

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #6

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: Agriculture TITLE NUMBER: 61

AMENDMENT TO AN EXISTING RULE: YES , NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

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

TITLE OF RULE BEING PROPOSED: Frozen Desserts & Imitation Frozen Desserts

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

AUTHORIZATION IS CITED IN (house or senate bill number) Sb1

SECTION 64-9-1 (gg), PASSED ON March 14, 1992

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON
THE FOLLOWING DATE: May 11, 1992



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TITLE 61
LEGISLATIVE RULE
DEPARTMENT OF AGRICULTURE

OFFICE OF AGRI. POLICY
SECRETARY OF STATE

SERIES 4B
FROZEN DESSERTS AND IMITATION FROZEN DESSERTS

§61-4B-1. General

1.1. Scope - This rule establishes the requirements governing the manufacture and distribution of frozen desserts and imitation frozen desserts.

1.2. Authority - §19-11B-10

1.3. Filing Date -

1.4. Effective Date -

1.5. This regulation is a new legislative rule.

§61-4B-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, 1990)

2.1.b. Title 40 Code of Federal Regulations (July 1, 1990)

2.1.c. National Sanitation Foundation Standard 6 for Dispensing Freezers as adopted by The NSF Board of Trustees, revised February 1989; published by the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106.

2.1.d. 15th 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.e. 15th 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.f. 6th 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.

§61-4B-3. Definitions

3.1. "Active cultures" means microorganisms in the viable state that are added to a product to produce characteristic qualities in the finished product.

3.2. "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

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

3.4. "Product" means a frozen dessert or imitation frozen dessert.

3.5. "Summary suspensions" are suspensions issued in cases where conditions constituting a hazard to the public health, safety or welfare requires immediate action.

3.6. "Sterilized" means the condition achieved by the application of heat, chemical sterilant(s) or other treatment considered appropriate by the commissioner that renders the product or equipment free of viable microorganisms.

§61-4B-4. Definitions and Standards of Identity

4.1. 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, ice milk, goat's milk ice milk, mellorine, fruit sherbet and non-fruit sherbet.

4.2. Frozen yogurt is the food which is prepared by freezing while stirring a mix consisting of the ingredients permitted in ice cream. All dairy ingredients shall be pasteurized or ultrapasteurized. Safe and suitable sweetening agents may be used. Such ingredients are cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. Fruit, nuts or other flavoring materials may be added before or after the mix is pasteurized and cultured. The standard plate count requirement for frozen desserts applies only to the mix prior to culturing. Frozen yogurt, exclusive of any flavoring, shall contain not less than 3.25% milkfat, not less than 8.25% milk solids not fat, and have a titratable acidity of not less than 0.3% expressed as lactic acid. This characteristic acidity is developed as a result of the bacterial activity, and no heat or bacteriostatic treatment, other than refrigeration, which

results in destruction or partial destruction of the organisms, shall be applied to the product after such culturing. Frozen yogurt finished product shall weigh not less than 5 pounds per gallon. On the label the strains of bacteria may be collectively referred to as yogurt culture. The name of the food is frozen yogurt.

4.3. Frozen dietary dairy dessert is a frozen dessert prepared for persons who wish to restrict their intake of ordinary sweetening ingredients. It is produced by freezing while stirring a pasteurized mix consisting of the ingredients permitted in ice cream. It shall contain no sugars other than those naturally present in the milk solids or flavoring agents which have been added. It may contain edible carbohydrates other than sugars. The name of the food is frozen dietary dairy dessert.

4.3.a. The statement "Contains _____% milkfat" shall be placed prominently on the label. The blank shall be filled in with the percentage of milkfat in the product.

4.4. Milkshake is the food which is prepared by freezing while stirring a pasteurized mix consisting of the ingredients permitted in ice cream. Safe and suitable sweetening agents may be used. Caseinates may be added. Milkshakes, exclusive of any flavoring, shall not contain less than 3.25% milkfat and shall contain not less than 13.25% milk solids not fat. The name of the food is milkshake.

§61-4B-5. Frozen Dessert Manufacturer Permit

5.1. Individuals, churches, fraternal organizations and other organizations 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 19-11B-3.

