

Starting a Small Dairy Processing Plant: The Basics



Minnesota Department of Agriculture

Dairy & Meat Inspection Division

625 N Robert St
St. Paul, MN 55155

(651)-201-6300

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

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Section 1: Getting Started with Dairy Processing

This document is intended to be an educational resource that provides a starting basis for meeting the regulations and laws that apply to dairy processing plants. Included in this document is a basic overview of things that you should consider and some of the basic requirements for dairy processing plants in Minnesota. It does not and cannot cover every possible situation or question so you will need to consult other more detailed resources for questions on specific parts of your operation. It is also very important to work with the local inspector or other dairy program personnel as you put together your plans for your dairy plant so that you can be confident that you've completed all the necessary steps.

This document will cover many of the basics of dairy processing, including:

- An overview of the regulatory requirements
- Information on licensing, permitting and fees
- A description of what you can expect for inspections
- A brief overview of dairy product sampling requirements
- Product labeling information
- Information about required antibiotic testing
- A checklist to use as you begin your operation
- Other basic information you can use to help make sure you have considered the relevant information

Getting Started

It is important to ask many questions as you get started with your dairy plant. [Appendix A](#) contains a list of questions you may find helpful to consider as you begin your business

Section 2: Overview of the Regulatory Requirements

Dairy products are regulated under two separate and distinct sets of regulations. Grade A dairy products are regulated by the Pasteurized Milk Ordinance (PMO). Manufacturing Grade (also called Grade B) are regulated by a separate set of regulations found in the Federal Code of Regulations (7 CFR 58) and the USDA Guidelines for Milk for Manufacturing Purposes. These Federal standards are adopted by Minnesota State Statutes to be Minnesota's standards. All dairy products also have additional regulatory requirements listed in Minnesota State Statutes, with Chapter 32D specifically addressing dairy products.

The Minnesota Department of Agriculture (MDA) Dairy and Meat Inspection Division (DMID) administers and enforces these dairy laws and regulations which are designed to protect the public. Because all facilities must be approved and permitted by the MDA before dairy products are processed, manufactured or sold, it is very important to work in consultation with the MDA DMID staff as you are making your plans.

Definition of a Dairy Plant

According to Minnesota State Statutes (MS 32D.01 Subdivision 6), a "dairy plant" means any place where a dairy product is manufactured, processed, or handled and includes milk-receiving stations, creameries, cheese factories, condenseries, milk plants, transfer stations, and marketing organizations that purchase milk and cream directly from producers for resale and other establishments, but does not include any place where dairy products are not processed, but sold at wholesale or retail only.

On-Farm Dairy Processing Plant: An On-Farm Processing Plant is a dairy plant located at the same location as the farm from which they get the milk used to process dairy products.

Small Dairy Processing Plant: A small dairy processing plant is a dairy plant which is not located on a farm, processes dairy products, and less than 700,000 lbs of milk a year.

Both on-farm dairy processing plants and small dairy processing plants are required to meet many of the same rules and regulations as larger dairy plants. Whether it is located on or off the dairy farm, in most cases, the dairy processing plant must be licensed and inspected by the MDA.

Grade A vs Grade B

Dairy plants fall under different regulatory requirements according to the products that they produce. It is important to understand how the products you want 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.

Table 1: Grade A vs. Grade B Product Differentiation

Grade A	Grade B (Manufacturing Grade)
Fluid Milk and Milk products (For example, whole milk, low-fat milk, or skim milk) Cream (Heavy, light, whipping) Half and half Yogurt Cottage cheese Cultured or acidified milk Sour cream Some dry milk products Buttermilk Eggnog Other similar type products	Cheeses Butter Ice cream Ice cream products Some dry products Other food products whose primary ingredients are dairy or milk.

If you want to produce a product that does not appear on this list but that is made primarily from a dairy product, it is best to check with the dairy inspection program to determine whether or not the dairy regulatory requirements will apply.

Grade A

Grade A dairy facilities and processing plants are held to the strictest standards. Some of these basic requirements include:

- They must comply with all requirements of the PMO and Minnesota State Statutes.
- Grade A dairy plants are inspected at minimum four times per year and the products are typically sampled by the dairy inspector on a monthly basis.
- Only milk from Grade A dairy farms may be used in Grade A products.
- The milk used to make Grade A products must be pasteurized at the place of production. For example, if the plant buys pasteurized milk from another Grade A dairy facility it must be repasteurized at the plant where the product is being made.

Grade B

Grade B dairy facilities and processing plants must meet specific requirements as well. Some of these basic requirements include:

- They must comply with the Federal Code of Regulations and Minnesota State Statutes.
- Grade B dairy plants are inspected at minimum 2 times per year and the products are sampled by the dairy inspector typically on a yearly basis. Farmstead Cheese are inspected 4 times per year.
- Milk from either Grade A or Grade B farms may be utilized for Grade B dairy products.
- Depending upon the situation, milk may be required to be pasteurized on-site at the place of the product of the product. However, in some cases, pasteurization is not required.

Rules, Laws & References:

The following is a list of references to applicable regulations for dairy processing and manufacturing.

- [Grade A Pasteurized Milk Ordinance \(PMO\)](#)
- [Minnesota State Statutes, Chapter 32D, Dairy Law](#)
- [Minnesota State Statutes, Chapter 28A, Licensing of Food Handlers](#)
- [3A Standards for construction of dairy equipment](#)
- [USDA Milk for Manufacturing Purposes and its Production and Processing, Recommended Requirements](#)
- [7 CFR 58 – Grading and Inspection, General Specifications for Approved Plants and Standards for Grades of Dairy Products](#)
- [FDA Good Manufacturing Practices \(GMP's\)](#)
- [Code of Federal Regulations \(CFR\) 21 & 7](#)
- [Federal Milk Marketing Order](#)
- [Milk & Dairy Beef Drug Residue Prevention Manual](#)
- [FDA Food Safety Modernization Act](#)

Section 3: Licensing, Permitting & Fees

Various licensing, certifications and fees will apply depending on the type of dairy processing facility. MDA's DMID grants licenses and certifications unless otherwise noted. A detailed list of license and fees that may apply is included in the MDA Factsheet: *Fees and Licensing for On-Farm or Small Dairy Processors Fact Sheet* ([Appendix C](#)).

Licensing

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

Licensing the plant/operation:

- The type of license you need will be based on the type of activities that 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 1 processing license per physical location (separate addresses).
- If you are conducting mobile activities, such as selling products at a Farmer's market or festival, you also may need a mobile food handler's license.

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
 - Certifications to conduct drug testing (Appendix N certifications)

A licensing exemption is available to anyone who is producing product made from ingredient produced only on your farm. For example, unsalted butter can be made solely with milk produced by your cows on your farm and no other ingredients. If this were your only products, you may qualify for a licensing exemption; however, you would still need to meet the regulatory requirements for having a dairy plant.

Please Note; Licensing and Permitting are Different!

Even if you don't need a license, you will still need to be inspected and are required to meet the regulatory requirements for processing safe food.

Permitting

It is important to remember that 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. Dairy permits are represented by a certificate and an assigned permit number.

