GUIDELINE FOR ON-FARM AND/OR SMALL MILK PROCESSING PLANTS

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A milk plant is any place, premises or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, aseptically processed, packaged, or prepared for distribution. The establishment of a dairy processing facility of any size and location is a very involved undertaking. The Minnesota Department of Agriculture (MDA) Dairy, Food and Meat Inspection Division administers and enforces dairy laws and regulations designed to protect the general public health and be of service to the dairy industry. All dairy facilities must be approved and certified by the MDA before sale of any milk product can be made. It is imperative that consultation with the MDA Dairy, Food and Meat Inspection Division is necessary before any definite plans for dairy processing are made.

Rules or Laws
Grade A Pasteurized Milk Ordinance, 2001 Revision (PMO)  
Minnesota State Statutes, Chapter 32  
MDA, Dairy, Food & Meat Inspection Division Rulings  
Minnesota Rules, Chapter 1525  
3A Standards for construction of dairy equipment  
USDA Milk for Manufacturing Purposes and its Production and Processing, Recommended Requirements  
FDA Good Manufacturing Practices (GMP’s)  
Code of Federal Regulations (CFR) 21 & 7

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 from 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. 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.
4. Drainage: You must have a means of handling wash water from the dairy plant. 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?

Other items to address when determining the location of a dairy processing plant:
- City sewage service: Can the public sewage system handle the water/milk/chemical wastes that come from a dairy plant?
Personnel Traffic Into and Through the Processing Plant

- 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, coliform, campylobacter, and others) are serious public health threats and every effort must be taken to minimize the entrance of such pathogens into a plant. It is strongly recommended that sanitizing foot baths be provided at each entrance to the plant.

- 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.

Submission of Plan, Blueprints and Drawings

A copy of all construction plans must be submitted to MDA Dairy, Food & Meat Division 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, pasteurizer etc.
- 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
- Utility locations - boiler, water heaters, furnaces, glycol or sweet water tanks, compressors, CIP tanks and recorders
Licensing, Certifications & Fees

Various licensing, certifications and fees will apply depending on the type of dairy processing facility. The MDA Dairy and Food Division grants these licenses and certifications unless otherwise noted.

- Wholesale Food Processor/Manufacturer license will most likely apply:
  A. <700,000 lbs. of raw milk per year
     Annual license fee - $30.00
     Annual Inspection fee - $300.00
  B. >700,000 lbs of raw milk per year
     Annual license fee - $169.00
     Annual Inspection fee - $500.00
- Farmstead Cheese license may apply:
  Annual license fee - $30.00 – Cheese processing of on farm produced milk only
  Annual Inspection fee - $0
- Retail Food Handler License may apply (Dairy Distributor):
  $0 to $49,999 - $77.00 annually
- Possibly other product specific licenses or permits
- Other annual inspection fees that may apply:
  Pasteurization equipment testing
    - $140 Per unit
  Farm inspection fee
    - $25 for Manufacturing Grade Farm
    - $50 for Grade A Farm
- Certification for Appendix N Animal Drug Testing
- Dairy Processor Assessment Fee for fluid products only
- If you will be shipping product across state lines then your facility needs to be inspected for compliance with Interstate Milk Shippers. (MDA Dairy and FDA)
- You may need to contact the Federal Milk Market Administrator $^1$ to obtain a “Producer-Handler Status” for Grade A Fluid milk.
- If you buy milk directly from other Grade A producers, you will need to participate in the Federal Marketing Order. $^1$
- If you plan to process milk from other producers, you may also need:
  - Wholesale Produce Dealers License & Bond (MDA Ag Certification Division)
  - Field Representative Certification (MDA Dairy, Food & Meat Division)
  - Milk Grader and Sampler License (MDA Dairy, Food & Meat Division)

Labeling

Label design needs to be started as early as possible, since all labels must be submitted to and approved by MDA prior to selling the product. It is highly recommended you work with a graphics firm who is familiar with specific dairy labeling requirements. A “Food Labeling Fact Sheet” [http://www.mda.state.mn.us/dairyfood/labeling.pdf](http://www.mda.state.mn.us/dairyfood/labeling.pdf) is available from MDA, Dairy, Food & Meat Division. In addition to this fact sheet, the following statements apply specifically to milk products:

- All bottles, containers and packages enclosing milk or milk products shall be labeled in accordance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act, the Nutrition Labeling and Education Act of 1990 (NLEA), the Code of Federal Regulations (CFR), Minnesota Statutes and in addition, shall comply with applicable Grade A Pasteurized Milk Ordinance (PMO) requirements.
PMO Requirements:
1. The identity of the plant where pasteurized, ultra-pasteurized or aseptically processed.
2. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.
3. The word "Goat" or "Sheep" shall precede the name of the milk or milk product when the product is or is made from goat or sheep milk respectively.
4. The words "Grade “A”" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.
5. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

