

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #3

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2012 AUG 27 PM 1:03

OFFICE WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: DHHR - BUREAU FOR PUBLIC HEALTH TITLE NUMBER: 64

CITE AUTHORITY: WV Code §§16-1-4 and 16-7-5.

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 34

TITLE OF RULE BEING AMENDED: GRADE "A" PASTEURIZED MILK

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.



Authorized Signature

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 64CSR34 GRADE"A" PASTEURIZED MILK

Type of Rule: X Legislative Interpretive Procedural

Agency: Health and Human Resources

Address: One Davis Square
Suite 303
Charleston, WV 25301

Phone Number: 304-558-2971 Email: Ann.A.Goldberg@wv.gov

Fiscal Note Summary
Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

The Grade"A" Pasteurized Milk Program is an existing program with regulatory and laboratory personnel and equipment already in place. This amendment to the rule will not result in any additional costs or revenue to the state.

Fiscal Note Detail
Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2012 Increase/Decrease (use "-")	2013 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues	0	0	0

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

[Empty box for explanation of estimates]

Memorandum

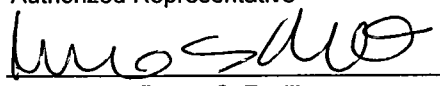
Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

The proposed rule adopts by reference the 2011 revision of the Federal Model Grade "A" Pasteurized Milk Ordinance which will bring West Virginia into compliance and conformity with the national standards.

[Empty box for memorandum content]

Date
8/27/12

Agency
Department of Health and Human Resources

Authorized Representative

Rocco S. Fucillo
Cabinet Secretary

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: August , 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) DHHR-WV Bureau for Public Health, Ann Goldberg
350 Capitol Street, Room 702, Charleston, WV 25301
304-558-2971 ann.a.goldberg@wv.gov OR
OEHS-Public Health Sanitation Division
350 Capitol Street, Room 313
Charleston, WV 25301

LEGISLATIVE RULE TITLE: _____

Grade "A" Pasteurized Milk, Title 64, Series 34

1. Authorizing statute(s) citation _____
West Virginia Code, §§16-1-4 and 16-7-5

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
filed for Public Comment July 5, 2012

b. What other notice, including advertising, did you give of the hearing?
n/a

c. Date of Public Hearing(s) *or* Public Comment Period ended:
Public Comment period ended August 6, 2012

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached _____ No comments received X

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

n/a

- f. Name, title, address and **phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Brad J. Cochran, Director
Public Health Sanitation Division
350 Capitol Street, Room 313
Charleston, WV 25301
Phone - (304)558-2981
Fax - (304) 558-1071

Email - Brad.J.Cochran@wv.gov

- g. **IF DIFFERENT FROM ITEM 'f'**, please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Richard Peggs
Public Health Sanitation Division
350 Capitol Street, Room 313
Charleston, WV 25301
Phone - (304)558-2981
Fax - (304)558-1071

Email - richard.l.peggs@wv.gov

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

n/a

b. Date of hearing or comment period:

comment period ran from July 5th to August 6th, 2012.

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

64CSR34, Grade "A" Pasteurized Milk
Legislative Rule
Department of Health and Human Resources
Bureau for Public Health
Office of Environmental Health Services

BRIEF SUMMARY

This proposed rule revises the current rule and adopts by reference the majority of the Federal Model Grade "A" Pasteurized Milk Ordinance, 2011 Revision, (PMO) published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. The federal rule establishes the sanitary standards for Grade "A" raw milk for pasteurization and Grade "A" pasteurized milk and milk products.

STATEMENT OF CIRCUMSTANCES

The use of the model ordinance facilitates the shipment and acceptance of Grade "A" milk and milk products of high sanitary quality in interstate and intrastate commerce. This rule change is necessary to bring West Virginia into compliance with the most recent federal requirements.

TITLE 64
LEGISLATIVE RULE
HEALTH

SERIES 34
GRADE "A" PASTEURIZED MILK

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

§64-34-1. 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 §§16-1-4 and 16-7-5.

1.3. Filing Date. -- ~~April 9, 2010.~~

1.4. Effective Date. -- ~~April 9, 2010.~~

~~1.5. Repeal and Replace. -- This rule repeals 64CSR34, "Grade 'A' Pasteurized Milk," of the West Virginia Board of Health, effective April 22, 2005.~~

1.6. 5. 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. 6. Enforcement. -- This rule is enforced by the Commissioner of the Bureau for Public Health.

§64-34-2. Incorporation By Reference of Federal Model Grade "A" Pasteurized Milk Ordinance.

2.1. The following portions of the Grade "A" Pasteurized Milk Ordinance, 2007 2011 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.a. Section 1. Definitions.