Permit numbers:

- Are assigned to each plant by dairy program staff;
- Start with a State specific prefix. Each State has an assigned prefix. The Minnesota prefix is “27”;
- Are formatted with a “27-XXX”, with the “XXX” representing a 3 number sequence that is unique to that plant; and
- 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 are:
- Granted by the dairy inspector when they conduct the final inspection and approval for operations to begin.
- Not able to be transferred 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 also required to pay fees. The fees fund the dairy inspection program activities. For an individual dairy plant, the fees that are required are dependent upon the type of operation, the products that are produced and where, where and how those products are sold. Specifically, plants may be subject to the following fees:

- Plant Inspection Fees
- Pasteurizer Inspection Fees
- Fees for approval of equipment plans 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

Other Considerations

Interstate Shipment

If you will be shipping Grade A products across State lines, then your plant needs to be surveyed as an Interstate Milk Shipment (IMS) plant. The plant would be required to meet all Grade A regulatory requirements for shipment of Grade A product into other States. There are no additional fees associated with IMS certification.

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

Purchasing Milk from Other Producers

If you are purchasing milk from other producers, you may need to obtain additional licenses, permits or certifications, including, but not limited to:

- Participating in the Federal Milk Marketing Order. If you purchase Grade A milk from other producers, this will likely be required. Contact them directly for more information on how to participate and what permits or certifications are required.
- Obtaining a Wholesale Produce Dealer's License and Bond (MDA Fruit, Vegetable and Grain Unit)
- Maintaining a field representative certification
- Milk tanker inspection and the appropriate permit for transporting milk

Section 4: Inspections

Routine inspections of dairy plants are conducted by the MDA DMID program staff as a tool to ensure regulatory requirements are met and that food safety issues are addressed. Additional inspections may be made by the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) depending upon the type and distribution of the product being produced. The inspection process starts prior to operations with plan reviews and site visits. Once operations begin, routine inspections will be conducted at the plant. Examples of inspection documents are included in [Appendix B](#).

Prior to Processing

All dairy plants must be approved by an MDA Dairy Inspector before they can begin operating. Before and during construction the dairy inspector will work closely with the processor, making visits to the facility when needed. Important points to remember about inspection work and reviews that take place before the plant is operating:

- Working with the inspector during the start-up phase helps ensure you meet the regulatory requirements and prevents the need to make larger scale changes after you've finished major construction and equipment installation.
- There is an hourly charge of \$45/hour for plan reviews and on-site inspection work that takes place in order to help get the dairy plant approved (called "Approval Services").
 - The 1 initial on-site inspection will not be billed to the plant and any subsequent contact or visits initiated by the inspector are not billed either.
 - Inspections or work initiated by the processor will be billed. A start up processor should expect to incur some expenses for approval of their plant, though these will vary depending upon the operator's experience, need for assistance and overall plan for implementation.

After You've Started

After start-up, the plant will be routinely inspected by the local dairy inspector. During these inspections, the inspector will make observations of 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 4 times per year for:
 - Grade A plants; and
 - Farmstead Cheese plants
- Conducted at least 2 times per year for other 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 is 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 and if a member of the public requests copies of these documents, the MDA will have to release the information.

During the Inspection

You can expect that the inspector will do a number of 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 plant while it is in production;

- 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 3 months for Grade A plants, farmstead cheese and culture plants and once every 6 months at other plants;
- Review pasteurization charts, cleaning records, recording charts and production records to ensure legal pasteurization temperatures are being met, antibiotic screening is being properly completed and documented and other production parameters are in compliance and adequately documented; and
- 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 on an inspection form, they will:

- Complete a standardized inspection “form” that will have the specific items they’ve found in violation marked with a “☒”.
- Complete a written narrative report with written orders. “Orders” include:
 - A description of the things they observed to be in violation
 - An statement on how to fix the violation; and
 - A compliance date (a deadline of when the item needs to be corrected).
- Create a signature document during which the plant owner or representative will be asked to sign as an indication that they have received the documentation; and
- Provide the plant with a copy of all inspection documentation after the on-site inspection is concluded.

Violations

When the inspector identifies something that is not in compliance with the regulatory requirements, he or she 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 or have a significant potential to directly affect the safety of product.
- More minor violations may not have as strong of potential to directly affect the safety of the product but taken with other findings may combine to affect product or the sanitary condition of the environment.

Since pasteurization is a critical to the production of safe milk, any violations found during pasteurizer testing need to be corrected immediately to continue processing milk.

- If the violation is serious enough, the inspector may order a recall of products processed in a determined span of time.
- When other critical violations are found, the inspector may issue a “Notice of Intent to Suspend” document which provides warning that inspector will be returning for a re-inspection and the violations will need to be corrected at that time or a suspension of the plant’s permit will result.
 - 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 that violations have been corrected during documentation of subsequent inspections so correction of violations in a timely manner is also an opportunity to demonstrate cooperation and a willingness to address food safety issues in your facility. Failure to correct violations may result in reinspections (including fees), a regulatory hearing, a permit suspension or other enforcement action.

Section 5: The Production Process

The following is an overview of the requirements at different processing steps for producing Grade A Dairy products. These requirements come from the PMO. Other dairy products may have similar requirements, but the actual requirements depend upon the type of product being manufactured.

Transporting Milk

The following information applies to both Grade A and Grade B dairy facilities:

- The type of vehicle or transportation method you need will depend upon the setup of your operation.
 - An on-farm processor may transport milk through a pipe from the bulk tank to the plant.
 - A small dairy plant may need a small bulk milk pick-up truck and tank to travel to one or two producers and pick up purchased milk.
- Work with your 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 food safety concepts to remember for the transportation process.

Fluid Milk Products:

Vitamin Addition

Vitamins A and D must be added to all reduced fat Grade A dairy products because:

- Vitamin A is removed from milk during the removal of fat from low or non-fat milks. Because Vitamin A is fat soluble and dissolves with fat, removing the fat also removes the Vitamin A. Whole milk still contains fat, and thus Vitamin A, this Vitamin does not have to be added to whole milk.
- Vitamin D is naturally present at low levels in milk. However, because it promotes the absorption of calcium by the intestine, historically regulations required the addition of this in order to address rickets in children. The need for normal levels of Vitamin D for other health problems, such as osteoporosis, makes the addition of Vitamin D a continued requirement.

For products that require the addition of vitamins, annual testing of products to determine that the appropriate levels are being added is required. This testing is initiated by the processor and is performed at the cost of the processor.

If you are producing reduced fat Grade A dairy products, consider the following questions as you formulate a plan for adding these Vitamins:

- From where will you source your vitamins?
- How will the vitamins be added?
- When in the processing procedure will they be added?
- What are the Minimum and Maximum levels required?
- How will you keep records of what you are adding?
- Where will you have your product tested?

Packaging and Capping

The requirements for bottling, packaging and capping (of bottled products) depend upon the type of product that is being produced. Some general requirements for this part of the process 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 (in other words, 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 (like plastic milk jugs) must be obtained from a specific source.
- The cap or closure for bottles must be “tamper proof” in that the cover cannot be removed without breaking a seal.

All Grade A and Grade B 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 is milk that is used to make aged cheese. In the case of aged cheese made with raw milk specific requirements must be met. See Aged Cheeses below.

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 that the bacteria are killed. The following chart lists the legally allowed pasteurization times and temperatures.