§61-4B-6. Labeling

6.1. Any person distributing product in a package of any form shall attach a label with the following information, except as provided in subsection 6.6 of this rule:

6.1.a. The brand name, if any, and the product name. The product name is the name established in the definition or the standard of identity, as described in section 4 of this rule, or a 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.

6.1.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.

6.1.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 _____".

6.1.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.

6.1.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.

6.2. 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.

6.3. No manufacturer or distributor may use the terms "home made" or "farm made" to describe a product unless the product is actually manufactured in the home or on the farm, except that the word "Homemade" may be used as a brand name.

6.4. No manufacturer or distributor may use the term "lowfat" to describe a product unless that product contains more than 0.5% and not less than 2.0% milkfat. If a product has a definition or standard of identity specified in section 4 of this rule, the product must meet all requirements of that definition, except that the product must meet the milkfat requirements as herein specified for "lowfat". However, in no case may the term "lowfat" be used as a qualifier for the product "ice cream".

6.5. No manufacturer or distributor may use the term "nonfat" to describe a product unless that product contains less than 0.5% milkfat. If a product has a definition or standard of identity specified in section 4 of this rule, the product must meet all requirements of that definition, except that the product must meet the milkfat requirements herein specified for "nonfat". However, in no case may the term "nonfat" be used as a qualifier for the product "ice cream".

6.6. A manufacturer or distributor shall not distribute any

package, of whatever form, without a complete label attached except for:

6.6.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 19-11B-4 and of this section for quantity and for the name and address of the manufacturer, packer or distributor.

6.6.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 19-11B-4 and of this section of the rule.

6.6.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 19-11B-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 19-11B-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.

6.6.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 19-11B-4 and of this section of the rule.

§61-4B-7. Misbranded

7.1. Any product referred to in WV Code 19-11B-1 et seq. or this rule is misbranded if:

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

7.1.b. it purports to be or is represented as a food for which a definition or standard of identity has been prescribed in section 4 of this rule and its quality does not meet the requirements of the definition or standard of identity; or

7.1.c. it purports to be or is represented as a food for special dietary uses, unless its label bears such information concerning its dietary properties as is necessary to fully inform purchaser as to its value for such uses.

§61-4B-8. Adulteration

8.1. A product is adulterated if:

8.1.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;

8.1.b. 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;

8.1.c. the bacterial counts except for sterile hermetically sealed products, exceed a count of 50,000 per gram for the standard plate count and 10 per gram for the coliform group count;

8.1.d. the bacterial counts for sterile hermetically sealed product exceed <1 per gram for standard plate count and <1 per gram for the coliform group;

8.1.e. the manufacturing conditions designated by these rules are not met;

8.1.f. the zone shown in the *Bacillus sterothermophilus* test is greater than or equal to 16mm, indicating adulteration with beta-lactam antibiotics; or

8.1.g. pathogenic bacteria are in the product.

8.2. Tolerances for the presence of pesticide residues are those tolerances designated in 40CFR Part 185, as adopted by reference in section 2 of these rules. Tolerances for the presence of antibiotics are those tolerances designated in 21CFR Part 556, as adopted by reference in section 2 of these rules. Tolerances for unavoidable poisonous or deleterious substances are those tolerances designated in 21CFR 109.30, as adopted by reference in section 2 of these rules. Laboratory tolerances for the method used will be added to these tolerances.

§61-4B-9. Manufacturing conditions

9.1. The entire manufacturing establishment, including fixtures, furnishings, machinery, apparatus, implements, utensils, receptacles and all equipment used to manufacture, store, keep, handle, distribute or serve product shall be maintained, operated and stored in a clean and sanitary manner by the manufacturer.

9.2. All equipment, utensils, containers and piping used by a manufacturer shall be constructed of a smooth, nontoxic, impervious, corrosion-resistant material and fabricated in such a manner that there could be no contamination of the products handled therein. All equipment shall be capable of being easily sanitized. All equipment shall be designed, installed and operated in accordance with the criteria set forth in Standard 6 adopted by the NSF Board of Trustees, in the document adopted by reference in section 2 of these rules, or as otherwise approved by the commissioner.

9.2.a. If equipment does not meet the standards outlined above, the manufacturer of the equipment or the manufacturer of the product may petition the commissioner to allow for the use of the equipment. The petition should outline the materials used in the manufacture of the equipment and their resistance to wear and corrosion under the conditions of intended use, the ability of the machine to be completely sanitized when assembled for use, the ability of sanitizer to be self draining after complete assembly, and the procedures for cleaning the equipment, including the procedures for disassembly. The commissioner may ask for additional information, if necessary, to determine the suitability of the equipment for its intended purpose.

