



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF AN EMERGENCY RULE

AGENCY: Agriculture

TITLE-SERIES: 61-15

RULE TYPE: Legislative

Amendment to Existing Rule: No

RULE NAME: Grade "A" Pasteurized Milk

CITE STATUTORY AUTHORITY FOR PROMULGATING EMERGENCY RULE:

§19-11E-8

IF THE EMERGENCY RULE WAS PROMULGATED TO COMPLY WITH A TIME LIMIT ESTABLISHED BY CODE OR FEDERAL STATUTE OR REGULATION, CITE THE CODE PROVISION, FEDERAL STATUTE OR REGULATION AND TIME LIMIT ESTABLISHED THEREIN:

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THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY THE SECRETARY OF STATE OR THE 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST. THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

Senate bill 496, passed during the 2019 Regular Legislative Session, transferred authority to regulate milk from the Department of Health and Human Resources to the Department of Agriculture effective July 1, 2019. It also provided for an MOU between DHHR and WVDA to provide for the orderly transition of those duties, with a full transfer to occur effective January 1, 2020. While DHHR's current rules governing milk regulation (64CSR34) remained in effect as part of SB496, the current regulations do not practically allow the milk program to operate after January 1 without emergency rulemaking for the following reasons:

1. Current rules do not permit WVDA to contract with other state regulatory entities in order to perform required functions (such as those of State Regulatory Office or Laboratory Evaluation Officer) Training for these positions takes approximately two years, and SB496 did not allow sufficient time for that training to take place. 2. Current rules do not permit WVDA to utilize industry inspections to maintain compliance with FDA requirements. Again, training for these positions takes approximately two years, and SB496 did not allow sufficient time for that training to take place. 3. DHHR was operating under 2011 version of the Pasteurized milk Ordinance (PMO), as adopted in 64 CSR 34. A 2019 version is expected soon, and once it is published, states will no longer be permitted to operate under the 2011 version. Absent approval of this legislative rule, WVDA is unable to undertake necessary steps to ensure that it has a full complement of regulatory officers available to oversee the Grade A milk program.

DOES THIS EMERGENCY RULE REPEAL A CURRENT RULE? No

HAS THE SAME OR SIMILAR EMERGENCY RULE PREVIOUSLY BEEN FILED AND OR EXPIRED? No

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 at this time

B. ECONOMIC IMPACT ON THE STATE OR ITS RESIDENTS:

N/A at this time.

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2019 Increase/Decrease (use "-")	2020 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

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

N/A at this time.

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 15
GRADE "A" PASTEURIZED MILK

§61-15-1. General.

1.1. Scope. -- This legislative rule establishes the minimum requirements for the production, transportation, processing, handling, sampling, examination, labeling, and sale of Grade "A" milk and milk products, imitation milk and imitation milk products, and non-dairy products; the inspection of dairy farms, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, milk tank trucks and bulk milk haulers/samplers; the issuing, suspension, and revocation of permits to milk producers, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, haulers, and distributors, and the fixing of penalties.

1.2. Authority. -- W. Va. Code §19-11E-8

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Sunset Date. – This rule shall expire and have no further force and effect five years from the effective date.

1.6. Applicability. -- This rule applies to every person, as defined in this rule, who in any manner establishes, conducts, controls, manages, maintains, owns, or operates a facility included under the scope of this rule.

1.7. Enforcement. -- This rule is enforced by the Commissioner of the West Virginia Department of Agriculture.

§61-15-2. Incorporation by reference of federal model grade "A" pasteurized milk ordinance.

2.1. The following portions of the Grade "A" Pasteurized Milk Ordinance, 2017 Revision, as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, including administrative procedures, public health reasons, tables and illustrations, are incorporated by reference:

2.1.1. Section 1. Definitions.

2.1.1.a. Except that definition "VV. Regulatory Agency" means the Commissioner of the West Virginia Department of Agriculture or their designee. The term, "Regulatory Agency", whenever it appears in the Ordinance shall mean the appropriate agency, including a Third-Party Certifier (TPC) authorized under the NCIMS voluntary International Certification Program (ICP), having jurisdiction and control over the matters embraced within this Ordinance.