Table 2: Pasteurization Specifications

Type of Product	Type of pasteurization	How this works	Minimum temperature	Minimum time
For regular milk products	Vat Pasteurization	Heating one batch at a time in an approved tank	145° F	30 minutes
	High Temperature-Short time	A continuous flow system	161° F	15 seconds
For milk products with added sweeteners, fat content > 10%, and total solids >18%:	Vat Pasteurization	Heating one batch at a time in an approved tank	150° F	30 minutes
	High Temperature-Short Time	A continuous flow system	166° F	15 seconds
Ice Cream Mix (Frozen Dessert Mix):	Vat Pasteurization	Heating one batch at a time in an approved tank	155° F	30 minutes
	High Temperature-Short Time	A continuous flow system	175° F	25 seconds
			180° F	15 seconds
Egg Nog:	Vat Pasteurization	Heating one batch at a time in an approved tank	155° F	30 minutes
	High Temperature-Short Time	A continuous flow system	175° F	25 seconds
			180° F	15 seconds
Cream for Butter:	Vat Pasteurization	Heating one batch at a time in an approved tank	165° F	30 minutes
	High Temperature-Short Time	A continuous flow system	185° F	15 seconds

Note: There are no time and temperature combinations in between these that comply with the requirements.

Other Important Facts about Pasteurization

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

- All raw products must be added before pasteurization begins. Once 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 on a routine basis.
 - The following table lists the frequencies of equipment testing:

Table 3: Pasteurization Equipment Testing Frequency

Type of Production/Plant	Testing Frequency
Grade A	Quarterly (4 times/yr)
Farmstead Cheese processor	Quarterly (4 times/yr)
Other Manufacturing Grade Plant	Semi-annually (2 times/yr)

- Various controls on the pasteurization units are sealed by the MDA inspectors so that temperatures, timing and pressures cannot be changed once they are tested.

Cooling

Proper cooling is also required for all dairy products, including Grade A and Grade B. By keeping the product cool, the temperature of the product stays in a range that helps limit or stop 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; and
- 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 a properly operating thermometer.

Warehousing

The following information applies to all Grade A and Grade B dairy facilities:

- Storage of finished product, ingredients, packaging materials, containers, single service items, filters, and chemicals and other items in a sanitary way is important.
 - All of 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.
- 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 surrounding areas is important to prevent introduction of these unwanted pests.

Aged Cheeses

Aged cheeses are the only product that is currently acceptable to be made with raw milk. Per the regulations, 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 Statute 32D.22:

- Cheese must be manufactured from milk or milk products which have been properly pasteurized;
- If the milk hasn't been pasteurized, the milk used to produce cheese must be subjected to a heat treatment equivalent to pasteurization during the process of manufacture or processing; or
- Cheese made with raw milk must be subjected to an aging process whereby it has been kept for at least 60 days after manufacture 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 6: 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 products, the sampling frequencies for different products are described in the PMO.
- Non-Grade A products are sampled on a more intermittent basis; however, they are tested for specific pathogens each time a sample is collected.
- Sample results are compared against the regulatory requirements to determine whether they are 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 need to be conducted.

Raw Milk from the Farm

Raw milk samples are collected from the farm bulk tank to determine compliance with bacteria (SPC), somatic cell count (SCC), temperature and antibiotic requirements. It is the plant's responsibility to ensure that these samples are collected and submitted to a laboratory. These samples must be:

- Representative of the entire herd's milk;
- Collected by a licensed bulk hauler or sampler on a monthly basis;
- Submitted to an approved laboratory for quality testing (SPC, SCC, temperature and antibiotics); and
Reported to the MDA on a monthly basis.

These sample results must be submitted to the MDA's dairy inspection program through the electronic qualities email system. Upon receipt of the results, the MDA will review them to determine if they meet the regulatory requirements. The following table details the regulatory requirements for these samples.

Table 4: Regulatory Standards for Raw Milk from Farms

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

Enforcement of raw milk farm sampling results

Raw milk sample results are kept as part of the farm and plant official record. The record is a running record that counts the compliance of counts over time.

- One count above the legal standard (with the exception of antibiotic results) does not result in regulatory action.
- Whenever 2 of the last 4 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 3 days, an additional sample must be taken.
- Whenever the standard is violated by 3 of the last 5 quality counts immediate suspension of permit or product will be instituted. Regulatory action will also be taken if the farm fails to submit counts in at least 4 out of every 6 months.
- Any positive antibiotic test will trigger the adulterated milk enforcement process and be counted as a violation.

Raw milk at the Plant

- All milk that is used for processing or manufacturing dairy products must be tested for Animal Drug Residues (Beta Lactams antibiotics) as per the requirements of Appendix N of the PMO and MN Statute 32D.19.
 - Proper certification is required in order to run this test in a processing plant setting. See the section on PMO Appendix N Testing below.
 - Results of these tests are recorded and kept by the plant for review by the inspector and laboratory evaluation program staff.
- A raw milk sample is also taken by the MDA on a monthly basis 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 which depends upon the type of product that the plant is producing. 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 are collected of all different types of finished products. For example, any of the following might be sampled by your MDA 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
- The different types of samples needed will vary depending upon the type of production you do.

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 that is done 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 are not usually routinely done.

Sample Results:

MDA dairy program personnel will send the results of any sampling done as soon as it is available. Keep in mind that the results do take time, sometimes up to 2 weeks, so it is important to conduct your own testing to achieve more timely information on your products.

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

Internal Testing and Quality Assurance

The sampling that is conducted by the Dairy Inspection program is designed to periodically check to see if your product is 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 quality assurance program. This program may consist of sampling that is used to assess whether the production process is consistently meeting the desired standards, as well as food safety based testing.

The specific number of samples that are tested, and what they are tested for, will depend upon many factors, including but not limited to:

- The type of product you produce;
- The plant history; and
- The complexity of your production system.

You may need to collect more samples of your product at during the start-up phase of your plant in order to develop a good baseline for your process. Each plant's quality assurance program will be specific to their unique situation. As you begin your operations, it is very important to start with a good foundation for quality and safety and development of this program will help contribute to that foundation.

Section 7: PMO Appendix N Testing & Adulterated Milk Enforcement

Appendix N Testing

The Appendix N testing is a drug residue testing program adopted by Minnesota from the PMO. It requires screening of all milk, regardless of final use, for Beta lactam drug residues. This testing must be performed by a certified laboratory analyst. This may be someone who works at the plant or someone who works at a separate certified laboratory. Results of these tests must be documented and shared with the inspector during the inspections.

To get started with setting up an Appendix N testing program, consider the following program requirements and options:

- You may choose to setup a certified laboratory to conduct this testing. If this is done:
 - The plant's lab area, testing equipment, records and each analyst's procedures will need to be evaluated and approved by a state Lab Evaluation Officer (LEO) for screening of milk before the plant starts production;
 - A reevaluation of the laboratory and analyst certification will be conducted every 2 years at the plant; and
 - You must participate in yearly split-sample testing where the LEO sends out known samples for each analyst to test and then compare with the LEO results.
- If you do not want to set up an Appendix N testing laboratory, you may take samples to an LEO approved lab and have them run the samples.
 - If you choose this option, you must have the milk represented by the sample in your control until the sample confirms negative.
- All Appendix N samples must be run on an FDA approved screening test (FDA M-a-85 Antibiotic Tests Rev #14 page 3).
 - Positive results are to be reported to the MDA on the appropriate forms, and the sample is to be sent to a Confirmation Lab for confirmation.

