dairy processing facilities are typically classified as commercial businesses and may require special permitting and/or be required to follow a conditional use approval process (CUP). Keep in mind, this falls outside the scope of regulation by the MDA Dairy Inspection Program. Contact your local authorities for more information on requirements related to site suitability and other requirements specific to your location, such as signage or advertising rules. Other important issues that must also be considered include:

- Access and space for trucks hauling shipments and deliveries
- Proximity to livestock housing, manure storage, and prevailing winds in your area
- Drainage: You must have a means of handling wash water from the dairy plant. Additionally, the facility should not be situated in a flood-prone area or an area where water will drain from the surrounding environment, particularly if livestock are nearby.

Buying an Existing Business

Buying an existing building or business may significantly reduce costs and time needed to get your new business operational. However, some facilities may require substantial upgrades which are not always feasible. Assess the current condition of any existing facilities, including sanitation and construction, as well as size and flexibility of current operations.

Most importantly, you will want to research the site and the facility's history with inspections and its general compliance with regulations. For any business already regulated by the MDA, you can make a data request to obtain copies of the facility's inspection results to understand its degree of compliance with food safety regulatory requirements. Instructions on how to request data from the MDA can be found at Data Access Procedures: Public Data. Other Minnesota regulatory authorities and entities also have a similar process for requesting government data. For more information, visit Requesting Data and Info. If you decide to purchase an existing facility, you may also arrange a joint pre-purchase inspection with the existing owner(s) and the local inspector(s).

Building and Equipment

When building a new facility, start with essentials and allow for expansion. The following items must be included in the building plan:

- Washable walls, ceilings, floors, and surfaces
- Good lighting
- Good ventilation
- Hand-washing sinks
- Separate room for clean protective clothing for staff and a changing area
- Good electric supply and a back-up generator
- Water supply, water systems, and water heating systems

- Cold and dry storage areas for ingredients, packaging, and finished products
- Toilet facilities
- Location of doors, windows, and rooms
- Receiving room for unloading and storing bulk raw milk
- Separate rooms for washing returnable bottles, crates
- Foot traffic and product control flow plan

Your dairy plant can have new and/or used equipment that is manual or automatic as long as it meets processing equipment standards. Be aware that these standards have changed over time: a piece of equipment used in an approved dairy processing facility at one time may not meet standards for processing today. Some of the more common items include:

- Pasteurizer – Vat or High Temperature Short Time (HTST) units
- Chillers and cooling plates
- Separators
- Bottling and filler machines
- Vats
- Packaging equipment
- Cleaning equipment - wash vats, brushes, etc.
- Recording charts
- Milk and cleaning pumps
- Milk transfer lines or tanks from the milk room to the plant
- Storage tanks and silos
- Warehousing and finished product storage

Action Items

- ☐ Identify a location and site for your processing plant
- ☐ Make a list of building and equipment needs
- ☐ Design a facility or make remodeling plans to satisfy processing plant regulatory requirements
- ☐ Obtain processing equipment that meets current standards for dairy processing

Plan Approval

Building and Plumbing Plans

The Minnesota Department of Labor and Industry (DLI) regulates and enforces building codes, plumbing, and other infrastructure requirements. Understanding these requirements is an important part of the building or remodeling process. Note the following:

- New plumbing installations, changes, additions, and improvements must be done by a licensed plumber or registered apprentice.
- The Minnesota Plumbing Code requires plumbing plans to be submitted for review and approval **prior to** installation of plumbing.

For information on submitting plumbing plans and fees, visit DLI Plumbing. For more information about plumbing requirements, contact Plumbing Plan Review at 651-284-5063 or ims.bldplb.dli@state.mn.us.

Septic and Well

Start-up requirements

Businesses located in a city or municipality are often connected to city water and sewer services. These businesses can rely on documentation from the city or public water source to show that they meet the requirements. However, a processing plant on private, rural property typically has a private well and septic system. If you are building or buying a plant on private and/or rural property, you will need to provide written documentation showing the existing well and septic meet applicable requirements and codes.

Septic systems that are installed on rural private properties are regulated and approved through the county and must meet Minnesota Pollution Control Agency (MPCA) rules. Typically, any business would be required to have an approved septic system separate from any home on the same property and built to commercial standards.

Well construction, code information, and information on well maintenance can be found by visiting Minnesota Department of Health Well Management. Whether you plan to use a public sewer service or a private on-site septic system, you will need to verify that it is equipped to handle the milk, water, and chemical wastes generated by a dairy plant.

Ongoing requirements

Businesses connected to a municipal water supply are required to provide annual documentation for potability which can be obtained from your city or municipality. (Potable water is water that is safe to drink.) Processors with private wells must have their water sampled at least semi-annually by their dairy inspector and submitted to an accredited laboratory. Business owners are responsible for ensuring these samples are taken.

Dairy Inspection Program Plan Review Process

The following information gives a general overview of the plan review process, which will vary from plant to plant depending on their situation. Your dairy inspector can help you work through this process.

A copy of all construction plans (e.g., blueprints, drawings) must be submitted to the MDA Dairy Inspection Program before construction begins. Your plans should include information on the following items:

- Basic building layout showing all doors and windows
- Plumbing layout, including drain locations, wash vats, and hand sinks with hot and cold water
- Electrical diagrams and lighting
- Position of the processing equipment, including tanks, fillers, pasteurizers, and all other processing equipment
- Diagram of the milk piping layout in the plant, drawn by the installer
    - Clean-in-place (CIP) or manual clean-up?
    - Flow of milk: raw and pasteurized
    - Valve locations
    - Equipment construction, size, material
    - Recorder locations
- Toilet facilities with proper waste disposal (toilet room cannot open into a processing area and must have a hand sink provided)
- Type of materials to be used for flooring, walls, and ceiling
- Storage facilities for ingredients, containers, raw product, finished product
- Ventilation plans
- Receiving room or area for transfer of milk into your facility

- Utility locations of the following items:
  - Boiler
  - Water heaters
  - Furnace
  - Glycol or sweet water tanks
  - Air compressors
  - CIP tanks
  - Temperature recorders

The review process typically takes 30 days but may take longer if there is a backlog of plans to review. During this time the plan reviewer may call with questions. Fees are charged for the plan review and plant approval process. Refer to Appendix C: Fees for Dairy Processors for current fee information. Once the review is complete and your plans have been approved, you will receive an approval letter from the MDA Dairy Inspection Program. **Construction should not begin until then**. Failure to wait for approval may result in having to redo something in the plant if it does not meet regulatory requirements.

