WEST VIRGINIA
SECRETARY OF STATE
-JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION

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OFFICE WEST VIRGINIA
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NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: West Virginia Department of Agriculture TITLE NUMBER: 61

CITE AUTHORITY: 19-11A-10

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 4C

TITLE OF RULE BEING AMENDED: Dairy Products and Imitation Dairy Products

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULES, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE, IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

Authorized Signature

$4.00

TITLE 61
LEGISLATIVE RULE
DEPARTMENT OF AGRICULTURE

SERIES 4C
DAIRY PRODUCTS AND IMITATION DAIRY PRODUCTS

§61-4C-1. General.

1.1. Scope - This legislative rule establishes the requirements governing the manufacture and distribution of dairy products and imitation dairy products. Frozen desserts, as defined by W. Va. Code, §19-11A-1 et seq., will be enforced by W. Va. Code, §19-11b-1 et seq., and legislative rules promulgated under that article.

1.2. Authority -- W. Va. Code §19-11A-10.

1.3. Filing Date -- ~~March 26, 1996.~~

1.4. Effective Date -- ~~June 7, 1996~~.

§61-4C-2. Incorporation by Reference.

2.1. The following documents are adopted in their entirety:

2.1.a. Title 21 Code of Federal Regulations ~~(April 1, 1995)~~ (April 1, 2003).

2.1.b. Title 40 Code of Federal Regulations ~~(July 1, 1994)~~ (July 1, 2002).

2.1.c. 16th edition of the "Standard Methods for the Examination of Dairy Products" published by the American Public Health Association, 1015 ~~Eighteenth~~ Fifteenth Street, N.W., Washington, D.C. ~~20036~~ 20005.

2.1.d. ~~16th edition and supplements to the "Official Methods of Analysis" published by the Association of Official Analytical Chemists, Suite 400, 2200 Wilson Boulevard, Arlington, Virginia 22201~~. 17th Edition and supplements to the Official Methods of Analysis of AOAC International (formerly known as the Association of Official Analytical Chemists), published by AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877-2417.

2.1.e. ~~7th edition and supplements to the "U.S. Food and Drug Administration Bacteriological Analytical Manual" published by the Association of Official Analytical Chemists, Suite 400, 2200 Wilson Boulevard, Arlington, Virginia 22201.~~ 8th Edition and supplements to the "U.S. Food and Drug Administration Bacteriological Analytical Manual" published by AOAC International, 481 North Frederick Avenue, suite 500, Gaithersburg, Maryland 20877-2417.

2.1.f. Grade "A" Pasteurized Milk Ordinance, 2001, published by the Food and Drug Administration, 200 "C" Street, SW, Washington, DC 20204

§61-4C-3. Definitions and Standards of Identity.

3.1. The provisions of 21 CFR Part 131 establish standards of identity for milk and cream, which include milk, acidified milk, cultured milk, cultured buttermilk, concentrated milk, condensed milk, sweetened condensed milk, sweetened condensed skimmed milk, lowfat dry milk, nonfat dry milk, nonfat dry milk fortified with vitamins A and D, evaporated milk, evaporated skimmed milk, lowfat milk, acidified lowfat milk, cultured lowfat milk, cultured lowfat buttermilk, skim milk, nonfat milk, acidified skim milk, acidified nonfat milk, cultured skim milk, cultured nonfat milk, dry whole milk, dry cream, heavy cream, heavy whipping cream, light cream, coffee cream, table cream, light whipping cream, whipping cream, sour cream, cultured sour cream, acidified sour cream, eggnog, half-and-half, sour half-and-half, cultured sour half-and-half, acidified sour half-and-half, yogurt, lowfat yogurt and nonfat yogurt.

3.2. "Milk products" includes products made from the milk products from a cow, goat or sheep.

3.3. The provisions of 21 CFR Part 133 establish standards of identity for cheese and related cheese products, which include asiago fresh, asiago soft, asiago medium, asiago old, blue, brick, caciocavallo siciliano, cheddar, colby, cook or koch kaese, cottage, dry curd cottage, lowfat cottage, cream, edam, gammelost, gorgonzola, gouda, gruyere, limburger, monterey, monterey jack, high moisture jack, mozzarella, scamorza, part-skim mozzarella, part-skim scamorza, muenster, munster, neufchatel, nuworld, parmesan, provolone, reggiano, romano, roquefort, samsoe, sap sago, swiss, emmentaler, sheep's milk blue-mold, blue-mold cheese from sheep's milk, swiss, emmentaler, cold-pack, and pasteurized blended cheese.