9.2.b. The commissioner will allow any manufacturer to continue to use any equipment for five years from the effective date of this rule that does not meet the conditions set forth in this subsection, if the equipment was in use on the effective date of this rule.

9.3. The manufacturer shall keep all equipment in good working order and condition at all times that the equipment is used to manufacture a product.

9.4. The manufacturer shall install all equipment so that no solution used in cleaning or sanitizing will remain inside the equipment in substantial amounts after the draining process.

9.5. The manufacturer shall completely disassemble and clean all equipment that contains product or residues of product within two hours of the time that the equipment has reached or exceeded a temperature of 45°F or when any condition causing, or likely to cause, adulteration of the product has occurred. Equipment designed to achieve a daily heat treatment for reduction of viable bacteria is exempt from the provisions of this subsection regarding temperature but not the provision of section 8 of these rules regarding any condition that has caused or is likely to cause adulteration.

9.6. The manufacturer shall provide wash tanks of adequate size to wash and sanitize all equipment parts and utensils at the location where the manufacturing takes place or in reasonable

proximity to it. The condition of the wash tanks shall not cause adulteration of the equipment parts or the utensils placed in it.

9.7. The manufacturer shall provide a hand washing facility with running hot and cold water, soap and individual towels or a mechanical hand dryer at all times in the vicinity of the freezer when it is producing a product, except for those manufacturers operating at fairs, outings, carnivals and other affairs of short duration, who may use single service cleaning towels.

9.8. The manufacturer shall make available to each person involved in the manufacturing operation proper, suitable and adequate toilets and lavatories for each person involved in the manufacturing operation.

9.9. The manufacturer shall not employ any person that has any contagious or infectious disease in or about the manufacturing operation. The clothing habits and conduct of the employees shall be conducive to and promote cleanliness and sanitization.

9.10. The manufacturer shall sanitize all intermediate containers, such as pails or pouring containers in which mix comes in contact immediately prior to their use.

9.11. The manufacturer shall not store non-perishables in locker rooms, toilet rooms or their vestibules, garbage rooms or mechanical rooms.

§61-4B-10. Prohibited acts

10.1. 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.

10.2. No person may offer for sale, transport or distribute frozen product that has been allowed to exceed a temperature of 0°F, except that;

10.2.a. a manufacturer may offer for sale at the point of manufacture a soft-serve type frozen product whose temperature has not exceeded 45°F at any time.

10.2.b. a person may offer for sale at retail any frozen product that is held in small quantities for the purpose of softening the product so that it can be dipped as long as that product temperature is not allowed to exceed 45°F at any time.

10.3. No person may produce any product in equipment that has not been sanitized.

10.4. No person may use a product that is drained from the

freezer at the end of a production run, called rerun, that has been allowed to exceed a temperature of 45°F or that is likely to cause adulteration of the product produced when it is used.

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

10.6. No person may reconstitute powdered mixes with non-potable water or in an unsanitary manner. Such product shall be cooled to a temperature of 35-40°F within 4 hours after reconstituting.

10.7. No person may thaw frozen mixes in such a manner that any portion of the product will be above 40°F for more than thirty minutes.

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

10.9. 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.

§61-4B-11. Animal Health

11.1. 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.

11.2. 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:

11.2.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;

11.2.b. the herd meets the U.S. Department of Agriculture requirements for an individually certified Brucellosis-free herd;

11.2.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

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

§61-4B-12. Powers and Duties of the Commissioner

12.1. The commissioner shall inspect and sample product from all frozen desserts and imitation frozen desserts manufacturers within the limits of his or her resources.

12.2. The commissioner recommends that each frozen dessert and imitation frozen dessert manufacturer supplement the sampling performed by the commissioner with independent tests by an approved laboratory.

12.3. All products from frozen dessert and imitation frozen dessert manufacturers taken by a sampler employed by an approved laboratory and all products taken by the commissioner for testing are considered official product samples. All test results on official product samples will be considered when applying the enforcement policy.