Periodic construction inspections and check-ins will be made by your inspector during any new construction. If you are using well water, a water sample will be collected by your inspector after all plumbing is complete. If the plant uses city water, an initial water sample may be collected by the inspector. If the on-farm or small dairy processing plant employs more than 25 employees, the Minnesota Department of Health will collect the water samples.

Action Items

- ☐ Obtain appropriate permits from county, city, and/or township for building, septic, and electrical (approvals required will vary by location)
- ☐ Submit construction plans for review to the MDA Dairy Inspection Program

Prior to Production

Label Review: Your product labels will need to be reviewed by the MDA dairy compliance officer before you can use them. More information on can be found in Label Requirements in Section 2. Submit labels for review using the Dairy Product Label Review Submission Form found in Appendix B.

Review of plant documentation: The inspector will review all records and documents you intend to use and/or have created for your facility. In some cases, there are regulatory requirements that these documents must meet. This review may include the following:

- Standard Operating Procedures (SOPs) with clear methods for documenting processes performed in the dairy plant
- Cleaning and sanitation procedures
- HACCP (Hazard Analysis Critical Control Point) plans or similar food safety plans
- Recall plans
- Pest control
- Allergen control
- Finished product testing
- Environmental monitoring
- Plans for documenting other regulatory requirements
- Ingredient supplier list
- Equipment list
- What days/how will you sell the finished product

Single Service Container Source Approval: For Grade A production, a list of container sources must be made available for review. All suppliers must be on the Interstate Milk Shipper's listing of approved sources. For more information, review Packaging and Capping in Section 4.

Final Inspection: When the plant is ready to operate, a full inspection and pasteurizer equipment testing will be conducted by your dairy inspector. Once you've passed the final inspection and equipment testing, you can apply for your plant license and operating permit and submit the appropriate fees. Monthly reports to be submitted should be reviewed for any questions. The following reports must be submitted by a processing plant each month if they are applicable:

- Processing Fee Reports
- Procurement Fee Reports

Read more about dairy plant inspections in Section 3: Inspections.

Action Items

- ☐ Submit product labels for review
- ☐ Schedule review of plant documentation with your dairy inspector
- ☐ Verify approved source for single service containers
- ☐ Complete final inspection and equipment testing
- ☐ Obtain dairy plant license and operating permit

A Note About Operating Multiple Food Businesses

Some dairy processors incorporate additional food business operations at their plants, such as retail stores. Whenever retail sales are part of a business plan, Minnesota Food Code rules will apply. In many cases, the area retail inspector and supervisor can work cooperatively with the area dairy inspector to answer questions about the retail rules and requirements and how they are applied in conjunction with a dairy processing operation. For example, an official Retail Food Establishment Plan Review is usually required if any changes are made to the retail portion of the facility, and some retail products are required to have HACCP plans or other documentation and testing. Multiple inspections may be necessary based on the type of operations the business is doing and the products that are made.

Who Can Help?

The following experts can help you plan your dairy processing business and navigate the process of getting started:

- **Marketing experts** can recommend strategies for optimum market visibility and increased sales revenues.
- **Food safety and food quality experts** can offer advice on preventing contamination, ensuring compliance with state and federal regulations, and developing a quality control program.
- **Extension dairy specialists** can help producers achieve optimal herd health and milk quality.
- **Food scientists** can guide the development of nutritional labels that meet FDA requirements.

Appendix B: Dairy Inspection Forms

Grade A dairy farm inspection report: FDA Form 2359a

DEPARTMENT OF AGRICULTURE	DAIRY FARM INSPECTION REPORT	Minnesota Department of Agriculture Dairy and Meat Inspection Division 625 Robert Street North, St. Paul, MN 55155-2538 *Telephone: 651-201-6300 Fax: 651-201-6116*
NAME AND LOCATION OF DAIRY FARM		**PLANT** **PERMIT NO.**

Inspection of your dairy farm today showed violations existing in the Items checked below. You are further notified that this inspection report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)

COWS

1. Abnormal Milk:

- Cows secreting abnormal milk milked last or in separate equipment (a)☐
- Abnormal milk properly handled and disposed of (b)☐
- Proper care of abnormal milk handling equipment (c)☐

MILKING BARN, STABLE, OR PARLOR

2. Construction:

- Floors, gutters, and feed troughs of concrete or equally impervious materials; in good repair (a)☐
- Walls and ceilings smooth, painted or finished adequately; in good repair; ceiling dust-tight (b)☐
- Separate stalls or pens for horses, calves, and bulls; no overcrowding (c)☐
- Adequate natural and/or artificial light; well distributed (d)☐
- Properly ventilated (e)☐

3. Cleanliness:

- Barn and Parlor Floors, Pens and Alleys (a)☐
- Walls and Ceilings (b)☐
- Outside of pipeline (c)☐
- No swine or fowl (d)☐
- Surcingles, Milk Stools and Anti-kickers (e)☐

4. Cowyard:

- Graded to drain; no pooled water or wastes (a)☐
- Cowyard clean; cattle housing area and manure packs properly maintained (b)☐
- No swine (c)☐
- Manure stored inaccessible to cows (d)☐

MILKHOUSE OR ROOM

5. Construction and Facilities:

Floors

- Smooth; concrete or other impervious material; in good repair (a)☐
- Graded to drain (b)☐
- Drains trapped, if connected to sanitary system (c)☐

Walls and Ceilings

- Milkroom Walls approved material and finish (a)☐
- Good repair (windows, doors, and hoseport included) (b)☐

Lighting and Ventilation

- Adequate natural and/or artificial light; properly distributed (a)☐
- Adequate ventilation (b)☐
- Doors and windows closed during dusty weather (c)☐
- Vents and lighting fixtures properly installed (d)☐

Miscellaneous Requirements

- Used for milkhouse operations only; sufficient size (a)☐
- No direct opening into living quarters or barn, except as permitted by Ordinance (b)☐
- Liquid wastes properly disposed of (c)☐
- Proper hoseport where required (d)☐
- Acceptable surface under hoseport (e)☐
- Suitable shelter for transport truck as required (f)☐

Cleaning Facilities

- Two-compartment wash and rinse vat of adequate size (a)☐
- Suitable water heating facilities (b)☐
- Water under pressure piped to milkhouse (c)☐

6. Cleanliness:

- Floors (a)☐
- Walls, Ceiling, Doors, Windows (b)☐
- Non-product Contact Surfaces (c)☐
- No Trash (d)☐
- Unnecessary Articles (e)☐
- No Animals or Fowl (f)☐

