

SECRETARY OF STATE

KEN HECHLER

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ADMINISTRATIVE LAW DIVISION

#2

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Department of Agriculture TITLE NUMBER: 61

RULE TYPE: Legislative; CITE AUTHORITY 19-11A-10

AMENDMENT TO AN EXISTING RULE: YES NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED:

TITLE OF RULE BEING AMENDED:

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 4C

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

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 24, 1995 AT 4:00 p.m.

ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

West Virginia Department of Agriculture
Regulatory Protection Division
Attn: John Liggett
1900 Kanawha Blvd., East
Charleston, WV 25305

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

[Handwritten signature]

ATTACH A BRIEF SUMMARY OF YOUR PROPOSAL

5.20 5.20

STATEMENT OF CIRCUMSTANCES

Regulatory Protection Division
West Virginia Department of Agriculture

Dairy Products and Imitation Dairy Products

LEGISLATIVE RULE
§61-4c-1 et seq.

To implement Chapter 19, Article 11-A of the West Virginia Code. These rules outline the procedures necessary for implementing Article 11-A with regard to the establishment of standards for the manufacture and sale of dairy products.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Dairy Products and Imitation Dairy Products

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Department of Agriculture

Address: Regulatory Protection Division
1900 Kanawha Blvd., East
Charleston, WV 25305

1. Effect of Proposed Rule

	ANNUAL FISCAL YEAR				
	INCREASE	DECREASE	CURRENT	NEXT	HEREAFTER
<u>ESTIMATED TOTAL COST</u>	\$ 4,000	\$ 0	\$ 4,000	\$ 4,000	\$ 4,000
PERSONAL SERVICES	0	0	0	0	0
CURRENT EXPENSE	4,000	0	4,000	4,000	4,000
REPAIRS & ALTERNATIONS	0	0	0	0	0
EQUIPMENT	0	0	0	0	0
OTHER	0	0	0	0	0

2. Explanation of above estimates:

The Annual Current Expense Estimate reflects the costs associated with the supplies necessary to collect and test dairy product samples.

3. Objectives of these rules:

To implement Chapter 19 Article 11A of the West Virginia Code. These rules outline the procedures necessary for implementing Article 11A.

Rule Title: Dairy Products and Imitation Dairy Products

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of Citizens.

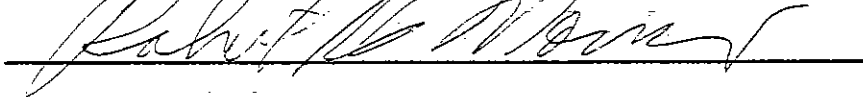
None

C. Economic Impact on Citizens/Public at Large.

None

Date: 6-23-95

Signature of Agency Head or Authorized Representative



Summary

Dairy Products and Imitation Dairy Products

§61-4C-1 et seq.

West Virginia Department of Agriculture

Legislative Rule

This legislative rule establishes the requirements governing the manufacture and distribution of dairy products and imitation dairy products. Frozen desserts, as defined by Chapter 19, Article 11A, will be enforced by Chapter 19, Article 11B of the West Virginia Code and legislative rules promulgated under that article.

The rule provides for an incorporation by reference of the Federal Regulations regarding the standards of identity. Additional incorporation is made of those methods that are required for the testing of various dairy products. The rule also gives several standards of identity that are not provided by the Federal Government.

The rule provides guidance for the proper labeling of dairy products for compliance with both Federal and State requirements.

This rule outlines what constitutes adulteration and misbranding. Additionally, the rule lists prohibited acts.

The powers and duties of the Commissioner are outlined as well as animal health standards.

An enforcement policy is outlined which applies a risk assessment inspection program. The Commissioner is also given embargo authority under the rule for the enforcement of its contents.

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 Chapter 19, Article 11A, will be enforced by Chapter 19, Article 11B of the West Virginia Code and legislative rules promulgated under that article.

