



**WEST VIRGINIA SECRETARY OF STATE**

**MAC WARNER**

**ADMINISTRATIVE LAW DIVISION**

**eFILED**

8/2/2024 12:58:43 PM

Office of West Virginia  
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-  
MAKING REVIEW COMMITTEE**

AGENCY: Agriculture TITLE-SERIES: 61-19  
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No  
RULE NAME: 61-19 WV Manufacture Grade Milk

**PRIMARY CONTACT**

NAME: Jodee Martin  
ADDRESS: West Virginia Department Of Agriculture  
1900 Kanawha Boulevard East  
Charleston, WestVirginia 25143  
EMAIL: jodeemartin@wvda.us  
PHONE NUMBER: 304-558-3200

CITE STATUTORY AUTHORITY: §19-11E-8(2)

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

- Propose rules for legislative approval in accordance with §29A-3-1 et seq. of this code, including adopting with any necessary modifications the Grade "A" Pasteurized Milk Ordinance promulgated by the Food and Drug Administration;
- (2) Adopt, promulgate, and enforce other rules for legislative approval in accordance with §29A-3-1 et seq. of this code as necessary to carry out the purpose of this article;
  - (3) Have access to and enter at all reasonable times all places where frozen desserts or imitation frozen desserts are manufactured, stored, held, transported, distributed, or used in the state and where records, papers, or documents relating to these transactions are kept;
  - (4) Inspect and photograph all places where milk is manufactured, packaged, stored, held, transported, or distributed; inspect, audit, and copy records and papers relating to the manufacturing, distribution, sampling, testing, and sale of milk; examine measuring and testing apparatus; and examine equipment used in manufacturing and transportation of milk;
  - (5) Sample milk, including, but not limited to, ingredients and packages that are used in the manufacture of these products and may open any package containing or believed to contain any milk or milk product or an ingredient to be used in the manufacture of milk or a milk product for the purpose of inspecting and sampling;
  - (6) Issue, suspend, revoke, or deny permits;
  - (7) Collect fees and expend moneys under the terms of this article;

(8) Collect evidence, including samples, of the condition of equipment, holding tanks, storage rooms, and vehicles used, or intended to be used, in the processing, packaging, transporting, or holding of milk or milk products;

(9) Examine the labels and labeling of milk and milk products;

(10) Issue embargoes for any milk or milk product which is or is believed to be adulterated, misbranded, or that is not in compliance with this article and to cause the manufacturing and distributing of same to cease: Provided, That nothing in this article may be construed as requiring the commissioner to issue embargoes for minor violations of this article when he or she believes that a written notice of violation will serve the public interest:

(A) When an embargo is issued, the commissioner shall affix to such product or manufacturing device in an appropriate manner a tag or other marking giving warning that such product is under embargo;

(B) The commissioner shall give written notice to the custodian of the product or process under embargo describing the violation and stating that the product is prohibited from being sold, offered for sale, exposed for sale, or distributed and is ordered to be held on the premises and, further, that all manufacturing processes for this product shall cease until the embargo is released. This notice shall notify the custodian of the right to request an immediate hearing under the rules adopted by the commissioner;

(C) The commissioner shall take action to seize and condemn any product that cannot be brought into compliance with this article and the rules issued under same within 90 days of notice to the custodian of the product;

(D) The commissioner may issue an embargo against a perishable product even if the practical result is to bring about the involuntary disposal of the product. The commissioner shall exercise this power using all reasonable means to determine if the product is adulterated or otherwise not in compliance with this article in as short a time frame as possible and shall promptly lift the embargo order if the product is found to be in compliance with this article;

(11) Approve sampling and testing methods, and evaluate and approve official laboratories;

(12) Obtain from any state court an order directing any person to submit to inspection and sampling subsequent to the refusal of any person to allow inspection and sampling;

(13) Conduct hearings as provided by this article; and

(14) Assess civil penalties and refer violations to a court of competent jurisdiction: Provided, That the commissioner is not required to report for prosecution minor violations of the article when he or she believes that the public interest will be best served by a suitable notice in writing.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 7/2/2024

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 8/2/2024

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: Yes

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

n/a

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

The rule establishes operating rules and procedure for WV Dairy Farms and milk facilities that produce, process, transport, store, or distribute manufacture-grade milk or manufacture-grade milk products for human consumption that are nob subject to the Grade A requirements.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

to maintain testing procedures, minimum quality standards

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

n/a

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

n/a

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

n/a

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2024 Increase/Decrease (use "-")	2025 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
<b>1. Estimated Total Cost</b>	0	0	0
<b>Personal Services</b>	0	0	0
<b>Current Expenses</b>	0	0	0
<b>Repairs and Alterations</b>	0	0	0
<b>Assets</b>	0	0	0
<b>Other</b>	0	0	0
<b>2. Estimated Total Revenues</b>	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

n/a

**BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.**

Yes

**Norman Bailey -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.**

TITLE 61  
LEGISLATIVE RULE  
DEPARTMENT OF AGRICULTURE

SERIES 19  
WV MANUFACTURE-GRADE MILK

**§61-19-1. General.**

1.1. Scope. – This legislative rule establishes operating rules and procedures for WV Dairy Farms and milk facilities that produce, process, transport, store, or distribute manufacture-grade milk or manufacture-grade milk products for human consumption that are not subject to the Grade A requirements.

1.2. Authority. – W. Va. Code §19-11E-8(2).

1.3. Filing Date. – ~~April 30, 2020~~

1.4. Effective Date. – ~~April 30, 2020~~

1.5. Sunset Date. – This rule shall expire and have no further force or effect ~~April 30, 2025~~ August 1, 2034.

**§61-19-2. Definitions.**

2.1. “Commissioner” means the Commissioner of Agriculture of the State of West Virginia or his or her duly authorized agent.

2.2. “Acceptable milk” means milk, or cream from the milk, which meets the requirements as to sight and odor, sediments, bacterial content, inhibitory substances, and which has been produced in compliance with the provisions set forth in this Rule.

2.3. “Barnyard” means an enclosed or unenclosed area adjacent to the milking barn which may include housing areas and feedlots in which the animals may congregate.

2.4. “Butter” means the food product that is made exclusively from milk or cream, or both, with or without salt, and with or without additional coloring matter, and that contains not less than 80 percent by weight of milk fat.

2.5. “Cheese” or “cheese related product” means the fresh or matured product that is obtained by draining after coagulation of milk, cream, skimmed or partly skimmed milk, or a combination of some or all of these products, and meets the standards of identity in 21 CFR Part 133.

2.6. “CIP” or “cleaned-in-place” means the procedure by which sanitary pipelines or pieces of dairy equipment are mechanically cleaned in place by circulation of wash, rinse, and sanitizer solutions.