TOILET AND WATER SUPPLY

7. Toilet:

- Provided; conveniently located (a)☐
- Constructed and operated according to Ordinance (b)☐
- No evidence of human wastes about premises (c)☐
- Toilet room in compliance with Ordinance (d)☐

8. Water Supply:

- Constructed and operated according to Ordinance (a)☐
- Complies with bacteriological standards (b)☐
- No connection between safe and unsafe supplies; no improper submerged inlets (in water - MAX 5 points off) (c)☐
- No connection between safe and unsafe supplies; no improper submerged inlets (Not in water - MIN 2 points off) (d)☐

UTENSILS AND EQUIPMENT

9. Construction:

- Smooth, impervious, nonabsorbent, safe materials; easily cleanable (a)☐
- In good repair; accessible for inspection (b)☐
- Approved single-service articles; not reused (c)☐
- Utensils and equipment of proper design (d)☐
- Approved CIP cleaned milk pipeline system (e)☐

10. Cleaning:

- Utensils and equipment clean (a)☐

11. Sanitization:

- All multi-use containers and equipment subjected to approved sanitization process (Refer to Ordinance) (a)☐

12. Storage

- All multi-use containers and equipment properly stored (a)☐
- Stored to assure complete drainage, where applicable (b)☐
- Single-service articles properly stored (c)☐

MILKING

13. Flanks, Udders, and Teats:

- Milking done in barn, stable, or parlor (a)☐
- Brushing completed before milking begun (b)☐
- Flanks, bellies, udders, and tails of cows clean at time of milking; clipped when required (c)☐
- Teats treated with sanitizing solution and dried, just prior to milking (d)☐
- No wet hand milking (e)☐

TRANSFER/PROTECTION OF MILK

14. Protection From Contamination:

- No overcrowding (a)☐
- Product and CIP cleaning circuits separated (b)☐
- Improperly handled milk discarded (c)☐
- Immediate removal of milk (d)☐
- Milk and equipment properly protected (e)☐
- Sanitized milk surfaces not exposed to contamination (f)☐
- Air under pressure of proper quality (g)☐

15. Drug and Chemical Control:

- Cleaners and sanitizers properly identified (a)☐
- Drug administration equipment properly handled and stored (b)☐
- Drugs properly labeled (name and address) and stored (c)☐
- Drugs properly labeled (directions for use, cautionary statements, active ingredient(s) (d)☐
- Drugs properly used and stored to preclude contamination of milk (e)☐

PERSONNEL

16. Handwashing Facilities:

- Proper handwashing facilities convenient to milking operations (a)☐
- Wash and rinse vats not used as handwashing facilities (b)☐

17. Personnel Cleanliness:

- Hands washed clean and dried before milking, or performing milkhouse functions; rewashed when contaminated (a)☐
- Clean outer garments worn (b)☐

COOLING

18. Cooling:

- Milk cooled to 45F (7C) or less within 2 hours after milking, except as permitted by Ordinance (a)☐
- Recirculated cooling water from a safe source and properly protected; complies with bacteriological standards (b)☐
- An acceptable recording device shall be installed and maintained when required (c)☐

PEST CONTROL

19. Insect and Rodent Control:

- Fly breeding minimized by approved manure disposal methods (a)☐
- Manure packs properly maintained (b)☐
- All milkhouse openings effectively screened or otherwise protected; doors tight and self-closing; screen doors open outward (c)☐
- Milkhouse free of insects and rodents (d)☐
- Approved pesticides; used properly (e)☐
- Equipment and utensils not exposed to pesticide contamination (f)☐
- Surroundings neat and clean; free of harborages and breeding areas (g)☐
- Feed storage not attraction for birds, rodents or insects (h)☐

REMARKS

DATE	**SANITARIAN**

NOTE: Item numbers correspond to required sanitation Items for Grade "A" raw milk for pasteurization in the Grade "A" Pasteurized Milk Ordinance.

Folder # GLM101111640	**Insp #** GLM101058854	**Unit Doc ID #** GLM-101218567

FORM FDA2359a (10/08)

Grade B (Manufacturing Grade) dairy farm inspection report

DEPARTMENT OF AGRICULTURE	**GRADE B PRODUCER INSPECTION REPORT**	**INSPECTING AGENCY** Minnesota Department of Agriculture Dairy and Meat Inspection Division 625 Robert Street North, St. Paul, MN 55155-2538 *Telephone: 651-201-6300 Fax: 651-201-6116*

Plant/Milkshed	**Plant/BTU No.**	**Patron No.**	**Inspection Date**
Name Grace Liebenstein Test Entity		**Inspector Signature**	**Inspecting Sanitarian**
Address	**Street/box number**	**city/state**	**zip code**

IMPORTANT: An approved farm requires that all "Facilities" listed below be rated "Satisfactory" except 1a, and that the Total score for the "Methods" is not less than 85% of the total maximum score of 100.

	POINTS OFF
FACILITIES	
1. Water Supply	
a. Well construction meets code	
b. Waste disposal	
2. No permanent housing for swine or fowl	
3. Herd Health	
METHODS	
4. Milkhouse/Milkroom	
a. Location - size	
b. Lighting and ventilation	
c. Construction	
_1. Floors	
_2. Walls and ceilings	
_3. Doors and windows	
d. Facilities (water, wash vats, racks)	
e. Milkroom - other usage	
f. Cleanliness and flies/pests	
g. Single service items properly stored	
h. Pesticides and antibiotics properly stored	

	POINTS OFF
5. Utensils and Equipment	
a. Milking units (head claw buckets, inflations, tubes, air hose, milking pails, etc.	
b. Transfer equipment (pails, strainers and other utensils) in good condition, clean and properly stored	
c. Milk lines	
d. Vacuum lines and pulsators	
e. Sanitized before use	
f. Cleaning supplies and brushes available and properly stored	
6. Bulk Milk	
a. Tank Construction	
b. Clean	
c. Milk cooled promptly and held at proper temp	
d. Properly located	
e. Outside slab and hoseport	
OR	
7. Can Milk	
a. Cooler is clean, and in good operating order	
b. Cans are clean and in good condition	
c. Milk cooled promptly and held at proper temp	
d. Properly located	

	POINTS OFF
8. Barn or Milking Area	
a. Size and arrangement	
b. Fowl, swine, and other animals properly confined	
c. Lighting and ventilation	
d. Floors clean and in good repair	
e. Walls and ceilings clean and in good repair	
f. Pens and alleys clean	
9. Yard, Loafing Area or Premises	
a. Well kept	
b. Truck Approach	
c. Clean and drained	
d. Manure properly handled and stored	
e. Swine and fowl	
10. Milking Procedures	
a. Abnormal Milk Program procedures followed	
b. Animal cleanliness	
c. Udders and teats, washed and wiped before milking	
d. Milkers/personnel cleanliness	
e. Milk stools and surcingles clean and properly stored	
f. Dusty Operations	
g. Feed bins properly enclosed and kept clean	

Score: 100

REMARKS (If additional space is required, please place information on the back of this Form or on a separate page.)

