

**WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION**

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OFFICE WEST VIRGINIA
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Form #6

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 34

TITLE OF RULE BEING AMENDED: Grade "A" Pasturized Milk

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) SB 341,

SECTION §64-5-2(e), PASSED ON April 8, 2005

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE

FOLLOWING DATE: ~~April 8, 2005~~ April 22, 2005

Martha Yeager Walker

Authorized Signature

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

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

SERIES 34
GRADE "A" PASTEURIZED MILK

§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. -- ~~December 21, 2004~~ April 22, 2005

1.4. Effective Date. -- ~~April 5, 2005~~ 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 February 1, 1980, and effective July 1, 1980.

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, 2001 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 hereby incorporated by reference:

2.1.a. Section 1, Definitions;

2.1.a.1. Except that definition "BB. 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 these milk rules.

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

2.1.a.2.A. "EE. 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. "FF. Adulterated Milk and Milk Products -- Any milk or milk product is deemed 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 such tolerances, if one has 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 thereto or mixed or packed therewith 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. "GG. 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 P, Milk Products: "This definition shall include cottage cheese and dry curd cottage cheese and such other products as may be 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.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.f. Section 6, The Examination of Milk and Milk Products;

2.1.f.1. The following is added to Section 6, The Examination of Milk and Milk Products number 4: "When multiple samples of the same milk or milk products or imitation milk or imitation milk products or non-dairy products, except for aseptically processed products, are collected from the same producer or processor from multiple tanks or silos 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 such 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: "9. 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 18p, Bottling and

Packaging: "Provided, that 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.5. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 18p, Bottling and Packaging, 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.6. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p, Capping, 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.7. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p, Capping, 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.8. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p, Capping, 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 such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures."

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."

2.1.j. Section 10, Transferring; Delivery Containers; Cooling;

2.1.k. Section 11, Milk and Milk Products From Points Beyond the Limits of

Routine Inspection, except under Administrative Procedures number 7 the words “This provision will expire on December 31, 2003 unless extended by future Conference action.” are deleted;

- 2.1.l. Section 12, Plans for Construction and Re-Construction;
- 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;
- 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 L, Applicable Regulations, Standards of Identity for Milk and Milk Products and the *Federal Food, Drug, and Cosmetic Act*;
- 2.1.z. Appendix N, Drug Residue Testing and Farm Surveillance; and
- 2.1.aa. Appendix O, Vitamin Fortification of Fluid Milk Products.

2.2. The Federal Model Grade “A” Pasteurized Milk Ordinance is available on the internet at: <http://www.cfsan.fda.gov/~ear/pmo01toc.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 Section 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 herein 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. Should operational practices require that such 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.

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.