2.7. “Dairy farm” or “farm” means a place or premises where one or more milking animals are kept, a part or all of the milk produced on the farm being used in the production of milk or dairy products by

the incorporation of approved methods.

2.8. "Inspection" means the inspection of the dairy farm premises, buildings, animals, equipment, utensils, water supply, and facilities and procedures used in the production of milk and/or dairy products in solely in the state of West Virginia including Certified Industry Inspections.

2.9. "Inspector" means a qualified, trained person employed by the West Virginia Department of Agriculture or any person designated by the Commissioner to inspect dairy farms and processing facilities including a Certified Industry Dairy Farm Inspector (CIDFI).

2.10. "Inhibitory Substances" means antibiotics and pesticides not registered for use on lactating dairy animals, and other substances as determined by the Commissioner.

2.11. "Milk" means the normal lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy hooved lactating mammals. Hooved mammals' milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. Hooved mammals for the purpose of this rule, include but are not limited to, the members of the Order Cetartiodactyla, such as: Family Bovidae (cattle, water buffalo, sheep, goats, yaks, etc.), Family Camelidae (llamas, alpacas, camels, etc.), Family Cervidae (deer, reindeer, moose, etc.), and Family Equidae (horses, donkeys, etc.). Milk product shall be produced according to the sanitary standards of this rule.

2.12. "Manufacture-Grade Milk" means the milk of a hooved mammal that is produced, processed, pasteurized, packaged, or prepared for human consumption in accordance with the standards set forth in this rule, is not subject to Grade A standards and is not used for fluid milk sales.

2.13. "Manufacture-Grade Milk Product" means: butter; cheese, natural or processed; condensed skim milk, plain or sweetened; condensed whole milk; cream; dry buttermilk; dry whey; dry whole milk; evaporated milk, whole or skim; nonfat dry milk; or any other product made with manufacture-grade milk that is regulated by the Commissioner.

2.14. "Manufacture Milk Plant" means a place, including a governmental operation, where manufacture-grade milk or a manufacture-grade milk product is collected, handled, controlled, manufactured, processed, stored, pasteurized, ultra-pasteurized, repasteurized, commercially sterilized, aseptically processed, bottled, or prepared for distribution, but does not include a place where a manufactured milk product is purchased in packaged form and is stored and handled for the sole purpose of sale to the ultimate consumer.

2.15. "Manufacture Milk Processor" means any person who operates or controls a manufacture milk plant, transfer station, receiving station, or milk transport cleaning facility that is located in this state or from which manufacture-grade milk or manufacture-grade milk products are sold or offered for sale for human consumption, as applicable in the state of West Virginia.

2.16. "Milkhouse" or "milkroom" means a room at the facility for handling and cooling milk and for washing and storing milking equipment and utensils.

2.17. "Pasteurization", "pasteurized", or similar terms means the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one (1) of the temperatures

given in this rule.

2.18. "Person" means any individual, firm, co-partnership, corporation, cooperative association, cooperative corporation or unincorporated association.

2.19. "Producer" means the person or persons who exercise control over the production of milk on a West Virginia dairy farm, where the milk or the cream from the milk is used to manufacture fluid milk or dairy products.

2.20. "Sanitize" or "sanitization" means the application of any effective method or substance to properly cleaned surfaces for the destruction of pathogens, and other microorganisms, as far as is practicable. Such method or substance shall not adversely affect the equipment, the milk and/or milk product, or the health of consumers, and shall be acceptable to the commissioner.

2.21. "Milk Products" means all milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR 131.120 Sweetened Condensed Milk, cottage cheese and dry curd cottage cheese, whey and whey products, modified versions of all the preceding products, modified versions of milk products packaged in combination with food(s) not yet included in this definition that are appropriately labeled with a statement of identity to describe the food(s) in final packaged form, e.g., "cottage cheese with pineapple" and "fat free milk with plant sterols", and all other products deemed a dairy product by the commissioner.

2.22. "PMO" means the grade A pasteurized milk ordinance as adopted in 61CSR15 of the West Virginia Administrative Law.

**§61-19-3. Minimum quality standards.**

3.1. No person may produce, provide, manufacture, sell, offer for sale, or store in the State of West Virginia, or bring, send, or receive into the State of West Virginia any milk for manufacturing purposes or dairy products which do not comply with the following standards:

3.1.1. The milk shall be free from visible foreign matter. It shall not be curdled, ropy, bloody, or mastitic as indicated by sight or odor. It shall be free from feed odors or other objectionable odors;

3.1.2. Milk for manufacturing purposes and dairy products shall be produced and processed to conform with the chemical, bacteriological, somatic cell, maximum length of time for milk storage on the farm, and temperature standards as identified in this section, and with the requirements set forth in this rule;

3.1.3. The temperature of milk for manufacturing purposes shall be cooled to one of the following:

3.1.3.a. In the case of manufacture-grade milk that is stored in a bulk tank on a producer's farm, cool the milk to and store it at a temperature of fifty degrees Fahrenheit (ten degrees Celsius) or lower within two hours after completion of the milking.

3.1.3.b. In the case of manufacture-grade milk that is stored in cans on a producer's farm, cool the milk to and store it at a temperature of sixty degrees Fahrenheit (sixteen degrees Celsius) or

lower within two hours after completion of the milking. Manufacture-grade milk stored in accordance with this paragraph shall be used exclusively in the manufacture of cheese.

3.1.3.c. This rule does not apply to raw milk that is delivered to a manufacture milk plant not later than two hours after completion of milking.

3.1.4. The bacteria count of milk for manufacturing purposes shall not exceed 500,000 bacteria per milliliter prior to commingling with any other milk, and the bacteria count of milk that is commingled shall not exceed 1,000,000 bacteria per milliliter prior to pasteurization.

3.1.4.a. Milk shipped from the farm in cans shall not have a raw milk bacteria count of more than one million bacteria per mL.

3.2. Milk for manufacturing purposes shall freeze at or below  $-0.530^{\circ}$  Hortvet.

3.2.1. Milk for manufacturing purposes shall test negative for animal drug residues by any method evaluated by the FDA and found acceptable for detecting drug residues in raw milk at current safe or tolerance levels.

3.2.2. The somatic cell count of unpasteurized cow's milk, sheep's milk, water buffalo's milk, or the milk from other mammals intended for human consumption, except goat's milk, shall not exceed 750,000 somatic cells per milliliter. The somatic cell count of raw goat's milk shall not exceed 1,000,000 somatic cells per milliliter.

3.3. Milk should not have more than 1.5 mg of sediment as determined by the Standard Methods for the Examination of Dairy Products.