Nutrition Labeling and Education Act of 1990 (NLEA) mandatory information:
1. Total calories
2. Calories from fat
3. Total fat
4. Saturated fat
5. Cholesterol
6. Sodium
7. Total carbohydrate
8. Dietary fiber
9. Sugars
10. Protein
11. Vitamin A
12. Vitamin C
13. Calcium
14. Iron

Misleading Labels: Misleading remarks, words or endorsements are not allowed.
1. The regulatory agency shall not permit the use of any misleading remarks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label when, in their opinion, are not misleading and are not so used as to obscure the labeling required by the Ordinance.
2. The use of super grade designations shall not be permitted. Grade designations such as "Grade AA Pasteurized", "Selected Grade A Pasteurized", "Special Grade A Pasteurized", "Premium", etc., give the consumer the impression that such a grade is significantly safer than Grade “A”.

BST Labeling and Advertising:
Minnesota labels can only claim:
- “Milk in this product is from cows not treated with rBGH”
- “Farmer certified rBGH-free”
  - The first label statement must be used if you decide to also use the second.
- “From cows not treated with rbST”
  - Must be accompanied with “no significant difference has been shown between milk derived from rbST – treated and non rbST treated cows”

New Organic Foods Requirements:
- USDA issued final rule for organic foods which replaces most of the State’s rule (See CFR 7 Part 202)
- “Organic Foods Production Act and the National Organic Program” (NOP)
- All growers with organic sales >$5000 must be certified by USDA accredited certifying agents
- See the MDA website for more information www.mda.state.mn.us/esap/organic/

- All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents.
Water Supply

Water for milk plant purposes shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

- Very likely you will be able to use the same well that serves your dairy farm for the processing plant. If a new water supply is needed, all distances from sources of contamination must be strictly followed as outlined by the Health Department Well Code.
- This water supply must be sampled by MDA every six months.
- The water supply must be protected from unsafe water (ie. submerged inlets) and the possibility of negative line pressure (ie. pressure-washers).

Captive Water Supplies

This list would include water used for heating or cooling. A boiler, water heater or other steam heating system is necessary. For cooling, some type of chilled water or glycol cooling system is needed. These systems do have special requirements that you need to meet. Only approved chemicals can be added to these systems. Glycol or Sweet Water need to be sampled by MDA every 6 months.

Milk Quality and Testing  (PMO Section 6 & 7)

Milk and milk products are sampled and tested on a regular basis to assure quality, safety, and labeling compliance of the product. It is the plant’s responsibility to provide farm raw milk sample results to MDA in a timely manner. MDA will also sample raw milk and finished products on a routine basis.

Milk sample results are kept as part of the farm and plant official record. Whenever 2 of the last 4 consecutive quality counts exceed the limit of the standard for that product, 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 will be taken. Immediate suspension of permit or product will be instituted whenever the standard is violated by 3 of the last 5 quality counts.

1. Raw Milk

- Once each month a sample must be submitted to an approved laboratory for quality testing to include the following: Bacteria, Somatic Cell Count, Temperature, and Drug Residues. These results must be sent to MDA. A licensed Grader/Sampler must draw this sample at the farm.

<table>
<thead>
<tr>
<th>Standards for Raw Milk</th>
<th>Grade A</th>
<th>Manufacturing Grade B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteria (Standard Plant Count)</td>
<td>&lt;100,000</td>
<td>&lt;500,000</td>
</tr>
<tr>
<td>Somatic Cell Count (SCC)</td>
<td>&lt;750,000*</td>
<td>&lt;750,000*</td>
</tr>
<tr>
<td>Temperature</td>
<td>&lt;45º F</td>
<td>&lt;45º F</td>
</tr>
<tr>
<td>Drug Residue</td>
<td>– Not Found</td>
<td>– Not Found</td>
</tr>
</tbody>
</table>

(*Goat milk SCC <1,000,000)

- All milk that is used for processing must be tested for Animal Drug Residues (Beta Lactams-antibiotics) as per the requirements of Appendix N of the PMO. Proper certification is required in order to run this test in a processing plant setting. Results of these tests are recorded and kept by the plant for review by the inspector.
o A raw milk sample will be taken by MDA on a monthly basis at a Grade A facility along with the finished product samples for routine analysis. A raw milk sample on a Manufacturing Grade facility will be taken at least once every 6 months.