3.4. The provisions of 21 CFR Part 135 establish standards of identity for ice cream, frozen custard, french ice cream, french custard ice cream, goat's milk ice cream, goat's milk frozen custard, goat's milk french ice cream, mellorine, fruit sherbet and non-fruit sherbet.

3.5. Goat milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat.

3.6. Butter is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 percent by weight of milkfat, all tolerances having been allowed for.

3.7. The provisions of 21 CFR Part 166 establish the standard of identity for margarine and oleomargarine.

3.8. A dairy product or imitation dairy product for which no standard of identity exists may be defined by the Commissioner according to current acceptable industry and government standards and practices.

§61-4C-4. Permits.

4.1. Permits are not transferable with respect to persons or locations.

4.2. An applicant for a permit shall complete forms supplied by the commissioner and shall provide any information considered necessary by the commissioner.

4.3. A permittee shall post his or her permit prominently at the place of operation.

4.4. The Commissioner shall issue a dairy products distributors permit to each person distributing dairy

products in this state, even if there is no permanent location maintained in this state. A person maintaining multiple permanent locations in this state or distributing into this state from several locations shall obtain a permit for each location. A person shall apply for a permit at least fifteen days before the date that the current permit expires or within fifteen days of the date that the person intends to engage in business. The application shall be accompanied by a fee of $75.00. The Commissioner shall add a penalty of $100.00 to all permits that are not applied for or renewed within this time limit. Permits expire on the thirty-first day of March following date of issue.

4.1.5. Persons interested in distributing a dairy product which is not covered by a standard of identity ~~must~~ shall obtain a temporary marketing permit prior to the distribution.

4.2.6. Persons interested in obtaining a temporary marketing permit for a dairy product shall apply by letter to the commissioner. A label for each product shall be submitted with the letter.

4.3.7. The commissioner has thirty days to review the information in the letter and either issue or deny a temporary marketing permit.

4.4.8. The commissioner shall issue temporary marketing permits valid for a one-year period from the date of issue; however, the commissioner may request information supporting the continued approval of the dairy product in the interim.

4.5.9. If no standard of identity exists at the time of the permit's expiration date, a person may reapply for a temporary marketing permit for the same dairy products.

4.6.10. The commissioner may suspend the temporary marketing permit at any time when he or she finds that the person or the dairy product is not in compliance with W. Va. Code, §19-11A-1 et seq. or this rule. A dairy product listed on the suspended temporary marketing permit must be removed from distribution in this State by the permittee.

4.11. Individuals, churches, fraternal organizations and other organizations distributing or manufacturing product for members of their group or their guests on an intermittent and infrequent basis are exempt from the permitting requirements of W. Va. Code, §19-11A-3.

§61-4C-5. Labeling.

5.1. Each dairy product or imitation dairy product for which no standard of identity exists must have a label attached with the following information, except as provided in subsection 5.5 of this rule:

5.1.a. The brand name, if any, and the product name. The product name is the name that accurately identifies and describes the product. The name shall not be so similar to the name of any other food so as to be confusing to the average consumer.

5.1.b. The quantity of the product in the container shall be expressed in pounds, ounces, gallons, pints, quarts or fluid ounces. A combination of numerical count and weight may be used for multi-unit packages. In addition to these units, metric declarations may be used. All statements of quantity shall be accurate with reasonable variations due to packaging allowed.

5.1.c. The name and address of the manufacturer, packer or distributor. The address shall include the city, state and zip code. A street address is required to identify the company when there are several companies of that name in that city or if the street address is not available through a city or telephone directory. When the

product is not manufactured by the company whose name appears on the label, the name shall be qualified by a phrase that reveals the company's connection with the food, such as "Manufactured for _____", or "Distributed by _____"; and

5.1.d. A lot designation or code date to provide identification of the product. ~~with a specific production time period~~. In addition, if the name on the label is not the manufacturer, the lot designation or code date shall identify the manufacturer. ~~in addition to a specific production time period.~~

5.2. If ingredient statements or nutritional claims are made on the product label or in labeling, the requirements of 21 CFR Part 101, as incorporated by reference in section 2 of this rule, must be met.

5.3. No person may use a product name on a menu, sign or any other advertising unless that name clearly reflects the accurate name of the product.

5.4. Products labeled as requiring refrigeration must be maintained under refrigeration throughout distribution and while on retail display.