2.1.2. Section 2. Adulterated or Misbranded Milk and/or Milk Products;

2.1.2.a. Footnote 1 referenced in Section 2 means the State of West Virginia.

2.1.2.b. The following is added to Section 2, Adulterated or Misbranded Milk or Milk Products: "Samples analyzed for added water and found to have a freezing point above -0.525 degrees Hortvet (or -0508 degrees Celsius) are adulterated unless proven free of added water."

2.1.3. Section 3. Permits;

2.1.3.a. Footnote 1 referenced in Section 3 means the State of West Virginia.

2.1.4. Section 4. Labeling;

2.1.5. Section 5. Inspection of Dairy Farms and Milk Plants;

2.1.5.a. Footnote 1 referenced in Section 5 means the State of West Virginia.

2.1.5.b. The words "the Regulatory Agency shall" whenever used in the section shall be amended to read "the Regulatory Agency may."

2.1.6. Section 6. The Examination of Milk and Milk Products;

2.1.6.a. In the fifth paragraph of Section 6. the word "shall" is amended to read "may".

2.1.7. Section 7. Standards for Grade "A" Milk and/or Milk Products;

2.1.7.a. Footnote 1 referenced in Section 7. Standards for Grade "A" Milk and Milk Products means the State of West Virginia.

2.1.7.b. The following is added to Section 7. Standards for Grade "A" Milk and Milk Products:

2.1.7.b.1. Item 10r. "Utensils and Equipment: "Regardless of whether a milk storage/holding tank has had a partial removal of milk, the milk storage/holding tank shall be cleaned and sanitized when emptied and shall be emptied at least every seventy-two (72) hours. Milk storage/holding tanks used in the production of goat milk shall be cleaned and sanitized when empty and shall be emptied at least every seven (7) days. In the event of an emergency, such as inclement weather or natural disaster, etc., a variance may be permitted at the discretion of the Regulatory Agency.

2.1.7.b.2. In Item 7p. "Water Supply," under "Administrative Procedures", numbered paragraph "8," the words, "samples shall be taken" shall be amended to read "samples may be taken".

2.1.7.b.3. In Item 12p. "Cleaning and Sanitizing of Containers and Equipment," under "Administrative Procedures," numbered paragraph "(2)(d)" the word "shall" is amended to read "may".

2.1.7.b.4. In Item 12p. "Cleaning and Sanitizing of Containers and Equipment," under "Administrative Procedures," in the "Note" immediately following "Table 2" the word "shall" is amended to read "may".

2.1.7.b.5. In Item 12p. "Cleaning and Sanitizing of Containers and Equipment," under "Administrative Procedures," numbered paragraph "(6)(c)" the word "shall" is amended to read "may".

2.1.7.b.6. Item 17p. "Cooling of Milk and/or Milk Products," under "Administrative Procedures," numbered paragraph "11" the words "shall be taken" are amended to read "may be taken".

2.1.8. Section 8. Animal Health;

2.1.9. Section 9. Milk and Milk Products Which May Be Sold, except that the words "In the State of West Virginia" are substituted for the words "From and after twelve (12) months from the date on which this Ordinance is adopted,"

2.1.9.a. The following is added to Section 9. Milk and Milk Products Which May Be Sold: "The practice of selling raw milk as pet food, as a means of providing unpasteurized milk to the final consumer, is prohibited." "Offering or selling raw milk to the public is prohibited".

2.1.10. Section 10. Transferring; Delivery Containers; and Cooling;

2.1.11. Section 11. Milk and/or Milk Products From Points Beyond the Limits of Routine Inspection

2.1.11.a. Footnote 1 referenced in Section 11. means The State of West Virginia.

2.1.12. Section 12. Plans for Construction and Reconstruction;

2.1.13. Section 13. Personnel Health;

2.1.14. Section 14. Procedure When Infection or High Risk of Infection Is Discovered;

2.1.15. Section 15 Enforcement

2.1.16. Section 16 Penalty

2.1.16.a. Any person who shall violate any of the provisions of this *Ordinance* may be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not more than \$100.00 and/or such persons may be enjoined from continuing such violation(s). Each day upon which such a violation(s) occurs shall constitute a separate violation.