When you get a positive:

ALL milk at the dairy plant must be tested for beta lactam antibiotics prior to using it in product. Ideally, this testing should be done before the milk is unloaded in order to avoid contaminating any other milk in the event that a sample comes back positive.

The initial testing that is done on the milk is a screening testing. When the test shows a positive result, this initial positive is considered to be a presumptive positive and needs to be confirmed.

Confirmation of that result must be done by a laboratory person who is certified to run confirmation tests – you may need to perform this test at an outside laboratory if you are not certified to do the confirmation. For the confirmation test, the milk must be retested in duplicate using the same test. If any of those tests are positive, then the milk is considered adulterated (“contaminated”) and discarded.

Reporting Requirement

All confirmed positive results must be reported to the MDA within 24 hours of receiving the test results. Copies of the forms can be found at the MDA website and may be faxed or emailed to the MDA.

Enforcement Actions and Penalties

The following penalties will be assessed for adulterated milk violations:

Table 5: Adulterated Milk Violation Actions and Penalties

Violation Number (Within the past 12 months)	Actions and Penalty
1	<ul style="list-style-type: none"> • Completion of the “Milk and Dairy Beef Residue Prevention Protocol” • A meeting with the inspector to discuss how the residue happened • Any contaminated milk needs to be discarded
2	<ul style="list-style-type: none"> • Completion of the “Milk and Dairy Beef Residue Prevention Protocol” • A meeting with the inspector to discuss how the residue happened • Any contaminated milk needs to be discarded
3	<ul style="list-style-type: none"> • An administrative meeting with a compliance officer from the MDA will be held to review the corrective actions that have occurred; the producer’s permit to sell milk may be revoked for 30 days depending upon the nature of the violation and the producer’s corrective actions.

Appendix A: Getting Started

Questions to Think About as You Get Started

As with most businesses, getting started in processing milk in an on farm or small processing facility takes a lot of forethought, preparation and time. While it sounds simple and may seem like it should be easy, it is important to consider all the steps that are involved as well as work with experts in the field to help you address all the necessary items prior to getting started. The following list of questions may help you get moving in the right direction:

Step 1 - Initial Questions to Consider

1. What value-added dairy products do you want to produce?

Consider this question carefully. Some products may seem easier to make than others and may have more value than bottled milk. The best answer to this question is one where you have looked at your market and understand what products your customers want. Once you are established, think about how you can expand (cheese, ice cream, milk, cheese curds, or cottage cheese for example).

2. Will you need to hire additional help?

In the case of an on-farm processing facility, managing both a farm and processing plant can be overwhelming for just one or two people, just like managing a small processing plant can be overwhelming for one or two people. Consider some of the following questions:

- How much time will production require?
- What skills do you have?
- Are there areas where you may not have skills where it would be beneficial to hire someone to help?
- Will you need to hire separate employees from farm employees to help for the processing plant?
- Will you need part time or full time help?

3. Have you researched the market?

The success of an on-farm or small processing plant depends on a number of things. Most importantly, you need someone to buy your product. Before starting, think about these questions:

- Have you looked at the market carefully and determined the demand for the product?
- Is it a good time to start producing specialty product?
- Is there a lot of competition in your area?

4. Can you afford it?

A dairy plant is a large investment that will take some time to see a significant return or profit. It is important to consider ongoing financing as well as the initial financing for the product.

5. Who will your customers be?

In order for an operation to be successful, someone needs to buy your product. Marketing of your product is very important. Consider that selling to just your friends and family may not be enough to make the operation profitable and other sales opportunities like local shops, restaurants and grocery stores will need to be identified.

6. What days/how will you sell your product?

Your production volumes and schedule will be determined by when you can sell your product. Consider the shelf life of your product as well when and how the product will be sold.

7. Are there other funding opportunities available to help with your project

Grants and low-interest loans are helpful for getting a business off the ground. At times, grants are made available by the state, or other sources. For more information on these grants and opportunities check the Minnesota Department of Agriculture website.

8. Do you know the process for producing the products?

It is very important that you learn and know the process for making the products you are trying to sell in order to ensure you can create a high quality product that consumers want. Consider the following questions:

- Are there classes you can take to learn the process?
- Will you need to hire an expert?
- Will you know how to run the necessary equipment?

Step 2 - Getting more Information

- Research the product(s) you decided you want to produce
- Visit different processing plants and gather ideas and knowledge for your own business
- Research the rules and laws that apply to the product as well as facilities
- Research and choose a suitable location

Step 3 – Planning your facility

1. Building the facility (start with essentials and allow for expansion)
 - 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, as well as a back-up generator
 - Water supply, water systems, and water heating systems
 - Cold and dry storage area
 - Storage warehouse
 - Toilet facilities
 - Location of doors, windows, and rooms
 - Receiving room for unloading bulk milk and storing raw milk
 - Separate rooms for washing returnable bottles, crates,

2. Equipment (manual/automatic) new and / or used dairy equipment can be used in a dairy plant. However, “buyers beware.” New and used equipment may not meet current standards for specific processing requirements. If a piece of equipment was used in an approved dairy processing facility at one time, it does not guarantee the equipment will be approved for processing today.
 - Placement and flow of the product
 - Pasteurizer – Vat or High Temperature Short Time (HTST) units
 - Separator (to make full-fat, skimmed and semi-skimmed milk)
 - 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
 - Etc.

Step 4 – Planning the business side

1. Develop a business plan including:
 - a. Company Description, what you plan to do, how you plan to do it, what markets you plan to serve
 - b. Create a clear mission statement of your goals and a timetable by when to reach them
 - c. Market Analysis
 - d. Structure of your business, who is in charge
 - e. Product line, what products you plan to produce and how you plan to produce them
 - f. Marketing and sales, how you plan to market your products, sales strategy
 - g. Funding, how you plan to fund your new business
2. Records and Documentation
 - a. Develop Standard Operating Procedures with clear methods for documenting processes and procedures performed in the dairy plant
 - b. Cleaning and sanitation procedures
 - c. Plans for documenting other regulatory requirements
 - d. HACCP (Hazard Analysis Critical Control Point) plans or similar food safety plans
 - e. Recall plans
 - f. Pest control
 - g. Allergen control
3. Labeling (brand name, design, required ingredient and nutritional information)
4. Marketing (website, location)
5. Ingredients, equipment (machines)
6. What days/how will you sell the finished product

Step 5 – Plan approval

1. Obtain approval from County Planning and Zoning, and apply for appropriate building, septic and electrical permits.
2. Submit plumbing plans to the Department of Labor and Industry (DOLI)
 - a. All licensed plumbers will need to submit these plans to DOLI before proceeding with any major installations. For more information please see the [DOLI Plumbing Plan Review](#)
3. Plan Review Process:
 - a. Submission of Plan, Blueprints and Drawings

A copy of all construction plans must be submitted to the MDA Dairy Inspection Program before construction begins. This should include information on the following items:

 - Basic building layout showing all doors and windows
 - Plumbing layout, drain locations, wash vats, and hand sinks with hot & cold water
 - Electrical diagrams and lighting
 - Position of the processing equipment, to include tanks, fillers, pasteurizers, and all other processing equipment
 - Diagram of the milk piping layout in the plant to be drawn by the installer
 - CIP (Clean-in-place) or manual clean-up?
 - Flow of milk - raw and pasteurized
 - Valve locations
 - Equipment construction, size, material
 - Recorder locations
 - Toilet facilities are required 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
 - compressors
 - CIP tanks
 - recorders
4. The review process typically takes 30 days and may take longer depending on the backlog of plans. During this time the plan reviewer may call with questions regarding the plans. Fees are charged for the plan review and plant approval process. The Fee is \$45/hour for all trips the inspector makes except for when they are doing an official inspection.