3.4. No inhibitory substances are permitted in milk.

3.5. The maximum length of time any milk for manufacturing purposes may be stored on the farm prior to processing or pickup for delivery to a processing plant shall not exceed 72 hours from the end of the first milking to the time of pickup or the start of processing. Milk for manufacturing purposes that is older than 72 hours shall be deemed to be a public health hazard and shall not be offered for sale or sold.

#### **§61-19-4. Minimum testing requirements.**

4.1. During at least four separate months within any consecutive six-month period, each dairy plant or co-operative association shall collect and submit producer raw milk samples to a laboratory for examination to determine the somatic cell count of the samples. Samples shall be representative of all raw milk shipped from bulk tanks and received in cans.

4.2. During at least four separate months within any consecutive six-month period, each dairy plant or co-operative association shall collect and submit individual producer raw milk samples to a laboratory for examination to determine the bacterial count of the samples. Samples shall be representative of all raw milk shipped from bulk tanks and all raw milk received in cans.

4.3. Samples shall be analyzed at an approved official or officially designated laboratory. All sampling

procedures and required laboratory examinations shall be in substantial compliance with the rules set by the commissioner.

4.4. Concurrent with all test results made to a producer regarding bacteria counts, sediment, or inhibited substances, the laboratory and/or dairy plant shall send a copy of the results to the designated representative of the Commissioner.

**§61-19-5. Bacterial count.**

5.1. Whenever the producer's raw milk bacteria count exceeds the standard as stated in Section 3 of this rule, the producer shall be notified of the excessive bacteria count.

5.2. Whenever at least two of the last four bacteria counts exceed the bacteria standard as stated in Section 3 of this rule, the Commissioner shall send a written warning notice to the producer. The notice shall be in effect so long as two of the last four consecutive samples exceed the bacterial standard.

5.2.1. An additional sample shall be taken no sooner than three days and no later than twenty-one days after sending of the warning notice required in subsection 5.2. of this rule. If this sample also exceeds the bacteria standard as established in Section 3 of this rule, the producer's permit shall be suspended until satisfactory compliance is obtained. Shipment may be resumed, and the producer's permit reinstated by the Commissioner when an additional sample of the producer's raw milk is tested and found satisfactory. The producer's permit shall remain in a warning status as long as two of the last four bacteria counts exceed the standard. The Commissioner shall suspend the producer's permit immediately for at least seven days, whenever three of the last five bacteria counts within any twelve-month period exceed the standard.

5.2.2. The Commissioner shall issue a temporary permit after determining by an inspection of the facilities and the operating methods that the conditions responsible for the violation have been corrected.

5.2.2.a. Samples shall be taken at the rate of not more than (2) per week on separate days within a 3-week period.

5.2.2.b. The Commissioner shall reinstate the permit upon compliance with the standards set forth in this rule.

**§61-19-6. Inhibitory substances.**

6.1. If milk from a dairy farm containing an inhibitory substance, the producer shall not use any more milk produced by such farm for at least two days following the test to ship or manufacture milk products. The producer shall not use any more milk until the production from the farm has been found to be free of inhibitory substances. The two-day exclusionary provisions cited shall be increased to three days for a repeat violation within six months and shall be increased to four days for subsequent violations within that period.

**§61-19-7. Abnormal milk.**

7.1. A producer shall not use milk for manufacturing milk which is found to be abnormal by sight or odor, which is from animals that show evidence of the secretion of abnormal milk in one or more quarters, or which is from animals that have consumed chemical, medicinal, or radioactive agents that may be secreted in the milk. Equipment, containers, and utensils used to handle abnormal milk shall be cleaned and sanitized by the producer before they are used for milk for manufacturing purposes. The equipment shall meet the construction requirements set forth in this rule. Milk from animals treated with or exposed to pesticides not approved for use on dairy animals by the United States Environmental Protection Agency shall not be used for manufacturing purposes until the milk has been tested and found acceptable by the Commissioner.

7.2. When a confirmatory test on a routine sample indicates a somatic cell count above 750,000 cells per milliliter except for goat milk, which is above 1,000,000 cells per milliliter; the Commissioner shall send written notification of the unsatisfactory cell count to the producer.

7.3. When two out of the last four routine samples have a somatic cell count above 750,000 cells per milliliter, except for goat milk, which is above 1,000,000 cells per milliliter, the Commissioner shall send a written notice of the counts to the producer and a representative of the Commissioner shall contact the producer to endeavor to determine and eliminate the source of the violative cell count. The notice shall be in effect so long as two of the last four consecutive samples exceed the somatic cell standard.

7.3.1. An additional sample shall be taken no sooner than three days and no later than twenty-one days after sending of the warning notice. If this sample also exceeds the somatic cell standard, the producer's permit shall be suspended until satisfactory compliance is obtained. Shipment may be resumed, and the producer's permit reinstated by the Commissioner when an additional sample of the producer's raw milk is tested and found satisfactory. The producer's permit shall remain in a warning status as long as two of the last four somatic cell counts exceed the standard.

7.3.1.a. The Commissioner shall suspend the producer's permit immediately for at least one day whenever three of the last five somatic cell counts within any twelve-month period exceed the standard.

7.3.1.b. The Commissioner shall issue a temporary permit whenever resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as set forth in this rule.

7.3.1.b.1. Samples shall be taken at the rate of not more than two (2) per week on separate days within a 3-week period.

7.3.1.b.2. The Commissioner shall reinstate the permit upon compliance with the standards set forth in this rule.

**§61-19-8. Drug residue level.**

8.1. Dairy plant responsibilities.

8.1.1. Sampling and testing program.

8.1.1.a. All raw milk shipped for processing or intended to be processed on the farm where it was produced shall be sampled and tested, prior to processing, and all individual producer raw milk samples submitted to an approved laboratory for examination to determine bacteria and somatic cell counts shall also be tested for beta lactam drug residue. Collecting, handling and testing of samples shall be done according to procedures approved by the Commissioner, and the laboratory results shall be transmitted to the department as requested by the Commissioner.

8.1.1.b. When so specified by the Commissioner, all raw milk shipped for processing, or intended to be processed on the farm where such raw milk was produced, shall be sampled and tested, prior to processing, and all individual producer raw milk samples submitted to an approved laboratory for examination to determine bacteria and somatic cell counts shall also be tested for other drug residues. Collecting, handling and testing of samples shall be done according to procedures approved by the Commissioner, and the laboratory results shall be transmitted to the department as requested by the Commissioner.

8.1.1.c. When the Commissioner determines that a potential problem exists with an animal drug residue or other contaminant in the milk supply, additional sampling and additional testing shall be conducted, as ordered by the Commissioner. The testing shall continue until such time that the Commissioner determines with reasonable assurance that the potential problem has been remedied.

