



# MARYLAND Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

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

### Maryland Department of Health Center for Milk and Dairy Product Safety (CMDPS)

Rev. 4/2018

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 Maryland Department of Health and Mental Hygiene (DHMH) Center for Milk and Dairy Product Safety (CMDPS) 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 permitted by DHMH before sale of any milk product can be made. It is imperative that consultation with DHMH, Center for Milk and Dairy Product Safety (CMDPS) is necessary before any definite plans for dairy processing are made.

### Rules or Laws

- Grade A Pasteurized Milk Ordinance, 2015 Revision (PMO):  
<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM513508.pdf>
- Code of Maryland Regulations: <http://www.dsd.state.md.us/COMAR/ComarHome.html>
  - 10.15.05 – Manufacture and Sale of Frozen Dairy Foods and Ices Manufactured for Sale in Maryland
  - 10.15.06 – Production, Processing, Transportation, Storage, and Distribution of Milk
  - 10.15.09 – Production, Processing, Transportation, Storage, and Distribution of Manufactured Grade Milk
  - 10.15.08 – Farmstead Cheese Program
- Health General Article, Title 21, Subtitle 2 and 4, Annotated Code of Maryland:  
<https://advance.lexis.com/annotated-code-of-maryland>
  - 3A Standards for construction of dairy equipment <http://www.3-a.org>
- USDA Milk for Manufacturing Purposes and its Production and Processing, Recommended Requirements:  
<https://www.ams.usda.gov/sites/default/files/media/Milk%20for%20Manufacturing%20Purposes%20and%20its%20Production%20and%20Processing.pdf>
- FDA Good Manufacturing Practices (GMP's)  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117>
- Code of Federal Regulations (CFR) Title 21 & Title 7 <https://www.ecfr.gov/cgi-bin/ECFR?page=browse>

## **Plan Review Process**

**First Step** – Obtain approval from County Planning and Zoning

**Second Step** - Waste water from the dairy plant and approved water source: In Maryland the County Environmental Health must be contacted to determine the proper method of sewage disposal of the plant and restroom waste. County Health Department approval must be obtained for a sewage disposal system. An approved water source must also be obtained, which is approved by both the County Environmental Health Department and CMDPS.

**Third Step** – Contact Center for Milk and Dairy Product Safety (CMDPS) for guidance

**Fourth Step** – Develop a business plan, identify your market, identify the products you want to process and how to process (SOP's), consult with dairy equipment dealers and other on-farm processors, County Environmental Health Department, etc.... **It is important to have a clear mission statement of your goals and a timetable to reach them.**

**Fifth Step** – **Submission of Plans** – A copy of all construction plans, SOP's and equipment list must be submitted to CMDPS for review and approval BEFORE construction begins. Refer to the following handout: “On Farm and/or Small Milk Processing Plants – Plan Review Submittals”

Applicant will receive a letter of approval from CMDPS to begin construction.

### **After Construction Begins:**

- Periodic consultation and construction inspections are made by CMDPS.
- Water sample taken after all plumbing complete.
- Approx. 2 weeks before processing plant is to begin operation:
  - Application for operating permit(s) is submitted and fee is paid;
  - Grade A lab certification
  - Plant sampler certification
  - Bulk Milk Sampler/Hauler Certification (if applicable)
  - Milk transportation vehicle permitted (if applicable)
  - Label approval – Need description and example of labels
  - SOP Approval – Receiving, Processing, Filling, Storing and Transportation steps for each different product to be processed.
  - Standard Operating Procedures or Operations Manual that addresses:
    - Step-by-step Manufacturing practices, Employee training/personnel hygiene practices, Traceback/Recall, and Plant and equipment sanitation.
  - Approval of all single service container sources – Need a list of container sources
  - Product sell by date approval
  - Production Sheet approval
  - Applicable Log approval (ph log, bottle washer log, sanitizer log, Appendix N logs, filler log, vitamin log, HVAC system filter log)
  - Discuss monthly reports to be submitted after operation begins (Drug Testing, Volume Control, Vitamin Testing)
- HACCP evaluation may be required for certain facilities.
- When plant is ready to operate, a full inspection and equipment tests will be conducted by CMDPS.

## **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. Zoning: **The first step** – check with your County Planning and Zoning Department if your property is properly zoned for an on-farm processing plant. CMDPS will not review plans until Planning and Zoning approval is obtained.
2. Waste water from the dairy plant: **The second step** – In Maryland the County Environmental Health must be contacted to determine the proper method of sewage disposal of the plant and restroom waste. County Health Department approval must be obtained for a sewage disposal system.
3. Potable water for the dairy plant: Potable water must be supplied. This is determined by both the County Health Department and CMDPS.
4. Accessibility with trucks for delivery of supplies and shipping of product.
5. Prevailing winds, i.e. the processing areas should not be downwind from strong odors from cattle housing and feed or manure storage.
6. 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.
7. Drainage: 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?

## **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, camphylobacter, 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, 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.

## **Licensing, Certifications & Fees**

Various licensing, certifications and fees will apply depending on the type of dairy processing facility. DHMH, Division of Milk Control issues these licenses and certifications.