5. A letter will be sent to the applicant as an approval from the MDA to begin construction.
6. Construction should not begin until plans are approved. Failure to wait for approval may result in having you redo something in the plant if it does not meet regulatory requirements.

The Next Steps: After Construction Begins

- Periodic consultation and construction inspections will be made by your dairy inspector. If you are using well water, a water sample will be taken by your inspector after all plumbing is complete. If the plant uses city water, an initial water sample may be taken by the inspector. If the on-farm or small dairy processing plant employs more than 25 employees the Minnesota Department of Health would take water samples.
- **Approx. 4 weeks before processing plant is to begin operation:**
- **Label Review:** The labels you plan to use on your products will need to be reviewed before you can use them. More information is available in the section titled: Labeling
- **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 includes documents such as SOP's, pH Logs, Bottle Washer Logs, Sanitizer Logs, CIP charts, Pasteurization charts, PMO Appendix N documentation and other related documents.
- **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.
- **After Construction- Prior to Production**
 - When the plant is ready to operate, a full inspection and equipment tests will be conducted by your dairy inspector.
 - Application for operating permit(s) is then submitted to the MDA and the appropriate fees are paid.
 - 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
 - Descriptions of the licenses, certifications, fees and monthly reports that typically apply can be found in the section titled: Licensing, Certifications and Fees.

Considerations for Planning your Processing Plant

Location

A number of issues should be addressed when choosing a location for a processing plant. A dairy plant on a dairy farm in close proximity to livestock presents special problems.

1. **Accessibility** with trucks for delivery of supplies and shipping of product.
2. **Prevailing winds**, i.e. the processing areas should not be downwind from strong odors, cattle housing, and feed or manure storage.
3. **Proximity to livestock:** Visitors to your facility may enjoy seeing your cattle; unfortunately it is difficult to maintain a sense of absolute cleanliness in a milk processing plant when animals are just outside the entrance.
4. **Insect Control:** Insect control alone can be an insurmountable task when cattle and the manure they produce are close by. Cattle odors and dust created by feeding and bedding can also be problematic.
5. **Drainage:** You must have a means of handling wash water from the dairy plant. Consider different environmental conditions as you evaluate draining. For example, when there are heavy rains will manure from the cattle housing run down the drive or area by the plant, is the area prone to flooding?
6. **City sewage service:** Depending on your location you may need to consider if the public sewage system can handle the water/milk/chemical wastes that come from a dairy plant.
7. **Private on-site septic systems:** If the plant will be using its own private septic system be sure to check with the regulatory agency (County) to ensure the requirements are met in regards to the septic system, as well as the ability for the system to handle all the waste coming from the dairy plant.

Personnel Traffic Into and Through the Processing Plant

- Specifically for on-farm processing plants, livestock workers as well as other farm employees cannot be allowed to enter the processing plant without showering and a complete change of clothes. It is necessary to maintain this strict policy in order 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.
- In cases where showering is not easily accomplished, people should complete their work in the processing plant and then move into the less sanitary zoned farm areas. This reduces the chance that something is moved from the farm into the dairy plant.
- It is strongly recommended that sanitizing foot baths or foamers be provided at 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 working or present in the plant.

- Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No person shall resume work after visiting the toilet room without thoroughly washing his hands. Signage of washing hands is required in all toilet facilities.
- Use of tobacco in the 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

Who can help?

It is important to enlist the help of others as you consider how to build your business. The following list of experts can help you navigate the process and are essential to helping you address all areas of your business.

- **Marketing experts** can recommend strategies for optimum market visibility and increased sales revenues.
- **Food safety and food quality experts** can offer advice on how to prevent contamination, ensure compliance with state and federal regulations, and develop a quality-control program.
- **Extension dairy specialists** can help their operations achieve optimal herd health and milk quality.
- **Food scientists** can guide in 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 HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	DAIRY FARM INSPECTION REPORT	INSPECTING AGENCY POUNDS SOLD DAILY PLANT PERMIT NO.
NAME AND LOCATION OF DAIRY FARM		
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: Clean and free of litter (a) _____ No swine or fowl (b) _____ 4. Cowyard: Graded to drain; no pooled water or wastes (a) _____ Cowyard clean; cattle housing areas 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 Approved material and finish (a) _____ Good repair (windows, doors, and hosoport 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 hosoport where required (d) _____ Acceptable surface under hosoport (e) _____ Suitable shelter or direct load 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, walls, windows, tables and similar non-product contact surfaces clean (a) _____ No trash, unnecessary articles, animals or fowl (b) _____ 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 intakes (c) _____ UTENSILS AND EQUIPMENT 9. Construction: Smooth, impervious, nonabsorbent, safe material; 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; dipped when required (c) _____ Teats cleaned, treated with sanitizing solution (if required) 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 or milk product-contact surfaces (e) _____ PERSONNEL 16. Handwashing Facilities: Proper handwashing facilities convenient to milking operations (a) _____ Wash and rinse wats not used as handwashing facilities (b) _____ 17. Personnel Cleanliness: Hands washed clean and dried before milking, or performing milkhouse functions; re-washed when contaminated (a) _____ Clean outer garments worn (b) _____ COOLING 18. Cooling: Milk cooled to 45°F (7°C) 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 (Refer to Ordinance) (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 harborage 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.		
FORM FDA 2359a (10/11) Edition		