§61-4B-13. Approved sampling and testing methods

13.1. 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, or procedures referenced in 21CFR, all adopted by reference in section 2 of these rules, whichever method is applicable to the product being tested.

13.2. 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.

13.2.a. Milkfat tolerances for lowfat and nonfat products are $\pm .15\%$. Tolerances for the method will be added to this tolerance.

13.3. 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.

13.4. The testing methods for drug residues in product are those listed in 21CFR Part 556, as adopted by reference in section 2 of these rules, where applicable.

§61-4B-14. Approved laboratories

14.1. Laboratories wishing to be approved under provisions of WV Code 19-11B-9 shall apply by letter to the commissioner. The application shall list the name and address of the laboratory, the owners of the laboratory, the laboratory director, and the names of the individuals that will be collecting the official product samples. In addition, the application shall specify the methods for analysis of products, give a listing of the equipment used in the analysis, the quality control and quality assurance measures for sample collection, handling and testing, and methods of record keeping and notification. Other information supporting the application may be submitted as supporting documents.

14.1.a. The commissioner has sixty days to review the application, make an inspection of the facility, if necessary, and approve or deny the application.

14.1.b. The approval shall be for a two year period, however the commissioner may request information supporting the continued approval of the laboratory in the interim.

14.1.c. The laboratory may make amendments to their application at any time. Amendments are subject to review by the commissioner.

14.2. The commissioner may make inspections of the approved laboratory at any time when he suspects that the laboratory may not be following the provisions of WV Code 19-11B-1 et seq. or these rules.

14.3. The commissioner may suspend the approval of the laboratory at any time when he finds that the laboratory is not in compliance with WV Code 19-11B-1 et seq. or these rules. The laboratory may not test official product samples under the provisions of WV Code 19-11B-1 et seq. or this rule during the time that the approval is suspended.

14.4. All official product samples collected under the authority of WV Code 19-11B-1 et seq. or these rules shall be randomly scheduled and collected by a sampler who is listed in the application for approval of the laboratory. The laboratory has a variance of four weeks from when a sample is requested in order to schedule a sample collection in a random manner. Evidence of collection of samples in a randomly scheduled manner will be submitted to the commissioner when requested in order to

substantiate this requirement.

14.5. Approved laboratories shall report all official analytical test results to the commissioner and to the manufacturer of the product no later than five working days after the test was completed for non-adulterated products, and within twenty-four hours for adulterated products.

14.5.a. All reports shall contain, the time and date when the product was sampled, the temperature of the product when collected, the name of the person collecting the official product sample, the place where the sample was collected, the test results, analytical information to support the quality control procedures, the name of the laboratory performing the work, and the signature of the laboratory director.

14.6. The manufacturer and the approved laboratory will keep on file all test results of official product samples for at least two years.

§61-4B-15. Enforcement policy

15.1. The commissioner may assess a violation of W.Va. Code §19-11B-1 et seq. or of these rules against the manufacturer of product and/or the distributor of the mix used to manufacture the product.

15.2. The commissioner will assess any violations of W.Va. Code §19-11B-1 et seq. or of this rule to the distributor for mix sampled from unopened containers. The company will not be assessed additional cumulative notices of violations until the commissioner has determined that the firm has had adequate notice of the previous notice, generally 10 days from the mailing of the notice of violation.

15.3. 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 or distributor whichever is appropriate. This notice shall notify the manufacturer or distributor of the violation of W.Va. Code §19-11B-1 et seq. or of these rules and the enforcement policy established by this section of the rule.

15.4. 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 or distributor whichever is appropriate.

15.4.a. The commissioner shall collect additional official product sample(s) within 21 days of the sending of a

Second Notice to the manufacturer or distributor, but shall not collect product samples before the lapse of 7 days from the sending of a Second Notice.

15.5. 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 or distributor whichever is appropriate.

15.5.a. The commissioner shall collect additional official product sample(s) within 21 days of the sending of the Third Notice to the manufacturer or distributor, but shall not collect additional product samples before the lapse of 7 days from the date of sending of the notice.