5.5. A manufacturer or distributor shall not distribute any package, of whatever form, without a complete label attached except for:

5.5.a. product sold at the place of manufacturing in any package that is not completely closed when offered for sale or that is closed at the time of sale. This product is exempt from the label requirements of W. Va. Code, §19-11A-4 and of this section for quantity and for the name and address of the manufacturer, packer or distributor;

5.5.b. product sold at the place of manufacturing that is placed in a package after the customer orders the product. This product is exempt from all labeling requirements of W. Va. Code, §19-11A-4 and of this section of the rule.

5.5.c. product sold in a container from which product is dipped, and commonly known as a "bulk container", and where the product is not offered for sale to the ultimate consumer in the bulk container. This product is exempt from the label requirements of W. Va. Code, §19-11A-4 and of this section for the name and address of the packer, manufacturer or distributor, provided that the product label identifies the manufacturing location by means of a plant number or other means. The product is also exempt from the label requirements of W. Va. Code, §19-11A-4 for the product name and quantity of the contents, provided that the quantity of contents of the size container(s) sold and the product name(s) are clearly indicated on the invoice; and

5.5.d. product packaged in units sold in a multi-unit container, provided that each individual unit remains within the multi-unit container during distribution and the multi-unit container is labeled according to the requirements of W. Va. Code, §19-11A-4 and of this section of the rule.

5.6 Any dairy product or imitation dairy product being shipped in interstate commerce must meet the labeling requirements of the U.S. Food and Drug Administration. If any portion of this section is found to be in conflict with the federal labeling requirements for products shipped in interstate commerce, the federal requirements take precedence.

5.7. The label shall meet the minimum labeling requirements for 21 CFR Part 101 "Nutritional Labeling".

§61-4C-6. Misbranded.

6.1. Any product referred to in W. Va. Code, §19-11A-1 et seq. or this rule is misbranded if:

6.1.a. its container is so made, formed or filled as to be misleading;

6.1.b. it purports to be or is represented as a food for which a definition or standard of identity has been prescribed in section 3 of this rule and its quality does not meet the requirements of the definition or standard of identity;or

6.1.c. it does not meet minimum labeling requirements of 21 CFR Part 101. ~~Title 21 Code of Federal Regulations. (April 1, 1995) or Section 5 of this rule;~~

§61-4C-7. Adulteration.

7.1. A dairy product or imitation dairy product is adulterated if:

7.1.a. any substance has been added to the product or mixed or packed with the product so as to make it appear of greater value than it is, and the substance is not clearly noted in the ingredient statement or by other means on the label;

7.1.b. the bacterial counts, except for sterile hermetically sealed products, exceed a count of fifty thousand (50,000) per gram for the standard plate count and/or ten (10) per gram for the coliform group count;

7.1.c. the bacterial counts for sterile hermetically sealed product exceed <1 per gram for standard plate count and/or <1 per gram for the coliform count;

7.1.d. any bactericidal substance has been added to the product, such as a sanitizer, preservative or any other chemical with bactericidal properties. A product is not adulterated due to the presence of any sanitizer residue where the residue is caused as a normal consequence of sanitizing the equipment while using standard industry practices;

7.1.e. pathogenic bacteria are in the product;

7.1.f. its quality does not meet the requirements of the definition or standard of identity as outlined in section 3 of this rule; or

7.1.g. its quality does not meet the requirements for currently accepted standards by industry and government. defined by the Commissioner.

7.2. ~~Tolerances for the presence of pesticide residues are those tolerances designated in 40 CFR Part 185, as adopted by reference in section 2 of this rule. Tolerances for the presence of antibiotics are those tolerances designated in 21 CFR Part 556, as adopted by reference in section 2 of this rule. Tolerances for unavoidable poisonous or deleterious substances are those tolerances designated in 21 CFR Part 109.30, as adopted by reference in section 2 of this rule.~~ Tolerances for the presence of pesticide residues, antibiotics, and unavoidable poisonous or deleterious substances are those tolerances designated in 40 CFR Part 180, as adopted by reference in section 2 of this rule.

§61-4C-8. Prohibited Acts.

8.1. ~~No~~ A person may not use non-pasteurized eggs or egg products in any product unless the product is pasteurized subsequent to the addition of the eggs or egg products.

8.2. ~~No~~ A person may not produce any product in equipment that has not been cleaned and sanitized.