1.2. Authority - §19-11A-10

1.3. Filing Date -

1.4. Effective Date -

1.5. This regulation is a new legislative rule.

§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, 1994)

2.1.b. Title 40 Code of Federal Regulations (July 1, 1993)

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

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.

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.

§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 milk fat, 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. A temporary marketing permit must be obtained prior to the distribution of a dairy product which is not covered by a standard of identity.

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

4.4. The temporary marketing permit shall be issued 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. 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 product(s).

4.6. The commissioner may suspend the temporary marketing permit at any time when he finds that the person or the dairy product is not in compliance with WV Code §19-11A-1 et seq. or these rules. A dairy product listed on the suspended temporary marketing permit must be removed from distribution in this state by the permittee.

4.7. 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 WV 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 5.1.h. 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 firm when there are several firms 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 _____".

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.

5.1.e. 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.

5.1.f. 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.

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

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

5.1.h.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 WV Code 19-11A-4 and of this section for quantity and for the name and address of the manufacturer, packer or distributor.

5.1.h.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 WV Code 19-11A-4 and of this section of the rule.

5.1.h.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 WV 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 WV 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.

5.1.h.D. product packaged in units sold in a multiunit container, provided that each individual unit remains within the multi-unit container during distribution and the multiunit container is labeled according to the requirements of WV Code 19-11A-4 and of this section of the rule.

§61-4C-6. Misbranded.

6.1. Any product referred to in WV 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;

6.1.c. it does not meet minimum labeling requirements of 21 Code of Federal Regulations (April 1, 1994) 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 50,000 per gram for the standard plate count and/or 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; or

7.1.e. pathogenic bacteria are in the product;

7.1.f. if its quality does not meet the requirements of the definition or standard of identity as outlined in Section 3 of these rules; or

7.1.g. if its quality does not meet the requirements for currently accepted standards by industry and government, as 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 these rules. Tolerances for the presence of antibiotics are those tolerances designated in 21 CFR Part 556, as adopted by reference in section 2 of these rules. Tolerances for unavoidable poisonous or deleterious substances are those tolerances designated in 21 CFR 109.30, as adopted by reference in section 2 of these rules.

§61-4C-8. Prohibited acts.

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

8.3. No person may use any spilled, overflowed and leaked products in manufacturing any other product.

8.4. No person may use steel wool or metal sponges for cleaning equipment and utensils used for manufacturing.

8.5. No person may 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.

§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 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 such 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 such 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 90 day intervals, and any herd where any animal has a positive milk ring test shall all animals that are producing milk, or that have recently produced milk, tested with the milk ring test within 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 sample(s) 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 the standards set forth in the Standard Methods for the Examination of Dairy Products, the Official Methods of Analysis, procedures referenced in 21 CFR, or other methods as approved by the commissioner, whichever method is applicable to the product being tested.

11.2. The Roesse-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 $\pm .15\%$. 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 these rules.

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 these rules, where applicable.

§61-4C-12. Enforcement policy.

12.1. The commissioner may assess a violation of W.Va. Code §19-11A-1 et seq. or of these rules 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 sample(s) 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 the retailer of the violation of W.Va. Code §19-11A-1 et seq. or of these rules and the enforcement policy established by this section of the rule.

12.2.a. The commissioner shall collect additional official product sample(s) within 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 consecutive official product sample(s) 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 sample(s) within 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 7 days from the sending of a Second Notice.

12.4. Whenever three of the last five consecutive official product sample(s) 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 sample(s) within 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 7 days from the date of sending of the 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 these rules.

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

12.9. Resamples may be considered 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 may issue a suspension of the Dairy Products Distributor Permit. 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 these rules. 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 firm 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 may issue an embargo order for any dairy product or imitation dairy product which is not in compliance with this article or rules and may also cause the manufacturing and distributing of the same to cease by authority of W.Va. Code §19-11A-10(i).