8.1.1.d. The dairy plant shall analyze samples for beta lactams and other drug residues by any method evaluated by the FDA and found acceptable for detecting drug residues in raw milk at current safe or tolerance levels. The dairy plant may employ on a temporary basis other test methods determined to demonstrate accurate compliance results. These test methods may be used until they are evaluated by the FDA and accepted or rejected by the Commissioner.

8.1.2. Individual producer sampling.

8.1.2.a. For bulk milk, a milk sample for beta lactam drug residue testing shall be taken at each farm and shall include milk from each farm bulk tank.

8.1.2.b. For can milk, a milk sample for beta lactam drug residue testing shall be formed separately at the receiving plant for each can milk producer included in a delivery, and shall be representative of all milk received from the producer.

8.1.2.c. For producer/processor, a milk sample for beta lactam drug residue testing shall be formed separately according to subdivisions 8.1.2.a. and 8.1.2.b. of this rule for milk produced or received by a producer/processor.

8.1.3. Load sampling and testing.

8.1.3.a. For bulk milk, a load sample shall be taken from the bulk milk pickup tanker after its arrival at the plant and prior to further commingling.

8.1.3.b. For can milk, a load sample representing all of the milk received on a shipment shall be formed at the plant, using a sampling procedure that includes milk from every can on the vehicle.

8.1.3.c. For producer/processor, a load sample shall be formed at the plant using a sampling procedure that includes all milk produced and received.

8.1.4. Sample and record retention. A load sample that tests positive for drug residue shall be retained according to guidelines established by the appropriate state regulatory agency. The records of all sample test results shall be retained for a period of not less than twelve months.

8.1.5. Dairy plant follow-up.

8.1.5.a. When a load sample tests positive for drug residue, dairy plant personnel shall notify the Commissioner immediately, in accordance with state policy, of the positive test result and of the intended disposition of the shipment of milk containing the drug residue. All milk testing positive for drug residue shall be disposed of in a manner that removes it from the human or animal food chain, except when acceptably reconditioned under United States food and drug administration compliance policy guidelines.

8.1.5.b. Each individual producer sample represented in the positive-testing load sample shall be individually tested in a laboratory approved by the Commissioner to determine the producer of the milk sample testing positive for drug residue. Identification of the producer responsible for producing the milk testing positive for drug residue, and details of the final disposition of the shipment of milk containing the drug residue, shall be reported immediately to the Commissioner, according to state policy.

8.1.5.c. Milk shipment from the producer identified as the source of milk testing positive for drug residue shall cease immediately and may resume only after a sample from a subsequent milking does not test positive for drug residue.

8.2. Regulatory agency responsibilities.

8.2.1. Monitoring and surveillance. The Commissioner shall monitor the milk industry's drug residue program by conducting unannounced on-site inspections to observe testing and sampling procedures and to collect samples for comparison drug residue testing. In addition, the Commissioner shall review industry records for compliance with state policy. The review shall seek to determine that:

8.2.1.a. Each producer is included in an effective routine drug residue milk monitoring program utilizing the official methods and federal drug administration approved methods to test samples for the presence of drug residue;

8.2.1.b. The Commissioner receives prompt notification from industry personnel of each occurrence of a sample testing positive for drug residue, and of the identity of each producer identified as a source of milk testing positive for drug residue;

8.2.1.c. The Commissioner receives prompt notification from industry personnel of the intended and final disposition of milk testing positive for drug residue, and that disposal of the load is conducted in a manner that removes it from the human or animal food chain, except when acceptably reconditioned under federal drug administration compliance policy guidelines; and

8.2.1.d. Milk shipment from a producer identified as a source of milk testing positive for drug residue completely and immediately ceases until a milk sample taken from the dairy herd does not test positive for drug residue.

8.2.2. Enforcement.

8.2.2.a. The Commissioner may deny, suspend or revoke the producer's permit for violation of this rule.

8.2.2.b. When there is a positive drug residue test, the Commissioner shall send a written notice of the positive result to the producer and a representative of the Commissioner shall contact the producer to endeavor to determine and eliminate the source of the positive drug residue test.

8.2.2.c. If a producer ships milk testing positive for drug residue three (3) times within a twelve-month period, the Commissioner may revoke the producer's permit.

**§61-19-9. Adulteration.**

9.1. Milk is considered to be adulterated if it contains any poisonous or deleterious substances, does not meet the quality standards set forth in this Rule, has been produced, processed, or held under unsanitary conditions, contains added water, or contains bacteria in excess of the standards set forth in this rule.

9.2. The producer shall not use milk if it is adulterated.

**§61-19-10. Milking facility and housing.**

10.1. The milking barn, stable, or parlor shall be of a size and arrangement that will promote a sanitary milking operation. It shall be provided with natural or artificial light, well distributed for day or night milking and have sufficient air space and air circulation to prevent condensate and excessive odors. The floors and gutters shall be in good repair and constructed of concrete or other impervious material. Concentrates and feed, when stored in the milking facility, shall be kept in a tightly covered box or bin. The facility shall be kept clean, the manure removed daily, and no swine or fowl shall be permitted in any part of the milking facility. The milking barn or parlor construction must be approved by the commissioner before milking can begin.

10.2. If milk is exposed in the milking facility, it shall be protected in a manner that prevents any contamination of the milk, equipment, containers, or utensils. No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination.

10.3. Milk stools, surcingles and antikickers shall be kept clean and stored off the floor.

10.4. The cowyard, housing area or loafing area shall be of ample size to prevent overcrowding, shall be kept clean and drained to prevent forming of standing water pools, insofar as practicable. The dairy animals shall be prevented from having any access to stored or accumulated manure.

**§61-19-11. Milking barn or parlor cleanliness.**

11.1. The interior of the milking barn or parlor facilities shall be kept clean.

11.2. The bedding material, if used, shall not contain more manure than that which has accumulated since the previous milking.

11.3. The gutter shall be kept reasonably clean, with manure removed daily.

11.4. All pens and stalls, if not separated from the milking barn or parlor, shall be kept clean.

**§61-19-12. Milkhouse construction and facilities.**

12.1. A milkhouse or milkroom shall be provided and be conveniently located and properly constructed, lighted, and ventilated for handling and cooling milk and for washing, handling, and storing the equipment and utensils. Other products which would be likely to contaminate milk, or otherwise create a public health hazard, shall not be handled in the milkhouse.

12.2. The milkhouse or milk room should meet the following requirements:

12.2.1. The milkhouse or milkroom that is a part of the barn or other building shall be partitioned and sealed to prevent the entrance of dust, flies, or other contamination. The floor of the milkhouse or milkroom shall be of concrete or other impervious material and graded to drain so that there are no pools of standing water. The walls and ceilings shall be constructed of smooth easily cleaned material. All newly constructed milkhouses shall have walls and ceilings constructed of smooth material kept in good repair and well painted with a light-colored washable paint or finished in an equally suitable manner. All outside doors shall open outward and be self-closing, unless they are provided with tight-fitting, self-closing, screen doors that open outward or unless other effective means are provided to prevent the entrance of flies or insects. A direct opening between the milkhouse or milkroom and the milking barn, stable, or parlor is permitted when the opening has a tight fitting, self-closing, solid door. The milkhouse or milkroom shall have sufficient air space and air circulation to prevent condensate and excessive odors. It shall be provided with natural or artificial light well distributed for day or night milkhouse activities.

