

Form #2

OFFICE WEST VIRGINIA
SECRETARY OF STATE

ATTACH A BRIEF SUMMARY OF YOUR PROPOSAL

**Department of Health and Human Resources
Bureau for Public Health
Legislative Rule
Title 64, Series 34**

GRADE "A" PASTEURIZED MILK

BRIEF SUMMARY

The proposed legislative rule will update the current Grade "A" milk rule last amended in April, 2005. The proposed rule adopts by reference the majority of the federal model Grade "A" Pasteurized Milk Ordinance, 2007 Revision, published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, which establishes the sanitary standards for Grade "A" raw milk for pasteurization and Grade "A" pasteurized milk and milk products. The 2005 amendments adopted the 2001 federal model Grade "A" Milk Ordinance. This rule is necessary to bring West Virginia into compliance with the federal rule.

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.

Butter, cheese and ice cream are not Grade "A" milk products by definition and their production is regulated under The Code of Federal Regulations, Title 21-Food and Drugs, Chapter 1-Food and Drug Administration, Department of Health and Human Services, Subchapter B-Food for Human Consumption, Part 110-Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. The proposed rule is indirectly applicable to butter, cheese and ice cream production in that the federal model Grade "A" Pasteurized Milk Ordinance represents the Food and Drug Administration's Good Manufacturing Practices guidelines for the dairy industry for pasteurization processes and is, therefore, applicable to the pasteurization of milk for the manufacture of butter, cheese and ice cream. Additionally, butter, cheese and ice cream are often manufactured from Grade "A" raw milk which is regulated under the proposed rule.

**Department of Health and Human Resources
Bureau for Public Health
Legislative Rule
Title 64, Series 34**

GRADE "A" PASTEURIZED MILK

STATEMENT OF CIRCUMSTANCES

The existing rule governing production of Grade "A" raw and pasteurized milk is outdated (based on the 2001 federal model ordinance) and no longer provides the necessary standards to protect the public from milkborne disease or to be considered equivalent to national standards for the purpose of milk shipments in interstate commerce.

The Public Health Service (PHS), Food and Drug Administration (FDA) recommended Grade "A" Pasteurized Milk Ordinance is the basic standard used in the voluntary "Cooperative State - PHS/FDA Program for the Certification of Interstate Milk Shipments," a program participated in by all fifty (50) States, the District of Columbia and U.S. Trust Territories. The National Conference on Interstate Milk Shipments has determined that states having rules based on federal model milk codes dated prior to and including the 2001 are no longer substantially equivalent to the current Grade "A" Pasteurized Milk Ordinance, 2007 Revision.

The proposed rule adopts by reference the 2007 Revision of the federal model Grade "A" Pasteurized Milk Ordinance which would bring the State of West Virginia into conformity with national standards and up-to-date with technological advances in milk production and safety which have occurred since adoption of the 2001 federal model ordinance.

Agency:
CBD Number:
Resolution Number:
CBD Subject:

HEALTH AND HUMAN RESOURCES

Version: Bill Number:

FUND (S)

Sources of Revenue

General Fund ☒ Special Fund _____ Other Fund (Specify) _____

Does the proposed legislation create:

New Program _____ New Fund _____ Neither ☒

Fiscal Note Summary

Explain 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 rule revision will result in no additional costs or revenues.

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		
	2009 Increase/Decrease (use "-")	2010 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
Equipment	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

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

Please explain increases and decreases in personal services, current expenses, etc., including assumptions and data source and delineation between start-up and ongoing costs. Please also include a long-range schedule of costs and revenues if fiscal impact is expected to vary in future years.

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 2007 Revision of the federal model Grade "A" Pasteurized Milk Ordinance which would bring the State of West Virginia into conformity with national standards and up-to-date with technological advances in milk production and safety which have occurred since adoption of the 2001 federal model ordinance.

Date

6-24-09

Agency

Department of Health and Human Resources

Authorized Representative


Marya Yeager Walker
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: June , 2009

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) DHHR-WV Bureau for Public Health
350 Capitol Street, Room 702, Charleston, WV 25301-3712
Contact: Ann Spaner at 304-558-2971
OEHS-Public Health Sanitation Division
1 Davis Square, Suite 200
Charleston, WV 25301-1798

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:

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

c. Date of Public Hearing(s) *or* Public Comment Period ended:

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

Attached _____ No comments received _____

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

- 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

1 Davis Square, Suite 200, Charleston, WV 25301

Phone - (304)558-6730

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)

Phillip R. Jones Jr., Assistant Director

Public Health Sanitation Division

1 Davis Square, Suite 200, Charleston, WV 25301

Phone - (304)558-6728

Fax - (304)558-1071

Email - Phillip.R.Jones@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.

b. Date of hearing or comment period:

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

TITLE 64
LEGISLATIVE RULES
BUREAU FOR PUBLIC HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 34
GRADE "A" PASTEURIZED MILK

FILED

2009 JUN 25 AM 11:03

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. -- WV Code §§ 16-1-4 and 16-7-5.

1.3. Filing Date. -- April 22, 2005.

1.4. Effective Date. -- April 22, 2005.

1.5. Repeal and Replacement of Former Rules. -- This legislative rule repeals and replaces Division of Health rule, "Grade 'A' Pasteurized Milk," 64CSR34, filed April 22, 2005, and effective April 22, 2005.

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 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 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. 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. 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. 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 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. Misbranded Milk and Milk Products -- Milk and milk products are misbranded (1) when their container or containers bear or accompany any false or misleading written printed or graphic matter; (2) when they do not conform to their definitions as contained in this rule; and (3) when they are not labeled in accordance with this rule."

2.1.a.3. The following statement is added to Definition X. 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."

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 (-0508° Celsius) shall be considered to be 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 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 for 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 cheese, cheese dressings or cheese ingredients may be transported by

other methods which 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 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: “13. 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 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 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."

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, 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*;
 - 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>.

§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

pipng.

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

4.1. 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.

5.1. 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 WV Code §16-1-18.

§64-34-6. Administrative Due Process.

6.1. 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.