2.1.17. Section 17 Repeal and Date of Effect

2.1.18. Section 18 Separability Clause

2.1.19. Footnotes

2.1.20. Appendix A. Animal Disease Control;

2.1.21. Appendix B. Milk Sampling, Hauling and Transportation;

2.1.22. Appendix C. Dairy Farm Construction Standards and Milk Production;

2.1.23. Appendix D. Standards for Water Sources;

2.1.24. Appendix E. Examples of 3-Out-of-5 Compliance Enforcement Procedures;

2.1.25. Appendix F. Sanitization;

2.1.26. Appendix G. Chemical and Bacteriological Tests;

2.1.27. Appendix H. Pasteurization Equipment and Procedures and Other Equipment;

2.1.28. Appendix I. Pasteurization Equipment and Controls-Tests;

2.1.29. Appendix J. Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products;

2.1.30. Appendix K. HACCP Program;

2.1.31. Appendix L. Applicable Regulations, Standards of Identity for Milk and Milk Products and the *Federal Food, Drug, and Cosmetic Act*, and the *Federal Insecticide, Fungicide and Rodenticide Act*;

2.1.32. Appendix M. Reports and Records

2.1.32.a. All forms in Appendix M may be used unless another is approved by the Regulatory Agency.

2.1.33. Appendix N. Drug Residue Testing and Farm Surveillance;

2.1.34. Appendix O. Vitamin Fortification of Fluid Milk Products;

2.1.35. Appendix P. Performance-Based Dairy Farm Inspection System

2.1.36. Appendix Q. Operation of Automatic Milking Installations for the Production of Grade "A" Raw Milk for Pasteurization; and

2.1.37. Appendix R. Determination of Time/Temperature Control for Safety Milk and Milk Products.

2.1.38. Appendix S. Aseptic Processing and Packaging Program and Retort Processed After Packaging Program.

§61-15-3. Clarification of interstate responsibilities.

3.1. The Commissioner may enter into written agreements with the Regulatory Agency of states neighboring West Virginia for the purpose of clarifying regulatory responsibilities when a facility falling under the scope of this rule operates concurrently in West Virginia and the neighboring state.

§61-15-4. Certification of industry dairy farm inspectors (CIDFI).

4.1. Any person who has proven to the satisfaction of the WVDA to have sufficient education and experience to conduct dairy farm inspections and raw milk sampling may be certified as a Certified Industry Dairy Farm Inspector (CIDFI). All individuals to be certified shall submit paperwork for certification to the WVDA. The individual to be certified shall have had experience in the field of milk sanitation and shall be an employee of a milk plant, a producer association (CO-OP), or an officially designated laboratory, or shall be employed on a consulting basis.

4.2. All individuals to be certified by the WVDA must:

4.2.1. Understand and properly interpret the milk sanitation requirements as set forth in this rule;

4.2.2. Properly use the Dairy Farm Inspection Report form recommended by the WVDA

4.2.3. Adhere to the Dairy Farm Enforcement Procedures established by the WVDA; and

4.2.4. Promptly report any and all conditions that require action by the WVDA.

4.3. All Dairy Farm Inspection Reports as well as any spreadsheet(s) and the Receipt for the Grade A Dairy Farm Program Description comparing inspection results shall be maintained in the file for the individual CIDFI. In addition, observations made during the sampling evaluation will be reported on the most current Milk Sample Collector Evaluation Form. WVDA shall retain this form in the file for the CIDFI.

4.3.1. The certification of a CIDFI may be revoked by the WVDA upon finding that he/she:

4.3.1.a. Is not in agreement with the Certifying Official at least 80% of the time on items of sanitation as demonstrated during field evaluation;

4.3.1.b. Fails to submit all farm inspection reports in a timely manner;

4.3.1.c. Commits intentional/unintentional errors and/or omissions when recording inspection violations; or

4.3.1.d. Fails to comply with established administrative procedures of the WVDA, including maintaining proper inspection frequency.

§61-15-5. Reciprocity of certification.

5.1. A person who is a current CIDFI in another state and is responsible for dairy farms in West Virginia may be certified in West Virginia by reciprocity.