12.2.2. The milkhouse or milkroom shall be equipped with a two-compartment wash vat, utensil rack, milk cooling facilities and have an adequate supply of hot water available for cleaning milking equipment. If a farm bulk milk tank is used, it shall be situated in the milkhouse or milkroom to allow access to all areas of the milkhouse or milkroom and to the exterior of the bulk milk tank for cleaning and servicing. The farm bulk milk tank shall not be located over a floor drain or under a ventilator.

12.2.3. Concentrates and feed, if stored in the building, shall be kept in a tightly covered box or

bin.

12.2.4. The liquid wastes shall be disposed of in a sanitary manner. All floor drains shall be accessible and shall be trapped if connected to a sanitary sewer.

12.2.5. Vents and light fixtures shall be installed in a manner to prevent the contamination of milk and clean utensils.

12.2.6. The milkhouse structure, equipment, and other milkhouse facilities used in its operation shall be kept clean at all times and be free of trash, animals and fowl.

12.2.7. Pesticides or unapproved antibiotics shall not be stored in this room and when they are used, they shall be used in accordance with label instructions so as to prevent contamination of the milk.

**§61-19-13. Milking utensils and equipment.**

13.1. Construction of utensils and equipment shall meet the following requirements:

13.1.1. All multiuse utensils, equipment, and containers which are exposed to milk or milk products shall be made of smooth, impervious, nonabsorbent, safe materials of the following types:

13.1.1.a. Stainless steel of the AISI (American Iron and Steel Institute) 300 series;

13.1.1.b. Equally corrosion resistant nontoxic metal;

13.1.1.c. Heat resistant glass; or

13.1.1.d. Plastic or rubber and rubber like materials which are relatively inert, resistant to scratching, scoring, decomposition crazing, chipping, and distortion under normal use conditions. The materials shall be nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, and may not release component chemicals or impart flavor or odor to the product. The materials shall maintain their original properties under repeated use conditions.

13.1.2. Single-service articles shall be manufactured, packaged, transported, and handled in a sanitary manner.

13.1.3. Articles intended for single-service use shall not be reused.

13.1.4. All containers, equipment, and utensils shall be free of breaks and corrosion.

13.1.5. All joints in the containers, equipment, and utensils shall be smooth and free from pits, cracks, and inclusions.

13.1.6. Strainers shall be of perforated metal design or constructed to utilize single-service strainer media.

13.1.7. All milking machines, including heads, milk claws, milk tubing, and other milk contact

surfaces, shall be easily cleaned and inspected.

13.2. Utensils and equipment shall meet the following cleanliness requirements:

13.2.1. The contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk or milk products shall be cleaned after each use.

13.2.2. The contact surfaces of all multiuse containers, equipment, and utensils shall be sanitized immediately prior to use for the handling, storage, or transportation of milk or milk products.

13.3. Utensils and equipment shall be stored in the following manner:

13.3.1. All milk containers, utensils, and equipment, including milking machine vacuum hoses, shall be stored in a sanitizing solution or on racks until used.

13.3.2. All milk containers, utensils and equipment shall be stored in a clean and properly ventilated area.

13.3.3. Equipment shall be stored to drain completely.

13.3.4. Strainer pads, gaskets, and similar single-service articles shall be stored in a suitable container or cabinet and protected against contamination.

13.4. Utensils and equipment handling shall meet the following requirements:

13.4.1. After sanitation, all containers, utensils and equipment shall be handled in such a manner as to prevent contamination of any product contact surface.

13.4.2. Sanitized product contact surfaces shall be protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation, and other sources of contamination.

13.4.3. Any sanitized product contact surface, which has been exposed to contamination, shall be cleaned and sanitized again prior to being used.

**§61-19-14. Milking procedure.**

14.1. The milk producer shall ensure that milking is done only in an approved milking barn or parlor.

14.2. The animals' hair on flanks, bellies, tails, and udders shall be shortened as often as necessary to facilitate cleaning of those areas and shall be free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking, or as to adulterate the milk in any manner.

14.3. Udders and teats of all milking animals shall be cleaned and dry before milking. The animals' teats shall be treated with a sanitizing solution and shall be dry just prior to milking; and

14.4. Wet hand milking is prohibited.

**§61-19-15. Protection from contamination.**

15.1. Equipment and operations shall be located within the milking barn and milkhouse to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact.

15.2. All milk which has overflowed, leaked, spilled, or been improperly handled shall be discarded.

15.3. All product contact surfaces of containers, equipment, and utensils shall be covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination.

15.4. When milk is poured or strained in the milking barn, the receiving receptacle shall be raised above the floor (as on a dolly or cart) or placed at a distance from the animals to protect it from manure or splash. The receptacle shall have a tight-fitting cover which shall be closed except when milk is being poured.

15.5. Each pail or container of milk shall be transferred immediately from the milking barn to the refrigerated storage facility.

15.6. Pails, cans, and other equipment containing milk shall be properly covered during transfer and storage.

15.7. Antibiotics and medicines shall be stored in such a manner that they cannot contaminate the milk or milk product contact surfaces of the equipment, containers, or utensils.

**§61-19-16. Hand washing facilities.**

16.1. Hand washing facilities shall be located convenient to the milking barn, parlor, or flush toilet.

16.2. Hand washing facilities shall include soap or detergent, water, and single use towels.

16.3. Hand washing facilities shall be kept in good repair, clean, and shall not be used for storage.

**§61-19-17. Cleanliness and health.**

17.1. Hands shall be washed clean and dried with a sanitary towel immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities.

17.2. Any person milking an animal shall wear clean outer garments while milking or handling milk, milk products, milk containers, equipment or utensils.

17.3. No person affected with any disease in a communicable form, or while a carrier of such disease, shall work at any dairy farm or milk products facility in any capacity which brings him or her into contact with the production, handling, storage, or transportation of milk or milk products, containers, equipment, or utensils. No dairy farm operator or milk products producer shall employ in any capacity any person having or suspected of having a disease in a communicable form or being a carrier of such disease. Any producer who suspects that any employee or family member has contracted any disease in a communicable form, or has become a carrier of the disease, shall notify the Commissioner immediately.