15.6. The commissioner will issue a "Shut-down Order" for a period of 24 hours to a manufacturer or distributor when the record of the firm indicates that effective action has not been taken to correct the causes of the violations, for instance when three out of the last five samples from the same machine are violative. The "Shut-down Order" will normally be issued with the "Third Notice". The "Shut-down Order" will give the reasons for the order, state the portion of the manufacturing or distributing operation that is prohibited from operating while the order is in effect, give conditions of the order, state the length of time that the Shut-down Order will be in effect and specify a time and place for a hearing to be held in this matter. Except that in the case where the public health, safety or welfare is at risk, the commissioner will issue an immediate Shut-down Order and give notice to the manufacturer or distributor under the provisions of subdivision 15.6.a. of this rule.

15.6.a. The commissioner will issue an immediate Shut-down Order without giving the manufacturer or distributor the opportunity to be heard where there is a hazard to the public health, safety or welfare. In these cases, the manufacturer or distributor will be given the opportunity to request a hearing before the commissioner after the notification of the order is received by the manufacturer or distributor. All Shut-down Orders issued due to non-compliance with subdivisions 8.1.c., 8.1.d., or 8.1.g. of this rule are considered to involve a risk to the public health, safety or welfare.

15.6.b. The manufacturer or distributor will be responsible for causing all operations covered by the Shut-down Order to cease and follow all other conditions of the order. At the end of the period of the order, the manufacturer or distributor may resume operations without further action by the commissioner.

15.7. If after a Shut-down Order has been issued the commissioner finds that effective corrective action has not been

taken, he may issue a suspension of the Frozen Desserts Manufacturer 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 manufacturer the opportunity to request a hearing in this matter subsequent to the notification of the suspension.

15.7.a. All suspensions due to non-conformance to subdivisions 8.1.c., 8.1.d. or 8.1.g. of this rule are summary suspensions.

15.7.b. A suspension of the Frozen Desserts Manufacturer Permit remains in effect until the manufacturer submits and the commissioner accepts a written plan of correction and a request for a reinstatement of the permit.

15.7.c. The commissioner has seven days from the date of receipt of this application to respond to a suspension in the case of violations of subdivisions 8.1.c., 8.1.d. or 8.1.g. of this rule and fourteen days to respond for all other violations of W.Va. Code §19-11B-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.

15.8. If the commissioner finds that after the firm has resumed production following a suspension of their Frozen Desserts Manufacturer Permit that effective corrective action has not been taken, then the commissioner will hold a hearing to determine if the Frozen Desserts Manufacturer Permit should be revoked.

15.9. Persons who manufacture a product on an intermittent or infrequent basis, so that the standard enforcement policy cannot apply, will enter into a consent agreement with the commissioner for correction of all items found to be not in conformance with W.Va. Code §19-11B-1 et seq. or these rules.

15.10. 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.

15.11. 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.

15.12. 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 §19-11B-1 et seq. or these rules.

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

15.14. Resamples will only be taken from machines that were shown to be producing violative product the previous visit, except for resamples needed to check that the non-violative status is being maintained according to the following schedule:

15.14.a. After a first notice and one non-violative sample, resamples will be taken between 5 to 6 months after the non-violative sample.

15.14.b. After a second notice and one non-violative sample, resamples will be taken between 3-4 months after the non-violative sample.

15.14.c. Other resamples may be considered necessary to determine that the non-violative status is being maintained.

§61-4B-16. Cleaning and sanitizing

16.1. Procedures used for cleaning and sanitizing equipment and utensils that come in contact with product shall substantially comply with the guidelines set forth in this section.

16.1.a. The manufacturer shall thoroughly rinse all equipment used during the manufacturing process with lukewarm water until the water runs clear.

16.1.b. The manufacturer shall use a suitable detergent designed to remove the product from all surfaces of the equipment, including inside the freezer. The cleaning process must be sufficient to remove all product and lubricant residues and should be performed in hot (approximately 120°F) water.

16.1.c. The manufacturer shall sanitize all clean surfaces that are likely to come in contact with product with a suitable bactericidal chemical before use for manufacturing or storage of a product.

16.1.d. Prior to use, the manufacturer will not handle or expose to the air any portion of equipment or containers that have been sanitized.

16.1.e. When adding mix to the freezer after sanitizing, the manufacturer will hold the freezer draw tube open to allow all remaining sanitizer to be removed from the machine.

16.1.f. The manufacturer is encouraged to use an acidic milkstone remover occasionally.

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check spacing

TITLE 61
LEGISLATIVE RULE
DEPARTMENT OF AGRICULTURE

SERIES 4B
FROZEN DESSERTS AND IMITATION FROZEN DESSERTS

§61-4B-1. General.