5.2. Each CIDFI shall submit all qualifications to the WVDA for approval before completing inspections in West Virginia.

§61-15-6. Submission of inspections, reports, and records.

6.1. Each individual, partnership, corporation, milk cooperative, company, firm, trustee, or association receiving raw milk for pasteurization shall furnish to the WVDA a complete list of the names and addresses of all dairy farms in a format acceptable to the WVDA. It is the responsibility of each CIDFI to update WVDA of producer changes (e.g. out-of-business, changes in producer milk shipments, producer identification numbers).

6.2. All Dairy Farm Inspection Reports as well as spreadsheet(s) and the Receipt for the Grade A Dairy Farm Program Description comparing inspection results shall be maintained in the file for the individual CIDFI. In addition, observations made during the sampling evaluation will be reported on the most current Milk Sample Collector Evaluation Form. WVDA shall retain this form in the file for the CIDFI.

§61-15-7. Farm inspection requirements for CIDFI.

7.1. CIDFIs shall perform unannounced routine and follow-up sanitation inspections of dairy farms permitted by the WVDA. Sanitation inspections of each Grade A producer (farm) shall be conducted at least every 6 months. A copy of the report of each sanitation inspection shall be forwarded promptly to the WVDA.

7.2. Inspections of dairy farms performed by CIDFIs do not preclude routine inspections or surveillance of individual dairy farms by the WVDA. State regulatory inspections are intended to supplement and complement the CIDFI Program and do not substitute for industry inspections. In order to assure satisfactory USPH/FDA ratings, it is essential that industry maintain its 6-month inspection frequency. The WVDA shall perform all enforcement actions. All inspections for the issuance of a permit or reinstatement of a suspended or revoked permit shall be conducted under the supervision of the WVDA. A copy of the report for each reinstatement or issuance of a permit shall be forwarded promptly to the WVDA.

§61-15-8. Seasonal milk producers.

8.1. "Seasonal milk producer" means a milk producer that stops producing milk for 30 days or more and then starts producing milk again within 12 months, consistently.

8.2. A seasonal milk producer or his/her designated CIDFI shall notify the WVDA prior to the first shipment of milk during the milking "season".

8.3. A seasonal milk producer's milk quality record will begin anew with each milking season.

§61-15-9. Official regulatory milk samples.

9.1. After collection of all raw milk samples, the producer association will randomly select, from the samples collected by the milk hauler, one sample each month to be used by the WVDA as the official regulatory sample for that month.

9.2. If more than one result is reported to the WVDA during the month, the first taken/reported sample is used as the official regulatory sample for that month. If multiple tanks are sampled on the same farm, on the same day, the results will be averaged.

9.3. The producers Co-Op is responsible for promptly notifying the WVDA of any violative sample results for the monthly official regulatory sample within 10 days of being made aware of the violation.

9.4. If the integrity of a monthly sample is called into question, the CIDFI may request results be discarded. WVDA has the authority to approve this request. If an official sample is disregarded, an additional sample for that month must be collected.

9.5. The WVDA shall send a Notice of Intent to Suspend Permit to a producer when at least two of the last four samples violate a standard (standard plate, somatic cell, or cooling temperature standards) Following such Notice, an additional sample may be collected.

§61-15-10. West Virginia milk advisory board.

10.1. The purpose of the West Virginia Milk Advisory Board is to advise the commissioner with respect to the status of the dairy industry in West Virginia, obstacles to manufacture, processing, and sale of milk and milk products, recommendations with respect to changes in statutes and regulation, changes in technology and processes utilized by the dairy industry, and other hindrances to growth of the industry in West Virginia.

10.2. The West Virginia Milk Advisory Board shall consist of not less than seven (7) voting members who shall be appointed by and serve at the will and pleasure of the commissioner. The commissioner may appoint any non-voting members on the board as necessary.

10.3. The commissioner shall designate one voting member to serve as chairman of the West Virginia Milk Advisory Board.

10.4. An annual meeting of the West Virginia Milk Advisory Board shall be held, and other meetings can be scheduled as needed.

10.5. All suggested changes, suggestions, or upcoming obstacles to the dairy law, rule, or any part of the dairy industry must be stated specifically and made known to the commissioner.