2.1.a.1. Except that definition "JJ. LL. Regulatory Agency" means the Commissioner, Bureau for Public Health, West Virginia Department of Health and Human Resources, or his or her designee. The term "regulatory agency" also means the appropriate agency having jurisdiction and control over matters embraced within this rule.

2.1.a.2. The following definitions are added to Section 1.:

2.1.a.2.A. "RR. TT. Imitation Milk and Imitation Milk Products and Non-Dairy Products -- Products manufactured from vegetable fats, (oils), or other derivatives other than milk fat and milk solids."

2.1.a.2.B. “~~SS. UU.~~ UU. Adulterated Milk and Milk Products -- Any milk or milk product is ~~considered to be~~ adulterated (1) if it bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health; (2) if it bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by State or Federal rules or regulations, or in excess of those tolerances, if any have been established; (3) if it consists, in whole or in part, of any substance unfit for human consumption; (4) if it has been produced, processed, prepared, packaged, or held under insanitary conditions; (5) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (6) if any substance has been added to the milk or milk product or mixed or packed with the milk or milk product so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.”

2.1.a.2.C. “~~TT. VV.~~ VV. Misbranded Milk and Milk Products -- ~~Any Milk and milk or milk products are is~~ misbranded: (1) when ~~their the~~ the container ~~or containers bear bears~~ or accompany accompanies any false or misleading written, printed or graphic matter; (2) when ~~they do~~ the milk or milk product does not conform to ~~their definitions as the definition of the same~~ the definition of the same contained in this rule; and (3) when ~~they are~~ the container is not labeled in accordance with this rule.”

2.1.a.3. The following statement is added to Definition ~~X. Z.~~ Z. Milk Products: “This definition ~~shall include~~ cottage cheese and dry curd cottage cheese and any other products designated as a milk product by the ~~Regulatory Agency~~ regulatory agency.”

2.1.b. Section 2. Adulterated or Misbranded Milk or Milk Products;

2.1.b.1. Footnote 1 referenced in Section 2 means the State of West Virginia.

2.1.b.2. 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° Hortvet (or -0508° Celsius) ~~shall be considered to be~~ are adulterated unless proven free of added water.”

2.1.c. Section 3. Permits;

2.1.c.1. Footnote 1 referenced in Section 3 means the State of West Virginia.

2.1.d. Section 4. Labeling;

2.1.e. Section 5. Inspection of Dairy Farms and Milk Plants;

2.1.e.1. Footnote 1 referenced in Section 5 means the State of West Virginia.

2.1.f. Section 6. The Examination of Milk and Milk Products;

2.1.f.1. The following is substituted for Section 6, The Examination of Milk and Milk Products number 4, after the second “NOTE:”: “When multiple samples of the same milk or milk products or imitation milk or imitation milk products or non-dairy milk products, except for aseptically processed products, are collected from the same producer or processor from multiple tanks or silos or containers on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.”

2.1.g. Section 7. Standards for Grade “A” Milk and Milk Products;

2.1.g.1. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 5p. Separate Rooms, Administrative Procedures: “7. Cottage cheese vats shall be located in a separate room, maintained free from insects and other vermin, and kept in a clean condition. Provided, that in facilities existing prior to the effective date of this rule, cottage cheese vats may be located in the processing room when there is no evidence of overcrowding, excessive traffic, condensation or splash. ~~and cottage~~ Cottage cheese vats located in the processing rooms shall be equipped with multi-service or single-service covers, which shall be kept in place at all times during the setting operation.”

2.1.g.2. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 7p. Water Supply, Administrative Procedures: “11. Water supply outlets are provided immediately available to the cottage cheese vats. The hose used for the transport of water for washing cottage cheese curd shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product.”

2.1.g.3. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 10p. Sanitary Piping: “~~Provided, that cottage~~ Cottage cheese, cheese dressings or cheese ingredients may be transported by other methods ~~which~~ that protect the product from contamination.”

2.1.g.4. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 15p. Protection from Contamination, 15p. (B) 2. after the second sentence: “~~Provided that the~~ The rinsing of cottage cheese curd with sanitized and/or acidified potable water may be accepted by the Regulatory Agency.”

2.1.g.5. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 18p. Bottling, Packaging and Container Filling after the first sentence: “Cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese may be transported in sealed containers in a protected, sanitary manner from one plant to another for creaming and/or packaging. If suitable equipment is not available for packaging dry curd cottage cheese, other methods of packaging which eliminate possible chances of contamination may be approved by the Regulatory Agency.”

2.1.g.6. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 18p. Bottling, Packaging and Container Filling, Administrative Procedures: “~~4.12.~~ 12. If cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese are protected in a sanitary manner, they may be transported in sealed containers from one plant to another for creaming and/or packaging.”