Folder # GLM101111640	**Insp #** GLM101058854	**Unit Doc ID #** GLM-101218568

CIS AG-xxxx (01/13)

Grade A dairy plant inspection report: FDA Form 2359b

DEPARTMENT OF AGRICULTURE

MILK PLANT INSPECTION REPORT
(Includes Dry Milk/Condensing Plants)

INSPECTING AGENCY

Minnesota Department of Agriculture
Dairy and Meat Inspection Division
625 Robert Street North, St. Paul, MN 55155-2538
Telephone: 651-201-6300 Fax: 651-201-6116

NAME AND LOCATION OF PLANT

Folder # GLM101111640	Insp # GLM101058854	Unit Doc ID # GLM-101218570

Facility Name:	Unit Loc ID 292101003858		
Street Address (Actual Inspection Location):	City:	State:	Zip Code:
Plant Number:	County:	Date of Inspection:	

Inspection of your plant today showed violations existing in the items checked below and on the Plant Universal Section report.

1. FLOORS
Smooth; impervious; no pools; good repair; trapped drains (a) ☐

2. WALLS AND CEILINGS
Smooth; washable; light-colored; good repair (a) ☐

3. DOORS AND WINDOWS
All outer openings effectively protected against entry of flies and rodents (a) ☐
Outer doors self-closing; screen doors open outward (b) ☐

4. LIGHTING AND VENTILATION
Adequate light in all rooms (a) ☐
Well ventilated to preclude odors and condensation; filtered air with pressure systems (b) ☐

5. SEPARATE ROOMS
Are there separate room or size requirement violations (a) ☐
No direct opening to barn or living quarters (b) ☐
Storage tanks properly vented (c) ☐

6. TOILET FACILITIES
Complies with local Ordinances (a) ☐
No direct opening to processing rooms; self-closing doors (b) ☐
Clean; well-lighted and ventilated; proper facilities (c) ☐
Sewage and other liquid wastes disposed of in a sanitary manner (d) ☐

7. WATER SUPPLY
Constructed and operated in accordance with Ordinance (a) ☐
No direct or indirect connection between safe and unsafe water (b) ☐
Condensing water and vacuum water in compliance with Ordinance requirements (c) ☐
Reclaim water complies with Ordinance (d) ☐
Complies with bacteriological standards (e) ☐

8. HANDWASHING FACILITIES
Located and equipped as required; clean and in good repair; improper facilities not used (a) ☐

9. MILK PLANT CLEANLINESS
Neat; clean; no evidence of insects or rodents; trash properly handled (a) ☐
No unnecessary equipment (b) ☐
No excessive product dust (c) ☐

10. SANITARY PIPING
Smooth; impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a) ☐
Clean-in place lines meet Ordinance specifications (b) ☐
Pasteurized products conducted in sanitary piping; except as permitted by Ordinance (c) ☐

11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT
Smooth; impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a) ☐
Self-draining, strainers and sifters of approved design (b) ☐
Approved single-service articles; not reused (c) ☐

12. CLEANING AND SANITIZATION OF CONTAINERS AND EQUIPMENT
Containers, utensils and equipment effectively cleaned (a) ☐
CIP cleaning requirements of Ordinance in compliance; records complete; milk tank trucks cleaned at permitted location (b) ☐
Approved sanitization process applied prior to use of product-contact surfaces (c) ☐
Required efficiency tests in compliance (d) ☐
Multi-use plastic containers in compliance (e) ☐

13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT
Stored to assure drainage and protected from contamination (a) ☐

14. STORAGE OF SINGLE-SERVICE ARTICLES
Received, stored and handled in a sanitary manner; paperboard containers not reused, except as permitted by the Ordinance (a) ☐

15. PROTECTION FROM CONTAMINATION
Operations conducted and located so as to preclude contamination of milk, milk products, ingredients, containers, equipment, and utensils (a) ☐
Air and steam used to process products in compliance with Ordinance (b) ☐
Approved pesticides, safely used (c) ☐
No direct connections between pasteurized and raw milk or milk products (d) ☐
Overflow, spilled and leaked products or ingredients discarded (e) ☐
No direct connections between milk or milk products and cleaning and/or sanitizing solutions (f) ☐

16a. PASTEURIZATION VAT/BATCH
1. Indicating and Recording Thermometers
Comply with Ordinance specifications (a) ☐
2. Time and Temperature Controls
Adequate agitation throughout holding; agitator sufficiently submerged (a) ☐
Each pasteurizer equipped with indicating and recording thermometer; bulb submerged (b) ☐
Recording thermometer reads no higher than indicating thermometer (c) ☐
Product held minimum pasteurization temperature continuously for 30 minutes, plus filling time if product preheated before entering vat, plus emptying time, if cooling is begun after opening outlet (d) ☐
No product added after holding begun (e) ☐
Airspace above product maintained at not less than 5.0 degrees F higher than minimum required pasteurization temperature during holding (f) ☐
Approved airspace thermometer; bulb not less than 1 inch (25 mm) above product level (g) ☐
Inlet and outlet valves and connections in compliance with Ordinance (h) ☐

16b. PASTEURIZATION HTST/HHST
1. Indicating and Recording Thermometers
Comply with Ordinance specifications (a) ☐
2. Time and Temperature Controls
Flow-diversion device complies with Ordinance requirements (a) ☐
Recorder controller complies with Ordinance requirements (b) ☐
Holding tube complies with Ordinance requirements (c) ☐
Flow promoting devices comply with ordinance requirements (d) ☐
Product held minimum pasteurization time and temperature (e) ☐

3. Adulteration Controls
Satisfactory means to prevent adulteration with added water (a) ☐

16c. REGENERATIVE HEATING
Pasteurized product in regenerator automatically under greater pressure than raw product in regenerator at all times (a) ☐
Accurate pressure gauges installed as required; booster pump properly identified, when required, and installed (b) ☐
Regenerator pressures meet Ordinance requirements (c) ☐

16d. RECORDING CHARTS
Batch pasteurizer charts comply with applicable Ordinance requirements (a) ☐
HTST/HHST pasteurizer charts comply with applicable Ordinance requirements (b) ☐