2. “Finished” Milk Products – Pasteurized, Aged, Processed

o There are many types of finished milk products. MDA will collect samples for routine analysis according to the specifications indicated in the applicable rule. The PMO applies to all Grade A products. Manufacturing Grade product standards can be found in the CFR’s, and the USDA “Milk for Manufacturing Purposes and its Production and Processing”. Minnesota State Statutes may also apply.

o Bacteria, drug residue, butterfat, solids-non-fat, coliforms, phosphatase, added water, yeasts & molds, salmonella, moisture, total solids, staphylococcus, are some of the items tested for in various products.

o Recalls of product may become necessary when it is determined it is a public safety hazard. Recall costs are the plant’s responsibility.

o Vitamin A & D content analysis of Grade A fluid milk needs to be completed on a yearly basis. This sample is submitted and paid for by the plant.

Vitamin Addition

Regulations do require that you add vitamins to any reduced fat dairy products.

Some reasons for the need for addition:

o Vitamin A is fat soluble, that is it will dissolve when mixed with fat and will not dissolve in water. For this reason Vitamin A is found in whole milk and to a lesser degree in low fat and absent in non-fat milk, unless these products are fortified.

o Vitamin D is the major regulator of calcium absorption in the intestine. Fortification of fresh milk with Vitamin D, is acknowledged to have virtually eliminated rickets in milk drinking children. Since normal levels of Vitamin D are necessary for optimal calcium absorption in children, it is also known that these levels are required as one increases in age. It has been associated with reducing the incidence of osteoporosis in premenopausal women.

The following items on vitamin addition need to be considered.

How will the vitamins be added
When in the processing procedure will they be added
What is the Minimum and Maximum levels required
Record keeping requirements to assure the proper addition of vitamins, vitamin inventory
Annual vitamin testing is required – at the cost of the processor

Ingredients

All ingredients added to milk and milk products must be of an approved source and listed on the label as required. All ingredients must be stored properly.
**Pasteurization**

Minnesota Statute 32.393 states “No milk, fluid milk products, goat milk, or sheep milk shall be sold, advertised, 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 same has been pasteurized and cooled”. Milk for all other products is also to be pasteurized unless it meets the requirements of aged cheese.

All milk must be pasteurized at the place of processing and packaging. Pasteurizing is the process of heating every particle of milk in properly designed and operated equipment for the required time and temperature. HTST is High Temperature Short Time or a continuous flow system and Vat or Batch pasteurization is heating one batch at a time in an approved tank.

The most common times and temperatures are as follow:
- 145 degrees Fahrenheit for 30 minutes VAT
- 161 degrees Fahrenheit for 15 seconds HTST

There are no temperatures in between these standards that comply. If you add sweeteners or if the fat content is 10 percent or more then higher temperatures are required as follows:
- 155 degrees Fahrenheit for 30 minutes VAT
- 175 degrees Fahrenheit for 25 seconds HTST

All raw product must be added before the pasteurization process begins. There is to be no cross-connections between raw and pasteurized products. Valve separation is not allowed.

Equipment used for pasteurization must be approved and tested by MDA on a routine basis. Testing procedures and frequencies are dictated by the PMO for all Grade A products and “Milk for Manufacturing Purposes and its Production and Processing” states the frequency of testing equipment for manufacturing grade products. Various controls on the pasteurization units are sealed by the MDA so temperatures, timing, and pressures cannot be changed once they are tested.

**Cooling**

All raw milk and milk products shall be maintained at 45°F or less until processed.
All milk except when being pasteurized or further processed must be at or below 45°F. So after pasteurizing a cooling medium must be used to cool the milk as soon as possible before it is bottled or stored. Once bottled it must be maintained below 45° at all times in an approved cooler with a properly operating thermometer.
Every room or tank in which milk or milk products are stored shall be equipped with an accurate thermometer.
Delivery tucks must also maintain temperatures below 45° at all times.

**Packaging and Capping**

All bottling and packaging of milk and milk products must be done at the place of pasteurization in a sanitary manner with approved mechanical equipment. Capping and/or closure of the container must be done in a sanitary manner by approved mechanical capping and/or closing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with regard to fluid product containers, removal cannot be made without detection.

Packaging material and containers must be made of food grade materials and from approved sources.
Warehousing

Storage of finished product, ingredients, packaging materials, containers, single service items, filters, and chemicals and other items is important. All items must be stored so as to not become contaminated by other substances. Most products need to be stored in a clean dry place above the ground, away from wet walls.

Quality Assurance Programs

It is highly recommended, but not required that you have a quality assurance program in place, to monitor the effectiveness of your pasteurization and processing procedures. This may be accomplished on site or you may contract with an independent laboratory. Following is a list of things to employ in a quality assurance program. (*Starred items are required)

- *What code date (sell by date) will you use?*
- Will you test your own product to meet label requirements such as butterfat?
- Will you monitor products to make sure they are still wholesome when they reach the end of the code date?
- Will you be able to respond to consumer complaints about your products?
  These can include the following:
  o Why is the texture of my dairy product strange?
  o Why does my milk have an off odor?
  o Why did my milk spoil before the code date run out?
  o My milk tastes funny.
  o My milk tastes sour.
  o Someone got sick after drinking my milk.
  o Why doesn’t my whipping cream whip?
  o My milk tastes like vitamins.