Grade A Dairy Plant Inspection Report: FDA Form 2359b

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		MILK PLANT EQUIPMENT TEST REPORT		
TEST NO.	TEST	TEST FREQUENCY	TESTED (X or NA)	RESULTS OF TEST (See Reverse for Working Notes)
1.	Indicating Thermometers (including air space): Temperature Accuracy	3 months		
2.	Recording Thermometers: Temperature Accuracy	3 months		
3.	Recording Thermometers: Time Accuracy	3 months		
4.	Recording Thermometers: Checked against Indicating Thermometer	3 months		Daily by operator
5.	Flow-Diversion Device (FDD): Proper Assembly and Function (HTST and HHST)			
5.1	Leakage Past Valve Seat(s)	3 months		
5.2	Operation of Valve Stem(s)	3 months		
5.3	Device Assembly (micro-switch) Single Stem	3 months		
5.4	Device Assembly (micro-switches) Dual Stem	3 months		
5.5	Manual Diversion - Parts (A, B, and C) (HTST only)	3 months		
5.6	Response Time	3 months		
5.7	Time Delay Interlock (dual stem devices) (Inspect)	3 months		
5.8	Time Delay Interlock (dual stem devices) (CIP)	3 months		
5.9	Leak Detect Flush Time Delay (HTST only as applicable)	3 months		
6.	Leak-Protect Valves: Leakage (Vals only)	3 months		
7.	Indicating Thermometers on Pipelines: Thermometric Response (HTST only)	3 months		
8.	Recorder-Controller: Thermometric Response (HTST only)	3 months		
9.	Regenerator Pressure Controls			
9.1	Pressure Switches (HTST only)	3 months		
9.2	Differential Pressure Controllers			
9.2.1	Calibration	3 months		
9.2.2	Interwiring Booster Pump (HTST only)	3 months		
9.2.3	Interwiring FDD (HTST* and HHST)	3 months		
9.3	Additional Booster Pump Interwiring (HTST only)			
9.3.1	With FDD	3 months		
9.3.2	With Timing Pump	3 months		
10.	Milk-Flow Controls: Cut-in and Cut-out Temperatures (10.1, 10.2*, or 10.3*)	3 months		Daily by operator (HTST)
11.	Timing System Controls			
11.1	Holding Time (HTST, except Magnetic Flow Meters)	6 months		Adjusted product holding time if applicable
11.2.a	Magnetic Flow Meters (HTST only)	6 months		
11.2.b	Flow Alarm (HTST and HHST)	6 months		
11.2.c	Loss of Signal Alarm (HTST and HHST)	6 months		
11.2.d	Flow Cut-In/Cut-out (HTST only)	6 months		
11.2.e	Time Delay (after divert) (HTST with a FDD located at the end of the holding tube)	6 months		
11.2.f	High Flow Alarm Response Time (All Magnetic Flow Meter Systems)	6 months		
11.3	HHST Indirect Heating	6 months		
11.4	HHST Direct Injection Heating	6 months		
11.5	HHST Direct Infusion Heating	6 months		
12.	Controller: Sequence Logic (HHST) (12.1* or 12.2*)	3 months		
13.	Product Pressure-Control Switch Setting (HHST)	3 months		
14.	Injector Differential Pressure Injection Heating (HTST* and HHST)	3 months		
15.	Electro-Magnetic Interference from Hand-Held Communication Devices (HTST and HHST)	3 months		
*For HTST systems with the FDD located downstream of the regenerator and/or cooler section.				
REMARKS (If additional space is required please place information on the back of this Form or on a separate page.)				
PLANT	IDENTITY OF EQUIPMENT	LOCATION	DATE	SANITARIAN
NOTE: This Form is a supplement to the Milk Plant Inspection Report, FORM FDA 2359, and these tests are in addition to the equipment requirements for which compliance is determined by inspection. (Refer to Appendix I of the Grade "A" Pasteurized Milk Ordinance.)				

FORM FDA 2359b (10/11) (PREVIOUS EDITIONS ARE OBSOLETE)

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Manufacturing Grade Dairy Plant Inspection Report: FDA Form 2359c