17. COOLING OF MILK AND MILK PRODUCTS
Raw milk maintained at 45 degrees F (7 degrees C) or less until processed or as provided for in the Ordinance (a) ☐
Pasteurized milk and milk products, except those to be cultured, or as provided for in the Ordinance, cooled immediately to 45 degrees F (7 degrees C) or less in approved equipment; all milk and milk products stored there until delivered (b) ☐
Approved thermometer properly located in all refrigeration rooms and storage tanks as required (c) ☐
Recirculated cooling water from a safe source and properly protected; complies with bacteriological standards (d) ☐

18. BOTTLING, PACKAGING AND CONTAINER FILLING
Performed in a plant where contents finally pasteurized, except for dry milk and whey products (a) ☐
Performed in a sanitary manner by approved mechanical equipment (b) ☐
Dry milk and whey products packaged in new containers; stored and transported in a sanitary manner (c) ☐

19. CAPPING, CONTAINER CLOSURE AND SEALING
Capping and/or closing/sealing performed in a sanitary manner by approved mechanical equipment (a) ☐
Imperfectly capped/closed products properly handled (b) ☐
Caps and/or closures comply with Ordinance (c) ☐

20. PERSONNEL CLEANLINESS
Hands thoroughly washed before performing plant functions; rewashed when contaminated (a) ☐
Clean outer garments and hair covering worn (b) ☐
No use of tobacco in processing areas (c) ☐
Clean boot covers, caps and coveralls worn when entering dryer (d) ☐

21. VEHICLES
Vehicles clean; constructed to protect milk (a) ☐
No contaminating substances transported (b) ☐

22. SURROUNDINGS
Neat and clean; free of pooled water; harborages, and breeding areas (a) ☐
Tank unloading areas properly constructed (b) ☐
Approved pesticides, used properly (c) ☐

REMARKS

DATE	**SANITARIAN**

FORM FDA2359 (10/11)

Manufacturing Grade Dairy Plant Inspection Report: FDA form 2359c

DEPARTMENT OF AGRICULTURE	**Manufacturing Grade Plant Inspection**	**INSPECTING AGENCY** Minnesota Department of Agriculture Dairy and Food Inspection Division 625 Robert Street North, St. Paul, MN 55155-2538 *Telephone: 651-201-6300 Fax: 651-201-6116*

NAME AND LOCATION OF PLANT

Folder # GLM101111640	Insp # GLM101058854	Unit Doc ID # GLM-101218571

Facility Name:	Unit Loc ID 292101003858		
Street Address: (Actual Inspection Location):	City:	State:	Zip Code:
Plant Number:	County:	Date of Inspection:	

Inspection of your plant today showed violations existing in the items checked below and on the Plant Universal Section report.

1. FLOORS
Smooth; impervious; no pools; good repair; trapped drains (a) ☐

2. WALLS AND CELININGS
Smooth; washable; light-colored; good repair (a) ☐

3. DOORS AND WINDOWS
All outer openings effectively protected against entry of flies and rodents (a) ☐
Outer doors self-closing; screen doors open outward (b) ☐

4. LIGHTING AND VENTILATION
Adequate light in all rooms (a) ☐
Well ventilated to preclude odors and condensation and filtered air with pressure systems (b) ☐

5. SEPARATE ROOMS
Are there separate room or size requirement violations (a) ☐
No direct opening to barn or living quarters (b) ☐
Storage tanks properly vented (c) ☐

6. TOILET FACILITIES
Complies with local ordinances (a) ☐
No direct opening to processing rooms; self-closing doors (b) ☐
Clean; well-lighted and ventilated; proper facilities (c) ☐
Sewage and other liquid wastes disposed of in a sanitary manner (d) ☐

7. WATER SUPPLY
Constructed and operated in accordance with the ordinance (a) ☐
No direct or indirect connection between safe and unsafe water (b) ☐
Condensing water and vacuum water in compliance with ordinance requirements (c) ☐
Reclaim water complies with ordinance (d) ☐
Complies with bacteriological standards (e) ☐

8. HANDWASHING FACILITIES
Located and equipped as required; clean and in good repair; improper facilities not used (a) ☐

9. MILK PLANT CLEANLINESS
Neat; clean; no evidence of insects or rodents; trash properly handled (a) ☐
No unnecessary equipment (b) ☐
No excessive product dust (c) ☐

10. SANITARY PIPING
Smooth; impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a) ☐
CIP cleaned lines meet ordinance specifications (b) ☐
Pasteurized products conducted in sanitary piping, except as permitted by ordinance (c) ☐

11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT
Smooth; impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection (a) ☐
Self-draining; strainers and sifters of approved design (b) ☐
Approved single-service articles; not reused (c) ☐

12. CLEANING AND SANITIZATION OF CONTAINERS AND EQUIPMENT
Containers, utensils, and equipment effectively cleaned (a) ☐
CIP cleaning requirements of ordinance in compliance; records complete; milk tank trucks cleaned at permitted location (b) ☐
Approved sanitization process applied prior to use of product-contact surfaces (c) ☐
Required efficiency tests in compliance (d) ☐
Multi-use plastic containers in compliance (e) ☐

13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT
Stored to assure drainage and protected from contamination (a) ☐

14. STORAGE OF SINGLE SERVICE ARTICLES
Received, stored and handled in a sanitary manner; paperboard containers not reused, except as permitted by the ordinance (a) ☐

15. PROTECTION FROM CONTAMINATION
Operations conducted and located so as to preclude contamination of milk, milk products, ingredients, containers, equipment, and utensils (a) ☐
Air and steam used to process products in compliance with the ordinance (b) ☐
Approved pesticides, safely used (c) ☐
No direct connections between pasteurized and raw milk or milk products (d) ☐
Overflow, spilled and leaked products or ingredients discarded (e) ☐
No direct connections between milk or milk products and cleaning and/or sanitizing solutions (f) ☐

16a. PASTEURIZATION VAT/BATCH
1. Indicating and Recording Thermometers
Comply with ordinance specifications (a) ☐
2. Time and Temperature Controls
Adequate agitation throughout holding; agitator sufficiently submerged (a) ☐
Each pasteurizer equipped with indicating and recording thermometer; bulb submerged (b) ☐
Recording thermometer reads no higher than indicating thermometer (c) ☐
Product held minimum pasteurization temperature continuously for 30 minutes, plus filling time if product preheated before entering vat, plus emptying time, if cooling is begun after opening outlet (d) ☐
No product added after holding time begun (e) ☐
Airspace above product maintained at not less than 5 degrees F (3 degrees C) higher than minimum required pasteurization during holding (f) ☐
Approved airspace thermometer; bulb not less than 1 inch (25 mm) above product level (g) ☐
Inlet and outlet valves and connections in compliance with the ordinance (h) ☐