2.1.g.7. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p. Capping, Container Closure and Sealing and Dry Milk Product Storage, Administrative Procedures, 1.: “~~Provided further, that if~~ If suitable equipment is not available for capping cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese, other methods of capping which eliminate possible chances of contamination may be approved by the Regulatory Agency.”

2.1.g.8. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p, Capping, Container Closure and Sealing and Dry Milk Product Storage, Administrative Procedures, 4.: “Closures for cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese containers shall extend over the top edges of the container so as to protect the product from contamination during subsequent handling.”

2.1.g.9. The following is added to Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p, Capping, Container Closure and Sealing and Dry Milk Product Storage, Administrative Procedures, 5.: ~~“Provided, that this~~ This requirement shall not apply to cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese container closures, when the closures are supplied in a totally enclosed package, or wrapped so as to protect the closures.”

2.1.g.10. Footnote 1 referenced in Section 7. Standards for Grade “A” Milk and Milk Products means the State of West Virginia.

2.1.h. Section 8. Animal Health;

2.1.i. 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.i.1. The following is added to Section 9. Milk and Milk Products Which May Be Sold: “The practice of selling shares or other interests in dairy animals as a means of providing unpasteurized milk to the final consumer is prohibited.” “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.j. Section 10. Transferring; Delivery Containers; and Cooling;

2.1.k. Section 11. Milk and Milk Products From Points Beyond the Limits of Routine Inspection, except under Administrative Procedures number 9. the words “This provision will expire December 31, ~~2009~~, 2013, unless extended by future conference action.” are deleted;

2.1.k.1. Footnote 1 referenced in Section 11. means The State of West Virginia.

2.1.l. Section 12. Plans for Construction and Reconstruction;

2.1.m. Section 13. Personnel Health;

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

2.1.o. Appendix A. Animal Disease Control;

2.1.p. Appendix B. Milk Sampling, Hauling and Transportation;

2.1.q. Appendix C. Dairy Farm Construction Standards and Milk Production;

2.1.r. Appendix D. Standards for Water Sources;

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

2.1.t. Appendix F. Sanitization;

2.1.u. Appendix G. Chemical and Bacteriological Tests;

2.1.v. Appendix H. Pasteurization Equipment and Procedures and Other Equipment;

- 2.1.w. Appendix I. Pasteurization Equipment and Controls-Tests;
- 2.1.x. Appendix J. Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products;
- 2.1.y. Appendix K. HACCP Program;
- 2.1.z. 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.aa. Appendix N. Drug Residue Testing and Farm Surveillance;
- 2.1.bb. Appendix O. Vitamin Fortification of Fluid Milk Products;
- 2.1.cc. Appendix Q. Operation of Automatic Milking Installations for the Production of Grade “A” Raw Milk for Pasteurization; and
- 2.1.dd. Appendix R. Determination of Time/Temperature Control for Safety Milk and Milk Products.
- 2.2. The Federal Model Grade “A” Pasteurized Milk Ordinance is available on the internet at: <http://www.cfsan.fda.gov/~ear/pmo07toc.html>. <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipmentsNCIMSMModelDocuments/default.htm>

§64-34-3. Imitation Milk and Imitation Milk Products and Non-Dairy Products.

3.1. All plants processing imitation milk, imitation milk products or non-dairy products in West Virginia shall comply with the applicable requirements of Subdivisions 2.1.g, 2.1.j, 2.1.m, and 2.1.n of this rule.

3.2. All products and ingredients used in the manufacture of imitation milk, imitation milk products or non-dairy products shall be clean, safe and wholesome. Finished products shall meet the bacteriological standards established in this rule for pasteurized milk and milk products.

3.3. Imitation milk, imitation milk products and non-dairy products shall be processed after the completion of the day’s processing and bottling or packaging of all Grade “A” milk or milk products. If operational practices require that the products be processed during other periods, all food contact equipment and piping common to the products shall be disassembled, cleaned and sanitized or cleaned and sanitized by an approved clean-in-place system before processing or allowing Grade “A” milk or milk products to come in contact with equipment or piping.

§64-34-4. Clarification of Interstate Responsibilities.

The Commissioner may enter into written or verbal 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.

§64-34-5. Penalty for Violating Provisions of Rule.

Any person violating any of the provisions of this rule, or orders issued pursuant to this rule, is punishable by a fine of not less than fifty dollars (\$50.00) nor more than five hundred dollars (\$500.00) as

provided under W. Va. Code §16-1-18.

§64-34-6. Administrative Due Process.

Any person adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests, or privileges shall do so in accordance with the Bureau for Public Health rule, “Rules and Procedures for Contested Case Hearings and Declaratory Rulings”, 64CSR1.