



**WEST VIRGINIA SECRETARY OF STATE**

**MAC WARNER**

**ADMINISTRATIVE LAW DIVISION**

**eFILED**

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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: 61-15  
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No  
RULE NAME: 61-15 Grade A Pasteurized Milk

**PRIMARY CONTACT**

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CITE STATUTORY AUTHORITY: §19-11E-8(1)

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:

The commissioner has the power and duty to:

- (1) 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: 6/14/2022

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/14/2022

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:

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.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Adding Section 2.3. "Procedures Governing the Cooperative State-Public Health Service. Adding Section 2.4. "The Methods of Making Sanitation Ratings of Milk Shippers"

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

There is no economic impact.

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

There is no economic impact.

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

There is no economic impact.

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2022 Increase/Decrease (use "-")	2023 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
<b>1. Estimated Total Cost</b>	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
<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 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).

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, 2032.

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 ("WVDA").

**§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~~ 2019 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, except that definition "~~WV~~ YY. Regulatory Agency" means the Commissioner of the West Virginia Department of Agriculture or his or her designee.

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: "Samples analyzed for added water and found to have a freezing point above -0.525 degrees Hortvet (or -0.507 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. Whenever used in this section, the words "the Regulatory Agency shall" 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 means the State of West Virginia.

2.1.7.b. 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.c. 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.d. 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.e. 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.f. 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".

2.1.7.g. The following is added to Section 7, ~~in~~ item 10r. Utensils and Equipment - Cleaning: "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. 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."

2.1.8. 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.”~~ and “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, which shall read as follows: “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;~~ RESERVED;
- 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 and Fermented High-Acid, Shelf-Stable Processing and Packaging Program; and
- 2.1.39 Appendix T. Preventative Controls for Human Food Requirements for Grade "A" Milk and Milk Products.

2.2. The "Evaluation of Milk Laboratories," 2019 Revision, as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, and the National Conference on Interstate Milk Shipments, is incorporated in its entirety by reference, except that Definition 12 of "Regulatory Agency" means the Commissioner of the West Virginia Department of Agriculture or his or her designee.

2.3. The "Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments," 2019 Revision, as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug

Administration, and the National Conference on Interstate Milk Shipments, is incorporated in its entirety by reference, except that Definition BB "Regulatory Agency" means the Commissioner of the West Virginia Department of Agriculture or his or her designee.

2.4. The "Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and Closures for Milk and/or Milk Products Manufacturers," 2019 Revision, as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, is incorporated in its entirety by reference, except that Definition 30 of "Regulatory Agency" means the Commissioner of the West Virginia Department of Agriculture or his or her designee.

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

3.1. The Commissioner may enter into written agreements with the regulatory agencies 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.

3.2. The Commissioner may enter into written agreements with the regulatory agencies of other states for the purpose performing some or all of the services required to be performed by this rule.

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

4.1. Any person who has proven to the satisfaction of the Commissioner 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 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 Commissioner 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 adopted by WVDA;

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

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

4.3. All Dairy Farm Inspection Reports as well as any spreadsheets and the receipt for the Grade A Dairy Farm Program Description comparing inspection results shall be maintained in the WVDA 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.

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

4.4.1. Is not in agreement with the Certifying Official at least eighty percent (80%) of the time on items of sanitation as demonstrated during field evaluation;

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

4.4.3. Commits errors and/or omissions when recording inspection violations; or

4.4.4. 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 Commissioner 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 WVDA a complete list of the names and addresses of all dairy farms in a format acceptable to WVDA. It is the responsibility of each CIDFI to advise 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 any spreadsheets, and the receipt for the Grade A Dairy Farm Program Description comparing inspection results shall be maintained in the WVDA 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 WVDA. Sanitation inspections of each Grade "A" producer (farm) shall be conducted at least once every 6 months. A copy of the report of each sanitation inspection shall be forwarded promptly to WVDA.

7.2. Inspections of dairy farms performed by CIDFIs do not preclude routine inspections or surveillance of individual dairy farms by 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.

7.3. All inspections for the issuance of a permit or reinstatement of a suspended or revoked permit shall be conducted under the supervision of WVDA. A copy of the report for each reinstatement or issuance of a permit shall be forwarded promptly to WVDA.

7.4. WVDA shall perform all enforcement actions.

**§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 or her designated CIDFI shall notify WVDA prior to the first shipment of milk during the seasonal milk producer's milking "season".

8.3. The regulatory agency shall carry the seasonal milk producer's milk quality sample history forward through the months where there is no production.

8.4. A seasonal milk producer shall notify WVDA of the beginning and end of production periods in order to allow for compliance checks.

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

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

9.2. If more than one result is reported to WVDA during the month, the first taken/reported sample will be 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 marketing organization is responsible for promptly notifying WVDA of any violative sample results for the monthly official regulatory sample within ten (10) days of being made aware of the existence of the violative sample.

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. 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 shall be collected.

**§61-15-10. West Virginia Dairy Advisory Board.**

10.1. The purpose of the West Virginia Dairy 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 Dairy 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 Dairy Advisory Board.

10.4. An annual meeting of the West Virginia Dairy 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.