16b. PASTEURIZATION HHST/HTST
1. Indicating and Recording Thermometers
Comply with ordinance specifications (a) ☐
2. Time and Temperature Controls
Flow-diversion device complies with ordinance requirements (a) ☐
Recorder controller complies with ordinance requirements (b) ☐
Holding tube complies with ordinance requirements (c) ☐
Flow promoting devices comply with ordinance requirements (d) ☐
Product held minimum pasteurization time and temperature (e) ☐

3. Adulteration Controls
Satisfactory means to prevent adulteration with added water (a) ☐

16c. REGENERATIVE HEATING
Pasteurized product in regenerator automatically under greater pressure than raw product in regenerator at all times (a) ☐
Accurate pressure gauges installed as required; booster pump properly identified, when required, and installed (b) ☐
Regenerator pressures meet ordinance requirements (c) ☐

16d. RECORDING CHARTS
Batch pasteurizer charts comply with applicable ordinance requirements (a) ☐
HTST/HHST pasteurizer charts comply with applicable ordinance requirements (b) ☐

17. COOLING OF MILK AND MILK PRODUCTS
Raw milk maintained at 45 degrees F (7 degrees C) or less until processed or as provided for in the ordinance (a) ☐
Pasteurized milk and milk products, except those to be cultured, or as provided for in the ordinance, cooled immediately to 45 degrees F (7 degrees C) or less in approved equipment; all milk and milk products stored there at until delivered (b) ☐
Approved thermometer properly located in all refrigeration rooms and storage tanks as required (c) ☐
Recirculated cooling water from a safe source and properly protected; complies with bacteriological standards (d) ☐

18. BOTTLING, PACKAGING AND CONTAINER FILLING
Performed in a plant where contents finally pasteurized, except for dry milk and whey products (a) ☐
Performed in a sanitary manner by approved mechanical equipment (b) ☐
Dry milk and whey products packaged in new containers; stored and transported in a sanitary manner (c) ☐

19. CAPPING, CONTAINER CLOSURE AND SEALING
Capping and/or closing/sealing performed in a sanitary manner by approved mechanical equipment (a) ☐
Imperfectly capped/closed products properly handled (b) ☐
Caps and/or closures comply with ordinance (c) ☐

20. PERSONNEL CLEANLINESS
Hands thoroughly washed before performing plant functions; rewashed when contaminated (a) ☐
Clean outer garments and hair covering worn (b) ☐
No use of tobacco in the processing areas (c) ☐
Clean boot covers, caps and coveralls worn when entering the dryer (d) ☐

21. VEHICLES
Vehicles clean; constructed to protect milk (a) ☐
No contaminating substances transported (b) ☐

22. SURROUNDINGS
Neat and clean; free of pooled water; harborages, and breeding areas (a) ☐
Tank unloading areas properly constructed (b) ☐
Approved pesticides, used properly (c) ☐

REMARKS

DATE	**SANITARIAN**

CIS AG-xxxxx (11/16)

Bulk hauler inspection/evaluation form

DEPARTMENT OF AGRICULTURE

BULK MILK HAULER/SAMPLER EVALUATION REPORT

BULK MILK HAULER / SAMPLER PERMIT NO.	**TANKER PERMIT NO.**
BULK MILK HAULER / SAMPLER	**DAILY PICKUP NO.** **NEXT EVAL DUE BY**
ADDRESS OF BULK MILK HAULER / SAMPLER	**INSPECTION LOCATION (FARM NAME)**
	PLANT NAME
PATRON / PRODUCER NUMBER	

An evaluation of your sampling procedures showed violations existing in the Items checked below. You are further notified that this evaluation report serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (Refer to Sections 3 and 5 of the Grade "A" Pasteurized Milk Ordinance.)

HAULER SANITATION PROCEDURES

- 1. Pickup practices conducted to preclude contamination of milk contact surfaces ☐
- 2. Hands clean and dry, no infections ☐
- 3. Clean outer clothing, no use of tobacco ☐
- 4. Hose port used, tank lids closed during completion of pickup ☐
- 5. Hose properly capped between milk pickup operations, hose cap protected during milk pickup ☐
- 6. Hose disconnected before tank rinsed ☐
- 7. Observations made for sediment/abnormalities ☐
- 8. Sample collected from each producer's bulk tank picked up ☐

BULK TANK SAMPLING PROCEDURES

- 9. Thermometer - Approved Type ☐
  - a. Accuracy - Checked against standard thermometer every 6 months - accuracy (plus)(minus) 1 division ☐
  - b. Date checked and checker's initials attached to case ☐
- **10. Sample Transfer Instrument**
  - a. Clean, sanitized or sterilized and of proper construction and repair ☐
  - b. Sterile needle for aseptically dispensing a milk sample from the bulk tank sample septum into a sample container (i.e., vial) ☐
  - c. Or an approved in-line sampler ☐
  - d. Or a sanitized sampling cock ☐
- **11. Sampling Instrument Container**
  - a. Proper design, construction and repair for storing sample dipper in sanitizer ☐
  - b. Applicable test kit for checking strength of sanitizer (200 ppm chlorine or equivalent) ☐
- **12. Sample Containers**
  - a. Clean, properly sanitized or sterilized ☐
  - b. Adequate supply, properly stored or handled ☐
- **13. Sample Storage Case**
  - a. Rigid construction, suitable design to maintain samples at 0C - 4.4C (32F - 40F), protected from contamination ☐
  - b. Ample space for refrigerant, racks provided as necessary ☐
- **14. Sample Collection - Precautions and Procedures**
  - a. Sampling instrument and container(s) properly carried into and aseptically handled in milkhouse ☐
  - b. Bulk tank milk outlet valve sanitized before connecting transfer hose ☐
  - c. Smell milk through tank port hole ☐
  - d. Observe milk in a quiescent state with lid wide open and lights on when necessary ☐
  - e. Test thermometer sanitized (1 min. contact time) ☐
  - f. Non-acceptable milk rejected ☐
  - g. Dry measuring stick with single-service paper towel ☐
  - h. Measure milk only when quiescent ☐
  - i. Do not contaminate milk during the measuring process ☐
  - j. Agitate milk before sampling at least 5 min. or longer as may be required by tank specifications ☐
  - k. Do not open bulk tank valve until milk is measured and sampled ☐
  - l. Temperature of milk, time, date of pickup and bulk milk hauler/ sampler name and license or permit no. recorded on each farm weight ticket ☐
  - m. Tank thermometer accuracy
    - ____1. Tank thermometer accuracy checked monthly and recorded when used as test thermometer ☐
    - ____2. Accuracy of required recording thermometer checked monthly against standardized thermometer and recorded ☐
  - n. Temperature control sample provided at first sampling location for each rack of samples ☐
  - o. Temperature control sample properly labeled with time, date, temperature, producer ID and bulk milk hauler/sampler identification ☐
  - p. Sample containers legibly identified at collection points ☐
  - q. Sample dipper rinsed at least two times in the milk before transferring sample ☐
  - r. Dipper should be extended 6-8 inches into the milk to obtain a representative sample ☐
  - s. Sample cock properly sanitized and flushed prior to sampling ☐
  - t. Septum surface properly sanitized and single service sterile needle used ☐
  - u. Do not hold sample container over the milk when transferring sample into the container ☐
  - v. Fill sample container no more than three quarters full ☐
  - w. Rinse sample dipper in safe tap water, return to storage container, open tank valve, start milk transfer pump ☐
  - x. Immediately place milk sample in the sample case ☐
- **15. Sample Collection - Storage and Transportation**
  - a. Sample storage - refrigerant maintained no higher than milk level in sample containers - maintain sample temperature - 0C - 4.4C (32F - 40F), do not bury tops of containers in ice, protect against contamination ☐
  - b. Deliver samples to laboratory promptly ☐
  - c. Samples and sample data - submitted to laboratory - if by common carrier, use tamper proof shipping case with top labeled 'This Side Up' ☐