17.4. When reasonable cause exists to suspect the possibility of transmission of infection from any person handling milk or milk products, the Commissioner may require any or all of the following measures:

17.4.1. The immediate exclusion of the affected person from milk or milk products handling;

17.4.2. The immediate exclusion of the milk or cheese supply concerned from distribution and use; and/or

17.4.3. Adequate medical and bacteriological examination of the person, and of his or her associates.

**§61-19-18. Insect and rodent control.**

18.1. Effective measures shall be taken to prevent the contamination of milk and milk products, containers, equipment, and utensils by insects or rodents, and by chemicals used to control the vermin.

18.2. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds and free stall housing shall be properly bedded and managed to prevent fly breeding.

18.3. Milkhouses and all buildings shall be kept free of insects and rodents.

18.4. Milkhouses and all buildings shall be effectively protected against the entrance of vermin.

18.5. Insecticides not approved for use in a milkhouse or dairy facility shall not be stored in such facilities.

18.6. Only insecticides and rodenticides approved for use by the Commissioner and registered with the United States Environmental Protection Agency shall be used for insect and rodent control.

18.7. Insecticides and rodenticides shall be used only in accordance with the manufacturers label directions so as to prevent the contamination of milk and milk products, containers, equipment, utensils, feed and water.

**§61-19-19. Farm inspection.**

19.1. Each dairy farm that produces manufacture-grade milk or manufacture-grade milk products that are intended for consumption shall be inspected an inspector prior to issuance of a permit.

19.2. Each dairy farm will be inspected by an inspector at least once every six (6) months.

19.2.1. The inspector will use dairy farm inspection forms that are prescribed and furnished by the Commissioner.

19.2.2. The inspector will leave a copy of the inspection form with the producer, keep one copy for his/her records and file a copy with the Commissioner in a timely fashion.

19.2.3. Should a violation of any requirements set forth in this rule be found to exist during an

inspection, a second inspection may be required after the time deemed necessary to remedy the violation. Such second inspection may be used to determine compliance with requirements of this rule.

19.2.4. Any violation of the same requirement, marked as a repeat violation, may call for permit suspension. Permit suspension is at the discretion of the Commissioner.

**§61-19-20. Animal health.**

20.1. All animals in the herd shall be maintained in a healthy condition.

20.2. All animals' milk for processing milk or milk products shall be from herds under a brucellosis eradication program which meets one of the following conditions, or eradication program for animals' health:

20.2.1. The herd is located in a Certified Brucellosis-Free Area as defined by the United States Department of Agriculture and enrolled in the testing program for the areas;

20.2.2. The herd is located in a Modified Certified Brucellosis Area as defined by the United States Department of Agriculture and enrolled in the testing program for the areas;

20.2.3. The herd meets United States Department of Agriculture requirements for an individually certified herd;

20.2.4. The herd is participating in a milk ring testing program which is conducted on a continuing basis at intervals of not less than every three (3) months or more than every six (6) months with individual blood tests on all animals in herds showing suspicious reactions to the milk ring test; or

20.2.5. The herd has an individual blood agglutination test annually with an allowable maximum grace period not exceeding two (2) months.

20.3. All animals' milk for manufacturing milk products shall be from herds which are located in a Modified Accredited Tuberculosis Area as determined by the United States Department of Agriculture. A Modified Accredited Tuberculosis Area requires all dairy herds to be tested every six (6) years with an allowable maximum grace period of two (2) months. Herds located in an area that fails to maintain accredited status shall be accredited by the United States Department of Agriculture as tuberculosis free or shall pass an annual tuberculosis test.

20.4. For diseases other than brucellosis and tuberculosis the Commissioner may require any physical, bacteriological, or chemical tests he or she determines necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of the Commissioner. Any producer owning a diseased animal disclosed by the test shall dispose of the animal as the Commissioner directs.

20.5. Regardless of location or other herd status, a milk producer whose herd:

20.5.1. Has a suspicious milk ring test result shall have the entire herd blood tested within thirty days after the date of the laboratory test.

20.5.2. Is identified as the origin of a brucellosis reactor animal shall have the entire herd blood tested within thirty days after the laboratory tests, unless the test requirement has been waived by an epidemiological investigation conducted by the director.

20.5.3. Is identified as the origin of a tuberculosis reactor or suspect, shall follow all statutes, rules, and recommendations of the Commissioner concerning the testing and disposition of animals in the herd.

**§61-19-21. Farm exclusion.**

21.1. No farm shall process milk or milk products using raw milk from a dairy farm that is not in compliance with the provisions of this rule.

21.2. In the event of noncompliance with this rule or in the event of a refusal by a producer to allow an inspection of the dairy farm by an inspector of the West Virginia Department of Agriculture or designee, the milk from the dairy farm shall not be used to process milk or milk products until such time as the farm is found to be in compliance and/or access to inspect the dairy farm is permitted.

**§61-19-22. Water supply.**

22.1. The dairy farm and milk and milk products processing facility water supply shall be properly located, protected, and operated. It shall be easily accessible, ample, and of safe sanitary quality for the cleaning of dairy utensils and equipment. The water supply shall come from an approved public source or from a spring, dug well, driven well, bored well, or drilled well, that complies with the standards of the West Virginia Department of Health and Human Resources.

22.2. The water supply will be tested to meet standards set by the Commissioner.

**§61-19-23. Pasteurization of milk and milk products.**

23.1. All milk and milk products, except eggnog, shall be pasteurized to one (1) of the temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

<b>Batch (Vat) Pasteurization</b>	
<b>Temperature</b>	<b>Time</b>
63°C (145°F)*	30 minutes
<b>Continuous Flow (HTST and HHST) Pasteurization</b>	
<b>Temperature</b>	<b>Time</b>
72°C (161°F)*	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

\*If the fat content of the milk product is ten percent (10%) or greater, or a total solids of 18% or greater, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F).

23.2. Eggnog shall be heated to at least the following temperature and time specifications:

<b>Table 3. Pasteurization Temperature vs. Time</b>	
<b>Batch (Vat) Pasteurization</b>	
<b>Temperature</b>	<b>Time</b>
69°C (155°F)	30 minutes
<b>Continuous Flow (HTST) Pasteurization</b>	
<b>Temperature</b>	<b>Time</b>
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

23.3. There shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized non-dairy products not completely separated from pasteurized milk and milk products shall be pasteurized in properly designed and operated equipment at times and temperatures which meet at least the minimum times and temperatures provided for in the definition of Pasteurization.

23.4. Water that comes in contact with pasteurized milk and/or milk products shall:

23.4.1. Meet at least the minimum times and temperatures provided for in the definition of Pasteurization in equipment; or

23.4.2. Have undergone an equivalent process found acceptable by the WVDA.

23.5. a producer must provide means to prevent contamination of milk and/or milk products, containers, utensils and equipment by drippings, spillage and splash from overhead piping, platforms or

mezzanines.