- *Do you have an effective insect and rodent control program?*
- *Do your processing procedures eliminate the possibilities of contaminating product with allergens?*
- *Do you have the ability to recall all product if a problem is found?*
- *What type of equipment cleaning program are you using? It is imperative that all equipment be properly cleaned and sanitized before use, in order to maintain the highest quality of product for the consumer. It is recommended to use the services of a professional cleaning company to advise you in the selection of the proper chemicals and concentrations to use.*

- *Animal Drug Screening*
  o All milk needs to be screened for beta lactum drug residues with an approved test before processing.
  o Screening test must be performed by a certified industry analyst.

- HACCP “Hazard Analysis of Critical Control Points” Program
  o A HACCP program identifies potential hazards of a food product in all levels of the food processing system – from the farm to the consumer.
  Sample questions when possible hazards:
    - What systems are in place to prevent antibiotics from getting into the milk?
    - How is the consumer going to handle my product? Will it be left on the table for any length of time? Will this cause bacterial growth that could be harmful?
HACCP is a new directive in the food industry. This program has become mandated in food industries such as the fish & seafood, meat & poultry, and the juice industries due to outbreaks.

HACCP is a voluntary program for the dairy industry because the dairy inspection program currently in place has been very effective.

Hazards are identified as:
1. Biological – listeria, salmonella, staph, e-coli, and others
2. Chemical – antibiotics, sanitizers, pesticides, microtoxins (molds)
3. Physical – metal, glass, other foreign material

**Inspection:**

- The facility will need to be approved by an MDA Dairy Inspector before it can begin processing milk. Before and during construction the dairy inspector will work closely with the processor, making visits to the facility when needed.
- Inspections are made at least every 3 months on a Grade A plant and at least every 6 months at a Manufacturing Grade plant. These inspections are generally unannounced. Facility is open to inspection at any time during normal working hours.
- Violations noted on a plant inspection need to be corrected as soon as possible. Critical Control Point items may be a cause for recall of product or closing of a plant facility. When violations are not corrected by the next inspection, the inspector may order a reinspection or a regulatory hearing.
- Pasteurization equipment tests are performed every 3 months on a Gr A facility and 6 months at a Manufacturing Grade facility. Since pasteurization is a critical control point of safe milk, any violations found during 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.
- Another vital part of the inspection is chart and record reviews:
  - Pasteurization Charts are the legal record that the milk was pasteurized. All information as noted in the PMO needs to be present on these charts.
  - Appx N Antibiotic Screening records need to be kept and properly documented.
  - Processing dates of various products may be required on the product labels.
  - If milk is held for more than 24 hours in a plant tank, a recording chart must be provided to insure the proper cooling and washing of the tank.
  - CIP ("Clean-in-place") charts need to be maintained on mechanically cleaned systems. CIP temperature recording charts must be located on the return line of the system.
  - Milk, milk product, and ingredient sales and purchasing records will also be reviewed.
- The dairy plant inspection form covers most of the inspection items observed during an inspection. Each item is explained in more detail in the PMO.
Other Resources & Websites Available:

- MDA Website: [www.mda.state.mn.us](http://www.mda.state.mn.us)
  - Dairy Regulation Links: [www.mda.state.mn.us/dairyfood/dairyregs.htm](http://www.mda.state.mn.us/dairyfood/dairyregs.htm)
  - MDA Organic Production and Certification Link: [www.mda.state.mn.us/esap/organic/](http://www.mda.state.mn.us/esap/organic/)

- Minnesota State Statutes: [http://www.revisor.leg.state.mn.us](http://www.revisor.leg.state.mn.us)
- Uniform Minnesota Food Code
- 3A Standards for construction of dairy equipment: [www.3-a.org](http://www.3-a.org)
- AURIE
- MDA Dairy Development Specialist, Harold Stanislawski 651-296-8170
- U of M Extension Bulletins:
  - “MN Farmstead Cheese”

May 2001, Revised November 2003

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1 Federal Milk Marketing Administrator, Upper Midwest Marketing Area, Federal Order 30
   4570 West 77th Street, Suite 210 Minneapolis, MN 55435-5037 Phone: 953-831-5292

2 Approved Milk Laboratories are listed in the “IMS List of Sanitation Compliance and Enforcement Ratings of
   Interstate Milk Shippers” published quarterly by the US Dept of Health and Human Services, Food and
   Drug Administration, Milk Safety Branch, HFS-626, 200 C Street SW, Washington DC 20204-9998