REMARKS

DATE	**SANITARIAN**	**AGENCY**
		Minnesota Department of Agriculture Dairy and Meat Inspection Division 625 Robert Street North, St. Paul, MN 55155-2538 *Telephone: 651-201-6300 Fax: 651-201-6116*

Folder # GLM101111640 **Insp #** GLM101058854 **Unit Doc ID #** GLM-101218569

FORM FDA2399a (10/08) FRONT (PREVIOUS EDITIONS ARE OBSOLETE)

DEPARTMENT OF AGRICULTURE
625 ROBERT STREET NORTH, SAINT PAUL, MN 55155-2538
WWW.MDA.STATE.MN.US

Dairy and Meat Inspection Division, Phone: 651-201-6300, Fax 651-201-6116

Dairy Product Label Review Submission Form

Dairy Product Label Review Submission Form

The Minnesota Department of Agriculture (MDA), pursuant to Minnesota Statutes 31.04 and 31.101, requires new dairy plants and existing dairy plants making a new dairy product to submit copies of dairy product labels to ensure the labels are in compliance with state and federal labeling regulations.

Trade secret information (as defined in Minn. Stat. § 13.37) submitted by an applicant is classified as private or nonpublic. In order to protect data as trade secret information, the application must identify the specific formula, pattern, compilation, program, device, method, technique or process that the applicant wishes to protect, and provide an explanation of the economic value of keeping the data from being generally known to other persons. Determining what constitutes trade secret information is ultimately the responsibility of the MDA, and the MDA cannot guarantee that data marked by an applicant as trade secret information will be classified as such.

Business Information		
Legal Name of Business:		
DBA:		
Address:		
City:	State:	Zip:
County:	Phone Number:	

Contact Information		
Submitter:		
Phone Number: Extension:		Email Address:
Secondary Contact:		
Phone Number: Extension:		Email Address:

Label(s)

Type of Product: ☐ Grade A ☐ Non-Grade A ☐ Non Dairy

Product will be sold at (check all that apply):
☐ Grocery Stores ☐ Food Service / Restaurant ☐ Farmers' Market ☐ Seasonal Stands ☐ Online Orders
☐ Other:

General		
Is the following information on the product label?	YES	NO
Product Identity		
Net Weight Statement		
Ingredient List		
Business Name and Address		
Nutrition Facts Panel (If Required)		
Plant Number*		
Quality Assurance Statement*		
If no,	YES	NO
Is the product's shelf life over 90 days?		
Is the product aged?		
Is the product frozen?		

**If the Plant Number and/or Quality Assurance Statement are ink jetted, stamped or applied by other means onto the package, provide an example. The example can be attached to this form.*

Grade A Product		
Is the following information on the product label?	YES	NO
Grade A		
Pasteurized		
Ultra-Pasteurized		

Non-Grade A Raw Milk Cheese		
Is there a statement that the cheese was aged 60 days or more on the product label?		

Non-Grade A Ice Cream		
Is the Ice Cream Mix:		
Made by your firm		
Purchased from another company		
Made by another company at your firm's request using your formula		

Product Formulation. List all ingredients of product formula in order of predominance.				
Ingredient Name	**Weight (lbs.) No Volumetric Measurements** *The weight may be substituted with a range or percentage	**Type of Ingredient** Check appropriate box for each ingredient in formula		
		Single Ingredient (ex. Milk)	**Multi-Component Ingredient** A compound product made up of more than one ingredient. For each multi-component ingredient, attach a copy, photo, or specification sheet containing the product name and ingredient statement listing all sub-ingredients. (ex. Chocolate Dairy Powder) --- **Ingredient List Attached**	
			YES	NO

All the items below must be provided with this submission. Written notification will be sent for all incomplete submissions. Labels will not be reviewed until the submission is complete. Please review your submission and check the boxes below to indicate items included with your submission.

- ☐ Label Review Submission Form
- ☐ Product label(s)
- ☐ Completed ingredient list including product formulation (page 2 of this form)
- ☐ Copies of multi-component ingredient labels

Submit this form with attachments to:

Minnesota Department of Agriculture,

Attn: Dairy Compliance Officer,

625 Robert St. N, St. Paul, MN 55155; or

Email application to dairylabels@state.mn.us

Appendix C: Fees for Dairy Processors

Table 1: Licensing Fees

License Type	Applies to	Minnesota Statutory Reference	License Period	Cost
Farmstead Cheese License	Processors who make cheese on the same farm where the milk is produced	Chapter 28A.08, Subd. 3.7	January 1 – December 31	$30, billed annually
Dairy Plant License (Processor Manufacturer)	Plants processing raw milk	Chapter 28A.08, Subd. 3.4	January 1 – December 31	Sliding scale dependent on expected gross sales, billed annually