23.6. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk or milk products, unless the standardized milk or milk product is subsequently pasteurized.

23.7. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients.

**§61-19-24. Milk Processing Plant.**

**24.1 Premises.**

24.1.1 Shall be kept in a clean and orderly condition and be free from strong or foul odors, smoke, or excessive air pollution. Driveways and adjacent plant traffic areas shall be constructed of concrete, asphalt, or similar material and maintained to keep dust and mud to a minimum. The adjacent plant surroundings shall be free from refuse, rubbish, and waste materials to prevent the harborage of rodents, insects, and other vermin and a suitable drainage system shall be provided which will allow rapid drainage of all water from plant buildings and driveways, including surface water around the plant and on the premises. All water shall be disposed of in a manner as to prevent a nuisance or health hazard.

24.1.2 The building or buildings shall be of sound construction and shall be kept in good repair to prevent the entrance or harborage of rodents, birds, insects, vermin, and other animals. Any openings around service pipes through outside walls shall be effectively sealed around the openings or sealed with tight metal collars.

24.1.2.a. All openings to the outer air including doors, windows, skylights, and transoms shall be effectively protected or screened to prevent the entrance of flies and other insects, rodents, birds, dust, and dirt. All outside doors opening into processing rooms shall be in good condition and fit properly. All hinged, outside screen doors shall open outward. All doors shall be tight-fitting and self-closing. All doors and windows shall be kept clean and in good repair. Outside conveyor openings and other special-type outside openings shall be effectively protected to prevent the entrance of flies and rodents by means of doors, screens, flaps, fans, or tunnels. Outside openings for sanitary pipelines shall be covered when not in use.

24.1.2.b. The walls, ceilings, partitions, posts of rooms in which milk or dairy products are processed, manufactured, handled, packaged, or stored (except dry storage of packaged finished products and supplies) or in which utensils are washed and stored, shall have a smooth finish with a suitable material of light color, which is substantially impervious to moisture and shall be kept clean. These surfaces shall be refinished as often as necessary to maintain a neat, clean surface.

24.1.2.c. Floors:

24.1.2.c.1 The floors of all rooms in which milk or dairy products are processed, manufactured, packaged, or stored or in which utensils are washed shall be constructed of tile properly laid with impervious joint material, concrete, or other equally impervious material. The floors shall be smooth, kept in good repair, and graded so that there will be no pools of standing water or milk products after flushing. Drains shall be equipped with traps properly constructed and

shall be kept in good repair. The plumbing shall be installed to prevent the backup of sewage into the drain lines and onto the floor of the plant.

24.1.2.d. Lighting and ventilation:

24.1.2.d.1 Light shall be ample and well distributed. All rooms in which dairy products are manufactured or packaged or where utensils are washed shall have at least thirty foot-candles of light intensity on all working surfaces and at least fifty foot-candles of light intensity in areas where dairy products are graded or examined for condition and quality. In all other rooms, there shall be at least five foot-candles of light intensity when measured at a distance of thirty inches from the floor. Where contamination of product by broken glass is possible, light bulbs, fluorescent tubes, skylights, or other fixtures over the product shall be protected against breakage.

24.1.2.d.2 There shall be adequate heating, ventilation, or air conditioning in all to facilitate maintenance of sanitary conditions. Exhaust or inlet fans, vents, hoods, or temperature and humidity control facilities shall be provided as needed to minimize or eliminate undesirable room temperatures, objectionable odors, moisture condensation, or have an atmosphere relatively free from mold (not exceeding ten mold colonies per cubic foot of air). Inlet fans shall be screened and should be provided with an adequate air filtering device to eliminate dirt and dust from incoming air. Ventilation systems shall be cleaned periodically and shall be maintained in good repair. Exhaust outlets shall be screened or be provided with self-closing louvers to prevent the entrance of insects when not in use.

24.1.2.e Rooms in which any raw materials, packaging materials, ingredient supplies, or dairy products are handled, manufactured, packaged, or stored shall be designed, constructed, and maintained to assure desirable room temperatures and enhance clean, orderly operating conditions free from objectionable odors and vapors. Enclosed bulk milk receiving rooms when present shall be separated from the processing rooms by a partition. Rooms for receiving can milk shall be separated from processing rooms by a partition (partial or complete), by suitable arrangement of equipment, or by allowing enough distance between receiving and processing operations to avoid possible contamination of milk or dairy products during manufacturing and handling. Processing rooms shall be kept free from equipment and materials which are not routinely used.

24.1.2.e.1. Coolers and freezers used for storage of dairy products shall be clean, reasonably dry and maintained at proper uniform temperature and humidity levels by providing adequate circulation of air at all times to protect the product and minimize mold growth. Coolers and freezers shall be free from rodents, insects and pests. Shelves shall be kept clean and dry. Refrigeration units shall have provisions for the collection and disposal of condensate.

24.1.2.e.2. Supply rooms used for the storage of packaging materials, containers, and miscellaneous ingredients shall be kept clean, dry, orderly, free from insects, rodents, and mold and maintained in good repair. Such items stored therein shall be adequately protected from dust, dirt, or other extraneous matter and so arranged on racks, shelves, or pallets to permit access to the supplies and to permit cleaning and inspection of the room. Insecticides, rodenticides, cleaning compounds, and other nonfood products shall be properly labeled and segregated, and stored in a separate room or cabinet away from milk, dairy products, ingredients, or packaging supplies.

24.1.2.e.3. Toilet and dressing room facilities shall be conveniently located to all

processing operations.

24.1.2.e.3.1 Toilet rooms shall not open directly into any room in which milk or dairy products are processed, manufactured, packaged or stored. Doors shall be self-closing. Ventilation shall be provided by mechanical means or by screened openings to the outer air. Fixtures including but not limited to toilet stools, sinks, lights and lockers, shall be kept clean and in good repair.

24.1.2.e.3.2 If employees are furnished with a locker or other storage facility, the lockers or other storage facilities shall be kept clean and orderly. Adequate hand-washing facilities shall be provided. Durable, legible signs shall be posted conspicuously in each toilet or locker room directing employees to wash their hands before returning to work.

**§61-19-25. Milk Processing Plant Inspection.**

25.1 Each manufacture-grade milk plant shall be inspected by an inspector prior to issuance of a permit.

25.2 Each manufacture- grade milk plant shall be inspected by an inspector at least once every 3 months.

25.3 The inspector will use manufacture-grade dairy plant inspection forms that are prescribed and furnished by the commissioner.

25.4. The inspector will leave a copy of the inspection form with the manufacture-grade dairy plant, keep on copy for his/her records and file a copy with the Commissioner in a timely fashion.