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	MANUFACTURING PLANT INSPECTION REPORT (Single-Service Milk Containers and Closures)	INSPECTING AGENCY/FIRM
NAME AND LOCATION OF PLANT		
<p>1. FLOORS</p> <p>Smooth; impervious; in good repair (a) _____</p> <p>Joints between walls and floors tight; impervious (b) _____</p> <p>Floor drains properly trapped; sloped to drain (c) _____</p> <p>2. WALLS AND CEILINGS</p> <p>In fabrication areas—smooth; cleanable; light-colored (a) _____</p> <p>In fabrication and storage areas—good repair (b) _____</p> <p>Openings in walls and ceilings effectively sealed (c) _____</p> <p>3. DOORS AND WINDOWS</p> <p>All outside openings protected against entrance of insects, rodents, dust, and airborne contamination (a) _____</p> <p>Outer doors tight, self-closing (b) _____</p> <p>4. LIGHTING AND VENTILATION</p> <p>Adequate light in all rooms (a) _____</p> <p>Ventilation sufficient (b) _____</p> <p>Pressure ventilation systems properly filtered (c) _____</p> <p>5. SEPARATE ROOMS</p> <p>Fabrication areas separate from non-fabrication areas when required (a) _____</p> <p>Regrinding plastic and paper trim shredding, packaging and baling conducted in separate room(s) from fabrication areas or as Appendix J permits (b) _____</p> <p>6. TOILET FACILITIES—SEWAGE DISPOSAL</p> <p>Disposal of sewage, other waste; in public sewage system or in compliance with Local and State Regulations (a) _____</p> <p>All plumbing complies with Local and State plumbing Regulations (b) _____</p> <p>Solid, tight-fitting, self-closing doors (c) _____</p> <p>Toilet rooms and fixtures clean; in good repair (d) _____</p> <p>Adequate light and ventilation; ducts vented to the outside (e) _____</p> <p>Proper handwashing facilities (f) _____</p> <p>Open windows effectively screened (g) _____</p> <p>Employee handwashing signs posted (h) _____</p> <p>Eating/food storage prohibited (i) _____</p> <p>7. WATER SUPPLY</p> <p>Safe; complies with bacteriological and construction requirements (a) _____</p> <p>No direct or indirect connection between safe and unsafe water (b) _____</p> <p>Sampled and examined as required (c) _____</p> <p>Recirculated cooling water complies with bacteriological standards, tested semi-annually (d) _____</p> <p>Testing records maintained as required (e) _____</p> <p>8. HANDWASHING FACILITIES</p> <p>Hot and cold and/or warm running water, soap, individual towels or air dryers convenient to fabrication areas; covered trash containers when required; hand sanitizers used as Appendix J permits (a) _____</p> <p>Handwashing facilities clean (b) _____</p> <p>9. PLANT CLEANLINESS</p> <p>Floors, walls, ceilings, overhead beams, fixtures, pipes and ducts clean in rooms as required (a) _____</p> <p>Plant free of evidence of insects, rodents and birds (b) _____</p> <p>Machines and appliances clean (c) _____</p>	<p>10. LOCKERS AND LUNCHROOMS</p> <p>Separate from plant operation; self-closing doors (a) _____</p> <p>Eating/storage of food prohibited in fabrication and storage areas (b) _____</p> <p>Locker and lunchrooms clean (c) _____</p> <p>Cleanable trash containers provided; properly labeled; covered (d) _____</p> <p>Handwashing facilities convenient (e) _____</p> <p>Employee handwashing signs posted (f) _____</p> <p>11. DISPOSAL OF WASTES</p> <p>Stored in covered, impervious, leak-proof containers; does not apply to production scrap (a) _____</p> <p>Waste containers properly identified (b) _____</p> <p>Storage of garbage/rubbish meets requirements (c) _____</p> <p>12. PERSONNEL - PRACTICES</p> <p>Hands washed as required (a) _____</p> <p>Clean outer garments; hair restraints (b) _____</p> <p>No person affected by disease in a communicable form; while a carrier of such disease; or with inadequately protected wounds or lesions shall work in the fabrication areas (c) _____</p> <p>Tobacco use in authorized areas only (d) _____</p> <p>Insecure jewelry not permitted in fabrication areas (e) _____</p> <p>13. PROTECTION FROM CONTAMINATION</p> <p>Product contact surfaces protected; all materials in process properly protected (a) _____</p> <p>Air under pressure directed at materials or product contact surfaces in compliance (b) _____</p> <p>Air directed at materials or product contact surfaces by fans or blowers in compliance (c) _____</p> <p>Pesticides approved; EPA registered (d) _____</p> <p>Pesticides used in accordance with directions; precludes contamination of containers/closures (e) _____</p> <p>Single-service articles in process protected from contamination (f) _____</p> <p>Equipment cleaned after use of non-food-grade materials (g) _____</p> <p>Cross contamination with non-food-grade material prevented (h) _____</p> <p>No overcrowding of equipment and operations (i) _____</p> <p>Toxic chemicals separated from raw materials and finished products (j) _____</p> <p>Food containers manufactured by facility not used for storage of miscellaneous items or chemicals (k) _____</p> <p>14. STORAGE OF MATERIALS AND FINISHED PRODUCT</p> <p>Away from any wall; soiled outer turns or edges discarded (a) _____</p> <p>Stored in clean, dry place, protected from splash, insects, and dust (b) _____</p> <p>Containers and closures stored in original cartons and sealed until used; partially used cartons resealed during storage (c) _____</p> <p>Containers for storage of resin, raw and reuse materials are covered, clean, impervious and properly identified (d) _____</p> <p>In-process storage bins that touch the product contact surface constructed of cleanable, nonabsorbent material; clean (e) _____</p> <p>15. FABRICATING EQUIPMENT</p> <p>Contact surfaces clean; milk plant equipment utilized for preforming containers clean and sanitized prior to operation (a) _____</p>	<p>Makeshift devices not used; fasteners, guides, hangers, supports and baffles properly constructed; good repair (a) _____</p> <p>Take-off tables and other container contact surfaces properly constructed; clean; in good repair (b) _____</p> <p>Grinders, stradders and similar equipment properly installed; protected from contamination (c) _____</p> <p>Resin storage silos, other containers, constructed to protect resin from contamination; air vents filtered; air tubes good repair and properly protected (d) _____</p> <p>16. MATERIALS FOR CONSTRUCTION OF CONTAINERS AND CLOSURES</p> <p>Materials from approved source (a) _____</p> <p>Food-grade lubricants used on contact surfaces; stored to prevent cross contamination; storage clean and ventilated (b) _____</p> <p>Containers or materials on floor not used (c) _____</p> <p>17. WAXES, ADHESIVES, SEALANTS, COATINGS AND INKS</p> <p>Handled and stored to prevent cross contamination with non-food-grade materials; storage areas clean and ventilated (a) _____</p> <p>Unused materials covered, labeled and properly stored (b) _____</p> <p>Nontoxic; imparts no flavor or odor; non-contaminating; complies with 21 CFR Parts 175-178 (c) _____</p> <p>Transfer containers clean; covered, properly identified (d) _____</p> <p>Waxing, when used, performed as required; wax kept at proper temperature (e) _____</p> <p>18. HANDLING OF CONTAINERS AND EQUIPMENT</p> <p>Handling of container and closure surfaces minimized (a) _____</p> <p>Hands sanitized frequently or clean, single-use gloves worn; sanitizing dispensers convenient (b) _____</p> <p>19. WRAPPING AND SHIPPING</p> <p>Single-service articles properly containerized prior to shipping (a) _____</p> <p>Packaged contents protected from contamination (b) _____</p> <p>Transportation vehicles clean; in good repair; not used for unapproved uses (c) _____</p> <p>Paperboard containers, wrappers and dividers not reused (d) _____</p> <p>Packaging materials in compliance (e) _____</p> <p>20. IDENTIFICATION AND RECORDS</p> <p>Plant identification on outer wrapping as required (a) _____</p> <p>Glass containers properly labeled (b) _____</p> <p>Required bacteriological tests on file; maintained as required; and in compliance (c) _____</p> <p>Required bacteriological and chemical test records for all component parts used in final assembled product on file (d) _____</p> <p>Information on file from suppliers of raw materials, waxes, adhesives, sealants, coatings and inks indicating compliance (e) _____</p> <p>Information on file from suppliers of packaging materials indicating compliance (f) _____</p> <p>21. SURROUNDINGS</p> <p>Surroundings neat and clean and free of breeding areas, conditions attracting or harboring flies, insects or rodents (a) _____</p> <p>Driveways graded; no standing water (b) _____</p>
REMARKS (If additional space is required, please place information on the back of this Form or on a separate page.)		
DATE	SANITARIAN/CONSULTANT	
<p>NOTE: This Form has been developed for use with Appendix J of the Grade "A" Pasteurized Milk Ordinance.</p>		

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Appendix C: Fees and Licensing

Requirements for Small or On-farm Dairy Processors

On-farm processors are subject to several fees depending upon their activities and processes, just as other dairy plants. These include:

- Licensing fees
- Inspection fees
- Farm inspection fees
- Processing fees
- Procurement fees

Licensing Fees

All on-farm cheese or milk processing plants require a license. The type of license required depends upon a few different factors.

Farmstead Cheese License

- **Who needs one?** Minnesota farmstead cheese means cheese manufactured within the state of Minnesota on the same farm on which the milk is produced. This type of license applies strictly to cheese manufacturers that process only the milk they produce.
- **Regulatory Reference:** Minnesota Statutes 28A.08 Subdivision 3
- **Valid** from January 1st to December 31st of the year
- **Cost?** \$30 annually

Dairy Plant Wholesale Food Manufacturing (<700,000 lbs/yr raw milk processed/yr) License

- **Valid** from July 1st to June 30th of the year
- **Cost?** \$30 annually
- **Who needs one?** Any firm processing less than 700,000 pounds of raw milk per year is eligible for a reduced price wholesale food manufacturing license of \$30 (plants processing more than 700,000 lbs annually are subject to the full price wholesale food manufacturing license of up to \$2571).
- **Regulatory Reference: Minnesota Statutes:** 28A.08 Subdivision 3

Wholesale Produce Dealers License

- **Valid** from July 1st to June 30th of the year
- **Cost?** \$75 initially, after the initial fee, there is a sliding scale based on purchases the prior year.
- **Who needs one?** Any firm who purchases or contracts with other Minnesota dealers or farmers for milk and cream and products manufactured from milk and cream, and brokers who purchase more than \$12,000 annually directly from Minnesota farmers. If the small or on farm processor is purchasing milk from other farmers to process, and the on-farm or small dairy processing facility does not own the milk, they may be required to obtain a wholesale produce dealers license.
- **Regulatory Reference: Minnesota Statutes: 27.03**

Plant and Pasteurizer Inspection Fees

Farmstead Cheese Inspection Fee:

A Minnesota farmstead cheese plant must pay a fee for inspection services provided for the pasteurization units.

- **Billed** annually on January 1
- **Cost?** \$140 per HTST, HHST, or VAT unit
- **Regulatory Reference: Minnesota Statutes 32D.10 (b)**
- **Licenses this fee applies to:** Farmstead Cheese License

Grade A Plant Inspection Fees:

A processor or marketing organization of milk, milk products, sheep milk, or goat milk who wishes to market Grade A milk or use the Grade A label must apply for Grade A inspection service from the commissioner.