Table 2: Dairy Plant Inspection Fees

License Type	Applies to	Minnesota Statutory Reference	License Period	Cost
Farmstead Cheese Pasteurizer and Plant Inspection	Farmstead Cheese License holders and Cultured Dairy Food Plant License holders	Chapter 32D.10(b)	Billed annually on January 1	$140 per HTST, HHST, or Vat Pasteurizer
Grade B Plant Pasteurizer Unit Inspection	Dairy Plant Wholesale Food Manufacturing License holders who operate Grade B (manufacturing grade) dairy plants pasteurizing milk or milk by-products	Chapter 32D.10(b)	Billed annually on January 1	$140 per HTST, HHST, or Vat Pasteurizer
Grade A Plant Inspection	Dairy Plant Wholesale Food Manufacturing License holders who operate Grade A plants	Chapter 32D.10(a)	Billed annually on July 1	$500 for plants processing >700,000 lbs of milk/year or $300 for plants processing <700,000 lbs of milk/year

Table 3: Farm Inspection Fees. (These fees apply to dairy plants who procure milk from MN dairy farms.)

License Type	Applies to	Minnesota Statutory Reference	License Period	Cost
Grade A Farm Inspection	Processors and marketing organizations who procure milk from Grade A dairy farms and wish to market Grade A milk	Chapter 32D.06(b)	Billed annually on July 1	$50 per farm, billed annually
Grade A Farm Reinspection	Processors or marketing organizations whose Grade A farm requires reinspection	Chapter 32D.06(c)	Billed monthly on the 15th of the month	$60 per farm, <100 cows, $150 per farm, >100 cows
Grade B Farm Inspection	Processors or marketing organizations who procure milk from Grade B farms and wish to market manufacturing grade milk	Chapter 32D.08(b)	Billed annually on January 1	$25 per farm, billed annually
Grade B Farm Reinspection	Processors and marketing organizations whose Grade B farm requires reinspection	Chapter 32D.08(c)	Billed monthly on the 15th of the month	$45 per farm

Table 4: Other fees

License Type	Applies to	Minnesota Statutory Reference	License Period	Cost
Processor Assessment or Selected Fee	Fluid milk processed and milk used in manufacturing fluid milk products sold for retail in Minnesota*	Chapter 32D.12	Billed monthly on the 25th of the month	Sliding scale of $0.05 - $0.09/cwt of milk used in manufacturing of selected fluid milk products sold for retail in Minnesota
Procurement Fee	Any entity that procures milk from a Minnesota dairy farm	Chapter 32D.11	Billed monthly on the 25th of the month	$0.0110/cwt of milk procured directly from any MN dairy farm in the previous month
Annual Laboratory Evaluation Officer Fee	Processors who maintain an Appendix N screening lab	Chapter 32D.17	Billed annually after evaluations are performed	$200/analyst and $50 for each test method for which analyst is approved
Bulk Hauler Sampler License	Bulk haulers and samplers who collect official samples for regulatory purposes from farms and/or direct load tankers and may also transport raw milk from a farm to a milk plant, receiving station, or transfer station	Chapter 32D.03	New licenses expire December 31 of year issued. Renewals are valid 2 years, issued January 1, and expire December 31 of second year.	$60 new and $60 renewal
Pasteurizer reseals	Plants requiring a pasteurizer reseal	Chapter 32D.09, Subd. 3	Monthly as services are rendered	$45/hour of inspector time
Fees for approval services rendered	Plants seeking review of their plans and equipment, including plumbing and water systems and any upgrades	Chapter 32D.09, Subd. 3	Monthly as services are rendered	$45/hour of inspector time

*The Processor Assessment fee or selected fee applies to the following products: milk (skim, low-fat, non-fat, whole, Vitamin D, homogenized, flavored), flavored drink, cream (heavy, light, heavy whipping, light whipping, fluid dairy creamers), half & half, sour cream, acidified sour cream, buttermilk, cultured milk or kefir, cultured buttermilk, concentrated milk & milk products, reconstituted milk, reconstituted half & half, reconstituted skim milk, reconstituted flavored milk, reconstituted flavored drink, acidified milk, evaporated milk, egg nog, yogurt (low-fat, non-fat, full-fat, flavored), cottage cheese, dry curd cottage cheese. Any size, combinations, or variations of these categories are applicable to the selected dairy fee.

Appendix D: Commonly Asked Questions

I have my own recipe for cheese/yogurt that I'd like to start manufacturing and selling. May I manufacture this product in small-scale quantities in my home and sell it?

No. All dairy product manufacturing must be done in an approved plant. Approved plants could be at your home or farm but must be separate from your home kitchen and must still meet the regulatory requirements for manufacturing of that dairy product. If you are interested in testing your market to determine if investing in your own plant would be successful, there are other dairy plants or commercial kitchen locations you can use to co-manufacture your product and help you get going as an alternative to investing in your own plant from the start.

I would like to sell my products at the farmers' market. Can I sell these products without inspection as cottage foods?

No. Almost all dairy products are considered potentially hazardous and do not meet the conditions necessary to qualify for the Cottage Foods Exemption. Additionally, most dairy products are regulated by both state and federal laws, so exceptions or exemptions that exist for other food products are not available for dairy products. Products that are sold at farmers' markets must be manufactured in an approved dairy plant.

I would like to sell bottled milk, but the Grade A requirements are more than what I would like to commit to meeting. Do the Grade A requirements still apply to my product if I leave the "Grade A" statement off my product labels?

Yes. The Grade A requirements apply to a type of product and are not simply a labeling category. These requirements are more stringent than the requirements for producing non-Grade A products, like cheese or butter, because Grade A products, like fluid milk, can have significant food safety hazards associated with them and are generally highly perishable. Grade A products are regulated under a federal requirement called the Pasteurized Milk Ordinance (PMO), which is applied consistently throughout the United States so that consumers can have strong confidence that these products are produced safely and are of high quality.

I don't want to invest in building or renting a dairy processing facility. What other options do I have?

You have many options, including the following:

- Rent a licensed commercial kitchen. You can read more about this option from the Minnesota Institute for Sustainable Agriculture (MISA) Commercial Kitchen Guide.
- Lease a space to make product at an existing dairy processing facility.
- Work with an existing dairy plant to co-pack your product.

Could I use pasteurized milk purchased from a store as an ingredient to make a dairy product such as ice cream or cheese?

Yes. You can use purchased, pasteurized milk as an ingredient in your dairy product.

For additional information, contact the MDA Dairy and Meat Inspection Division at 651-201-6300 to get in touch with a dairy inspector in your area.

Starting and Operating a Small Dairy Processing Plant