25.5 Should a violation of any requirements set forth in this rule be found to exist during an inspection, a second inspection may be required after the time deemed necessary to remedy the violation. Such second inspection may be used to determine compliance with requirements of this rule.

25.6 Any violation of the same requirement, marked as a repeat violation, may call for permit suspension. Permit suspension is at the discretion of the Commissioner.

**§61-19-26. Pasteurization records, equipment tests and examinations.**

26.1 All temperature and flow rate pasteurization recording charts or alternative records, acceptable to the Commissioner in place of charts, shall be:

26.1.1. Reviewed, dated and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records were created;

26.1.2. Onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and

26.1.3. Retained for at least two (2) years after the date they were created. Offsite storage of these pasteurization records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

26.2 Shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this Item. The following information shall also be entered on the charts or other records acceptable to the Commissioner in place of charts as applicable:

26.2.1. Batch Pasteurizers:

26.2.1.a. Date

26.2.1.b. Number or location of recording thermometer when more than one is used;

26.2.1.c. A continuous record of the product temperature;

26.2.1.d. Extent of holding period, including filling and emptying times when required;

26.2.1.e. Reading of the airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart; provided, if the airspace thermometer is a digital combination airspace/recording thermometer, which provides a continuous recording of the airspace temperature and has been calibrated by the Regulatory Agency in accordance with Appendix I Test 4 of this Rule, the recording of the airspace temperature on the chart shall only be required at the start of the holding period;

26.2.1.f. Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart;

26.2.1.g. Quarterly, the time accuracy of the recording thermometer, as determined by the Regulatory Agency, or in the case of milk plants regulated under the NCIMS voluntary HACCP Program, a qualified industry person acceptable to the Regulatory Agency;

26.2.1.h. Amount and name of the pasteurized milk or milk product, represented by each batch or run on the chart;

26.2.1.i. Record of unusual occurrences;

26.2.1.j. Signature or initials of the operator; and

26.2.1.k. Name of the milk plant.

26.2.2 HTST and HHST Pasteurizers: Recording thermometer charts shall contain all the information specified in Subitem 26.2.1.a. above, except 26.2.1.d., and 26.2.1.e., and in addition, shall include the following:

26.2.2.a. A record of the time during which the FDD is in the forward-flow position;

26.2.2.b. The cut-in and cut-out milk or milk product temperatures, recorded daily by the operator, at the beginning of the run (HTST only), and initialed quarterly by the Regulatory Agency or a qualified industry person acceptable to the Regulatory Agency; and

26.2.2.c. 26.2.1.f. from above shall also be recorded immediately after a chart has been changed.

**NOTE:** The temperature shown on the recording thermometer chart shall be used to determine that the required temperature for milk or milk products containing higher fat and/or sweeteners has been achieved.

26.3 The Regulatory Agency shall perform the indicated Tests on the following instruments and devices identified in Table 4 initially upon installation; at least once each three (3) months thereafter, including the remaining days of the month in which the equipment Tests are due; whenever any alteration or replacement is made which may affect the proper operation of the instrument or device; or whenever a regulatory seal has been broken. Provided, that the pasteurization holding time Tests shall be conducted at least once each six (6) months thereafter, including the remaining days of the month in which the equipment Test is due. The test results for the required pasteurization equipment testing shall be recorded on records that are formed and provided by the Commissioner.

26.4 The regulatory agency shall provide a copy of the records to the milk plant and the milk plant shall retain these records for at least two (2) years after the date they were created. Offsite storage of these pasteurization equipment testing records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

26.5 Table 4 Equipment Tests- Batch Pasteurizers and HTST and HHST Pasteurized Systems Refer to

Appendix	I	of	the	PMO:
1.	Vat, HTST and HHST indicating and airspace thermometers			Temperature accuracy
2.	Vat, HTST and HHST recording thermometer			Temperature accuracy
3.	Vat, HTST and HHST recording thermometer			Time accuracy
4.	Vat, HTST and HHST indicating and recording thermometer			Recording vs. Indicating thermometer
5.1	HTST and HHST FDD			Leakage pass FDD
5.2	HTST and HHST FDD			FDD freedom of movement
5.3	HTST and HHST FDD			Device assembly (single stem)
5.4	HTST and HHST FDD			Device assembly (dual stem)
5.5	HTST FDD			Manual diversion
5.6	HTST and HHST FDD			Response time
5.7	HTST and HHST FDD			Time delay (inspect)
5.8	HTST and HHST FDD			Time delay (CIP)
5.9	HTST FDD			Time delay (leak-detect flush)
6.	Vat leak-protector valve(s)			Leakage
7.	HTST indicating thermometers			Response time
8.	HTST recording thermometers			Response time
9.1	HTST pressure switches			Regenerator pressures
9.2.1	HTST and HHST differential pressure controllers			Calibration
9.2.2	HTST differential pressure controllers			Regenerator pressure
9.2.3	HTST* and HHST differential pressure controllers			Regenerator pressure
9.3.1	HTST booster pump/FDD			Inter-wiring check
9.3.2	HTST booster pump/timing pump			Inter-wiring check
10.1	HTST FDD			Temperature cut-in/cut-out
10.2	HTST* and HHST FDD divert system (indirect heat)			Temperature cut-in/cut-out
10.3	HTST* and HHST FDD divert system (direct heat)			Temperature cut-in/cut-out
11.1	HTST holding tubes/timing pumps (except magnetic flow meter based timing systems (MFMBTS))			Holding time
11.2.a	HTST holding tubes/ MFMBTS			Holding time
11.2.b	HTST and HHST MFMBTS			Flow alarm
11.2.c	HTST and HHST MFMBTS			Loss of signal/low flow
11.2.d	HTST MFMBTS			Flow rate cut-in/cut-out
11.2.e	HTST MFMBTS			Time delay
11.2.f	All MFMBTS			High flow alarm response time
11.3	HHST holding tubes indirect heat			Holding time
11.4	HHST holding tubes direct injection heat			Holding time
11.5	HHST holding tubes direct infusion heat			Holding time
12.1	HTST* and HHST indirect heating			Sequence logic
12.2	HTST* and HHST direct heating			Sequence logic
13.	HHST			Pressure in the holding tube
14.	HTST* and HHST* using direct injection heating			Pressure differential across injector
15.	HTST and HHST (all electronic controls)			Electro-Magnetic Interference

**§61-19-247. Permit to operate.**

247.1. It is unlawful for any person who does not possess a permit from the Department of Agriculture to operate a dairy farm or a manufacture-grade milk and manufacture-grade milk products processing facility which produces and offers for sale manufacture-grade milk or manufacture-grade milk products as covered under the provisions of this Rule.

247.2. The producer and the manufacture-grade milk or manufacture-grade milk products processing facility shall apply for a permit on forms prescribed and furnished by the Commissioner. All permits expire December 31 of each year.