- **Billed** annually July 1
- **Cost?** \$500/ Plant
- **Regulatory Reference: Minnesota Statutes: 32D.10 (a)**
- **Licenses this fee may apply to:** Dairy Plant Wholesale Food Manufacturing License

Grade B Plant Pasteurization Unit Fees:

A manufacturing plant that pasteurizes milk or milk by-products must pay an annual fee based on the number of pasteurization units. A Grade B (Manufacturing Grade) processing plant or Farmstead Cheese Plant must pay a fee for testing services provided for each pasteurization unit. This fee is paid for Farmstead Cheese Plants in the Farmstead Cheese Plant Inspection Fee above.

- **Billed** annually January 1
- **Cost?** \$140/HTST,HHST,VAT units
- **Statutes:** 32D.10 (b)
- **Licenses this fee may apply to:** Dairy Plant Wholesale Food Manufacturing License

Fees for Approval Services Rendered:

No person shall operate a dairy plant in this state unless the dairy plant, and the equipment, water supply and plumbing system connected therewith shall have been first approved by the commissioner and a permit issued to operate. This fee applies to any approval work completed at the plant or on plant reviews done outside of the normal routine inspections. This may include plant plan reviews and approval of the dairy plant, equipment, water supply and plumbing systems. Anytime the inspector is called in to replace a state placed seal on any processing equipment this fee will apply.

- **Billed** as service is rendered
- **Cost?** \$45/hour of inspectors time
- **Regulatory Reference: Minnesota Statutes:** 32D.09 Subdivision 3
- **Licenses this fee may apply to:** Farmstead Cheese License, Dairy Plant Wholesale Food Manufacturing License

Farm Inspection Fees

Dairy Plants that procure milk directly from dairy producers or their own farms are billed for the farm inspections and or reinspections required on the dairy farm.

Grade A Farm Inspection Fees:

A processor or marketing organization of milk, milk products, sheep milk, or goat milk who wishes to market Grade A milk or use the Grade A label must apply for Grade A inspection service from the commissioner.

- **Billed** annually July 1
- **Cost?** \$50/ Farm
- **Regulatory Reference: Minnesota Statutes:** 32D.06 (b)
- **Licenses this fee may apply to:** Farmstead Cheese License, Dairy Plant Wholesale Food Manufacturing License

Grade B Farm Inspection Fees:

A processor or marketing organization of milk, milk products, sheep milk, or goat milk who wishes to market other than Grade A milk must apply for a manufacturing grade farm certification inspection from the commissioner.

- **Billed** annually January 1

- **Cost?** \$25/Farm
- **Regulatory Reference: Minnesota Statutes:** 32D.08(b)
- **Licenses this fee may apply to:** Farmstead Cheese License, Dairy Plant Wholesale Food Manufacturing License

Grade A Farm Reinspection Fees:

For a farm requiring a reinspection in addition to the required bi-annual inspections, an additional fee must be paid by the processor or by the marketing organization on behalf of its patrons.

- **Billed** monthly on the 15th day of the month
- **Cost?** <100 cows: \$60/farm, >100 cows:\$150/farm
- **Regulatory Reference: Minnesota Statutes:** 32D.06(c)
- **Licenses this fee may apply to:** Farmstead Cheese License, Dairy Plant Wholesale Food Manufacturing License

Grade B Farm Reinspection Fees:

For a farm requiring a reinspection in addition to the required annual inspection, an additional fee must be paid by the processor or by the marketing organization on behalf of its patrons.

- **Billed** monthly on the 15th day of the month
- **Cost?** \$45/farm
- **Regulatory Reference: Minnesota Statutes:** 32D.08(c)
- **Licenses this fee may apply to:** Farmstead Cheese License, Dairy Plant Wholesale Food Manufacturing License

Processor Assessment Fees

Processor Assessment Fees:

A manufacturer shall pay to the commissioner a fee for fluid milk processed and milk used in the manufacture of fluid milk products sold for retail sale in Minnesota. This fee is also referred to as the Selected Fee.

- **Billed** monthly on the 25th day of the month
- **Cost?** \$0.07/cwt of milk used in the manufacturing of fluid milk products sold for retail in Minnesota
- **This fee applies to the following products (in any size of container):**

Products
Milk: Skim, Low-fat, Non-fat, Whole, Vitamin D, Homogenized, Flavored
Flavored Dairy Based Drinks
Cream: Heavy, Light, Heavy Whipping, Light Whipping, Fluid Dairy Creamers
Half & Half
Sour Cream
Acidified Sour Cream
Buttermilk
Cultured Milk, Kefir
Cultured Buttermilk
Concentrated Milk & Milk Products
Reconstituted Milk, Half & Half, Skim Milk, Flavored Milk, or Flavored Drink
Acidified Milk
Evaporated Milk
Egg Nog
Yogurt: Low-fat, Non-fat, Full-fat, Flavored
Cottage Cheese, Dry Curd Cottage Cheese
Any size or combinations of the above categories are applicable to the Selected Dairy Fee.

- **Regulatory Reference: Minnesota Statutes: 32D.12**
- **Licenses this fee may apply to:** Dairy Plant Wholesale Food Manufacturing License

Procurement Fees

Milk Procurement Fees:

Each dairy plant operator within the state must pay to the commissioner on or before the 18th of each month a fee of \$.0071 cents per hundredweight of milk purchased the previous month.

- **Billed** monthly on the 25th day of the month
- **Cost?** \$0.0071/cwt of milk procured by a firm directly from any dairy farm
- **Regulatory Reference: Minnesota Statutes: 32D.11**
- **Licenses this fee may apply to:** Farmstead Cheese License, Dairy Plant Wholesale Food Manufacturing License

Annual Laboratory Evaluation Officer Fees

Annual Laboratory Evaluation Officer Fees:

Before laboratories can conduct tests to be used in the enforcement of the requirements for distribution of milk, milk products or goat milk under the Grade A label, they must be certified as meeting the requirements for laboratory approval. An application for initial certification or biennial recertification shall be accompanied by annual fees based on the number of analysts approved and the number of specific tests for which they are approved.

- **Billed** After evaluation has been performed
- **Cost?** \$200.00/analyst plus \$50.00/test approved
- **Regulatory Reference: Minnesota Statutes: 32D.17**
- **Licenses this fee may apply to:** Farmstead Cheese License, Dairy Plant Wholesale Food Manufacturing License

Appendix D: Commonly Asked Questions

The following list of questions is not all-inclusive but provides some answers to questions that the MDA dairy program staff commonly receive when new or prospective dairy plant owners or manufacturers begin to work through the process.

I have my own recipe for cheese that I'd like to start manufacturing and selling on a small-scale basis. May I manufacture this product in my home on a small scale basis 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 particular 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 Farmer's Market. Can I sell these products without inspection under the "Pickle Bill"?

No. Almost all dairy products are considered to be potentially hazardous and do not meet the conditions necessary to qualify for the "Pickle Bill" exemption. Also, most dairy products are regulated by both State and Federal regulations so many of the exceptions and exemptions that exist for other food products are not available for dairy products. Products that are sold at the Farmer's Market must be manufactured in an approved dairy plant.

I would like to sell bottled milk, but find that the Grade A requirements are more than 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 of 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 also generally highly perishable. Also, Grade A products are regulated under the Federal requirement, called the Pasteurized Milk Ordinance, which is applied consistently across the entire United States so that consumers can have strong confidence that these products are produced safely and are of high quality.