- Milk Processor (Grade A or Manufactured Grade) \$100/annually
- Milk Processor - Farmstead Cheese Producer \$100/annually
- Frozen Dessert
  - 0-25,000 gallons \$10/annually
  - >25,000-100,000 gallons \$50/annually
  - >100,000-250,000 gallons \$100/annually
- Milk Processor-Farmstead Cheese Producer \$100/annually
- Certification for Appendix N Animal Drug Testing \$0.00  
*(Stephanie Rowles, Laboratory Evaluation Officer – 410.767.8403)*
- Milk Bulk/Hauler Sampler \$50.00
- Milk Transportation Company \$5.00/company and  
\$5.00/truck
- Certified Plant Sampler \$0.00
- Milk Bulk Truck Cleaning Facility \$25.00
- Interstate Milk Shippers (IMS) Certification \$0.00  
*(If you will be shipping product across state lines then your facility needs to be inspected by one of the MD Rating Officers for compliance with IMS)*

## **Labeling**

Label design needs to be started as early as possible, since all labels must be submitted to and approved by CMDPS prior to selling the product. 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)*, Maryland Statutes **and in addition**, shall comply with applicable *Grade A Pasteurized Milk Ordinance (PMO)* requirements.

PMO Requirements:

1. Name of Product
2. The plant license number where pasteurized, ultra-pasteurized or aseptically processed Ingredients, in order of predominance.
3. The address of the manufacturer. (a) If listed in the local phone book, the address may consist of city and state; (b) If not listed in the phone book, the entire address must be included.
4. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.
5. The net weight of the product in English and metric units.
6. 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.

7. 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.
8. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.
9. The batch identification of the product.
10. Nutritional information (if required).

**Misleading Labels:** Misleading remarks, words or endorsements are not allowed.

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.

The use of super grade designations shall not be permitted. Grade designations such as "Grade A 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".

This product does not contain any growth hormones – misleading. All milk contains natural growth hormones. Permit to state, "no growth hormones added".

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 PMO and Maryland Department of the Environment, COMAR 26.04.04

This water supply must be sampled by CMDPS every six months.

The water supply must be protected from unsafe water (i.e. submerged inlets) and the possibility of negative line pressure (i.e. pressure-washers). The water supply must not be directly connected with a non-potable water supply system by which non-potable water can be drawn or discharged into the potable water supply system.

## **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 CMDPS 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. CMDPS will also sample raw milk and finished products on a monthly basis on the processing side.

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**

Dairy Farm - Once each month a sample must be taken from the farm bulk tank and submitted to an approved laboratory<sup>i</sup> for quality testing to include the following: Bacteria, Somatic Cell Count, Temperature, and Drug Residues. These results must be sent to CMDPS. A licensed Hauler/Sampler must collect this sample at the farm.

<u>Standards for Raw Milk</u>	<u>Grade A</u>	<u>Manufacturing Grade B</u>
Bacteria (Standard Plant Count)	<100,000	<500,000
Somatic Cell Count (SCC)	<750,000*	<750,000*
Temperature	<45° F	<45° F
Drug Residue	– Not Found	– Not Found

(\*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.

Processing Plant - A raw milk sample will be taken by CMDPS each month from the raw milk storage tank at the processing plant (Grade A and Manufacturing Grade). A facility along with the finished product samples for routine analysis.

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

There are many types of finished milk products. CMDPS will collect samples for routine analysis each month.

Testing includes: Bacteria, drug residue, coliform, phosphatase, temperature.

Recalls of product may become necessary when it is determined it is a public safety hazard.

Recall costs are the plant’s responsibility.

## **Vitamin Addition**

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

Some reasons for the need for addition:

Vitamin A is fat soluble. 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.

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 are 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**

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 products 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 CMDPS 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 CMDPS so temperatures, timing, and pressures cannot be changed once they are tested.

CMDPS will conduct equipment testing every 90 days at both a Grade A plant and a Manufactured Grade plant.

## **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 trucks must also maintain temperatures below 45° at all times.

Cooling of cultured products - All pasteurized milk and milk products, except the following, shall be cooled immediately prior to filling or packaging to 45° F. or less:

*Cultured sour cream*

*Acidified sour cream*

*Yogurt*

*Cultured buttermilk*

*Condensed whey and whey products*

*The products listed above shall be cooled according to PMO procedures – Item 17p. Cooling of Milk and Milk Products.*

## **Packaging and Capping**

All bottling and packaging of Grade A 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. Manufactured Grade products *may* be manually packaged and capped. This must be done in a sanitary manner and approved by CMDPS.

Packaging material and containers must be made of food grade materials and from approved sources. A list of packaging materials and sources must be submitted to CMDPS.

## **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? This needs to be submitted to CMDPS for approval.**
- 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:

- Why is the texture of my dairy product strange?
- Why does my milk have an off odor?
- Why did my milk spoil before the code date run out?

- My milk tastes funny.
- My milk tastes sour.
- Someone got sick after drinking my milk.
- My milk tastes like vitamins.
- \*Do you have an effective insect and rodent control program?
- \*Does your processing procedures eliminate the possibilities of contaminating product with **allergens**?
- \*Do you have the ability to **recall** all products 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**
  - All milk needs to be screened for beta lactam drug residues with an approved test before processing.
  - Screening test must be performed by a certified industry analyst.
- **HACCP** “Hazard Analysis of Critical Control Points” Program
  - 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 and meat & poultry 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:
    - Biological – listeria, salmonella, staph, e-coli, and others
    - Chemical – antibiotics, sanitizers, pesticides, microtoxins (molds)
    - Physical – metal, glass, other foreign material

### **Inspection:**

The facility will need to be approved by a CMDPS 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 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 90 days on a Grade A facility and on 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.

Appendix 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.

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<sup>i</sup> 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.