8.3. ~~No~~ A person may not use any spilled, overflowed and/or leaked products in manufacturing any other product.

8.4. ~~No~~ A person may not use steel wool or metal sponges for cleaning equipment and utensils used for manufacturing.

8.5. ~~No~~ A person may not use any method for sanitizing that adversely affects the equipment, dairy product or the health of the consumers consuming the product. However, the commissioner will not prohibit the use of chemicals commonly used in the industry for cleaning and sanitizing dairy equipment using normal industry practices due to the causing of corrosion of the equipment as long as the corrosion caused by such use is minimal.

8.6. A person may not offer for sale, transport or distribute frozen product that has been allowed to exceed a temperature of 0°F.

§61-4C-9. Animal Health.

9.1. All products shall be made from milk products or milk-derived ingredients from herds which are located in a Modified Accredited Tuberculosis Area , Modified Accredited Advanced Tuberculosis Area or a Tuberculosis Free Area as determined by the U.S. Department of Agriculture, Provided, that herds located in an area that fails to maintain accredited status shall have been accredited by the U.S. Department of Agriculture as tuberculosis free, or shall have passed an annual tuberculosis test that is performed by a veterinarian accredited by the United States Department of Agriculture, Animal and Plant Health Inspection Service.

9.2. All products shall be made from milk products or milk-derived ingredients from herds which are under a brucellosis eradication program which meets one of the following conditions:

9.2.a. the herd is located in a Certified Brucellosis-free Area as defined by the U.S. Department of Agriculture and enrolled in the testing program for that area;

9.2.b. the herd meets the U.S. Department of Agriculture requirements for an individually Certified Brucellosis-Free Herd;

9.2.c. the herd is participating in a milk ring testing program at least four times per year at approximately ninety (90) day intervals, and any herd where any animal has a positive milk ring test shall have all animals that are producing milk, or that have recently produced milk, tested with the milk ring test within thirty (30) days from the date of the laboratory ring tests; or

9.2.d. the herd has had an individual blood agglutination test annually with an allowable maximum grace period not exceeding 2 months.

§61-4C-10. Powers and Duties of the Commissioner.

10.1. The commissioner shall inspect and sample product from all dairy products and imitation dairy products distributors within the limits of his or her resources.

10.2. The commissioner recommends that each dairy products and imitation dairy products distributor supplement the sampling performed by the commissioner with tests by an independent laboratory.

10.3. All products from dairy products and imitation dairy products distributors taken by the commissioner for testing are considered official product samples; except that,

10.3.a. The commissioner may have service samples taken of dairy products or imitation dairy products, which would be considered unofficial.

10.4. Only official samples will be considered when applying the enforcement policy.

§61-4C-11. Approved Sampling and Testing Methods.

11.1. Procedures for the collection and holding of official product samples, the selection and preparation of apparatus, media and reagents, and the analytical procedures, incubation, reading and reporting of results, shall be in compliance with the standards set forth in the Standard Methods for the Examination of Dairy Products; the Official Methods of Analysis of AOAC International; procedures referenced in 21 CFR Parts 131, 133, 135, or 166; or other methods as approved by the commissioner, whichever method is applicable to the product being tested.

11.2. The Roese-Gottlieb Fat Extraction Method of testing for milkfat is adopted as the approved method for determining the milkfat content of product and is approved for all milkfat testing.

11.2.a. Milkfat tolerances for lowfat and nonfat products are ± fifteen percent (.15%). Tolerances for the method will be added to this tolerance.

11.3. Aseptically processed products packaged in hermetically sealed containers shall be opened in accordance with procedures published in the U.S. Food and Drug Administration Bacteriological Analytical Manual, as adopted by reference in section 2 of this rule.

11.4. ~~The testing methods for drug residues in product are those listed in 21 CFR Part 556, as adopted by reference in section 2 of this rule, where applicable.~~ The testing of products for drug residues shall include any of those residues listed in 21 CFR Part 556, and shall use methods adopted by reference in section 2 of this rule.

§61-4C-12. Enforcement Policy.

12.1. The commissioner may assess a violation of W. Va. Code, §9-11A-1 et seq. or of this rule against the manufacturer, distributor and/or retailer of a dairy product or an imitation dairy product. Violations may be assessed cumulatively by standard of identity, standard of identity and container size, sampling location or by distributor depending upon the sampling scenario.

12.2. Whenever one of the last five consecutive official product samples taken on separate days within a one-year period are found to be adulterated or misbranded, the commissioner shall send a written "First Notice" to the manufacturer, distributor or retailer, whichever is appropriate. This notice shall notify the manufacturer,

distributor or retailer of the violation of W. Va. Code, §19-11A-1 et seq. or of this rule and the enforcement policy established by this section of the rule.

12.2.a. The commissioner shall collect additional official product samples within twenty-one (21) days of the sending of a First Notice to the manufacturer, distributor or retailer, but shall not collect product samples before the lapse of 7 days from the sending of a First Notice.

12.3. Whenever two of the last five (5) consecutive official product samples taken on separate days within a one-year period are found to be adulterated or misbranded, the commissioner shall send a written "Second Notice" to the manufacturer, distributor or retailer, whichever is appropriate.

12.3.a. The commissioner shall collect additional official product samples within twenty-one (21) days of the sending of a Second Notice to the manufacturer, distributor or retailer, but shall not collect product samples before the lapse of seven (7) days from the sending of a Second Notice.

12.4. Whenever three of the last five (5) consecutive official product samples taken on separate days within a one-year period are found to be adulterated or misbranded the commissioner shall send a written "Third Notice" to the manufacturer, distributor or retailer, whichever is appropriate.

12.4.a. The commissioner shall collect additional official product samples within twenty-one (21) days of the sending of the Third Notice to the manufacturer, distributor or retailer, but shall not collect additional product samples before the lapse of seven (7) days from the date of sending of the Third notice.

12.5. Whenever an antibiotic or pesticide residue test is found to be above tolerance, the commissioner shall notify the manufacturer and/or distributor immediately of this fact and shall begin an investigation to determine the cause of the residue. The commissioner shall require that any person found to be responsible for the residue shall correct the cause of the residue prior to the resumption of the manufacturing or distribution of the product.

12.6. A person who performs a recall by voluntarily removing product from sale and distribution in an effective manner so as to limit the potential harm to the health and well-being of the public may be eligible for exemptions from the normal enforcement policy. The commissioner shall consider the facts of each case when making a decision on an exemption.

12.7. The commissioner may apply the enforcement policy in a liberal manner in cases where all official product sample results that involve a product in the form actually sold to the public have been found to be in conformance with W. Va. Code, §19-11A-1 et seq. or this rule.

12.8. The commissioner may suspend the standard enforcement policy in cases where such action is necessary to protect the public's health, safety or welfare.

12.9. The commissioner may consider resamples necessary to determine that the non-violative status is being maintained.

12.10. The commissioner may take other action as considered necessary in order to carry out the provisions of W.Va. Code §19-11A-1 et seq. and these rules.

§61-4C-13. Suspensions, Embargo Orders.

13.1. If the commissioner finds that effective corrective action has not been taken by the distributor, he or she may issue a suspension of the Dairy Products Distributor Permit required in W. Va. Code §19-11A-3. The suspension shall state the time that the suspension will become effective, give the reasons for the suspension and specify a time and place for a hearing to be held in this matter. Except that in the case of a summary suspension, the commissioner will give the distributor the opportunity to request a hearing in this matter subsequent to the notification of the suspension.

13.1.a. All suspensions due to non-conformance to subdivisions 7.1.b., 7.1.c. and 7.1.e. of this rule are summary suspensions.

13.1.b. A suspension of the Dairy Products Distributor Permit remains in effect until the distributor submits and the commissioner accepts a written plan of correction and a request for a reinstatement of the permit.

13.1.c. The commissioner has seven days from the date of receipt of this plan of correction to respond to a suspension in the case of violations of subdivisions 7.1.b., 7.1.c. and 7.1.e. of this rule and fourteen days to respond for all other violations of W. Va. Code, §19-11A-1 et seq. or this rule. The commissioner will accept or deny the application for a reinstatement of the permit and will give the terms and conditions under which the permit will be reinstated.

13.2. If the commissioner finds that after the distributor has resumed distribution following a suspension of their Dairy Products Distributor Permit that effective corrective action has not been taken, then the commissioner will hold a hearing to determine if the permit should be revoked.

13.3. If the commissioner finds that effective corrective action has not been taken by the manufacturer, distributor and/or retailer, he or she may issue an embargo order for any dairy product or imitation dairy product which is not in compliance with W. Va. Code, §19-11A-1 et seq. or this rule and may also cause the manufacturing and distributing of any dairy or imitation dairy product to cease by authority of W. Va. Code, §19-11A-10(i).