1.1. Scope. -- This rule establishes the requirements governing the manufacture and distribution of frozen desserts and imitation frozen desserts.

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

1.3. Filing Date. -- April 23, 1992

1.4. Effective Date. -- May 11, 1992

§61-4B-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, 1990)

2.1.b. Title 40 Code of Federal Regulations (July 1, 1990)

2.1.c. National Sanitation Foundation Standard 6 for Dispensing Freezers as adopted by The NSF Board of Trustees, revised February 1989; published by the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106.

2.1.d. 15th 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.e. 15th 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.f. 6th 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.

§61-4B-3. Definitions.

3.1. "Active cultures" means microorganisms in the viable state that are added to a product to produce characteristic qualities in the finished product.

3.2. "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

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

3.4. "Product" means a frozen dessert or imitation frozen dessert.

3.5. "Summary suspensions" are suspensions issued in cases where conditions constituting a hazard to the public health, safety or welfare requires immediate action.

3.6. "Sterilized" means the condition achieved by the application of heat, chemical sterilant(s) or other treatment considered appropriate by the commissioner that renders the product or equipment free of viable microorganisms.

§61-4B-4. Definitions and Standards of Identity.

4.1. 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, ice milk, goat's milk ice milk, mellorine, fruit sherbet and non-fruit sherbet.

4.2. Frozen yogurt is the food which is prepared by freezing while stirring a mix consisting of the ingredients permitted in ice cream. All dairy ingredients shall be pasteurized or ultrapasteurized. Safe and suitable sweetening agents may be used. Such ingredients are cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. Fruit, nuts or other flavoring materials may be added before or after the mix is pasteurized and cultured. The standard plate count requirement for frozen desserts applies only to the mix prior to culturing. Frozen yogurt, exclusive of any flavoring, shall contain not less than 3.25% milkfat, not less than 8.25% milk solids not fat, and have a titratable acidity of not less than 0.3% expressed as lactic acid. This characteristic acidity is developed as a result of the bacterial activity, and no heat or bacteriostatic treatment, other than refrigeration, which results in destruction or partial destruction of the organisms, shall be applied to the product after such culturing. Frozen yogurt finished product shall weigh not less than 5 pounds per gallon. On the label the strains of bacteria may be collectively referred to as yogurt culture. The name of the food is frozen yogurt.

4.3. Frozen dietary dairy dessert is a frozen dessert prepared for persons who wish to restrict their intake of ordinary sweetening ingredients. It is produced by freezing while stirring a pasteurized mix consisting of the ingredients permitted in ice cream. It shall contain no sugars other than those naturally present in the milk solids or flavoring agents which have been added. It may contain edible carbohydrates other than sugars. The name of the food is frozen dietary dairy dessert.

4.3.a. The statement "Contains _____% milkfat" shall be placed prominently on the label. The blank shall be filled in with the percentage of milkfat in the product.

4.4. Milkshake is the food which is prepared by freezing while stirring a pasteurized mix consisting of the ingredients permitted in ice cream. Safe and suitable sweetening agents may be used. Caseinates may be added. Milkshakes, exclusive of any flavoring, shall not contain less than 3.25% milkfat and shall contain not less than 13.25% milk solids not fat. The name of the food is milkshake.

§61-4B-5. Frozen Dessert Manufacturer Permit.

5.1. Individuals, churches, fraternal organizations and other organizations 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 §19-11B-3.

§61-4B-6. Labeling.

6.1. Any person distributing product in a package of any form shall attach a label with the following information, except as provided in subsection 6.6 of this rule:

6.1.a. The brand name, if any, and the product name. The product name is the name established in the definition or the standard of identity, as described in section 4 of this rule, or a 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.

6.1.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.

6.1.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 _____".

6.1.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.

6.1.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.

6.2. 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.

6.3. No manufacturer or distributor may use the terms "home made" or "farm made" to describe a product unless the product is actually manufactured in the home or on the farm, except that the word "Homemade" may be used as a brand name.

6.4. No manufacturer or distributor may use the term "lowfat" to describe a product unless that product contains more than 0.5% ~~and~~ ^{but} ~~not~~ less than 2.0% milkfat. If a product has a definition or standard of identity specified in section 4 of this rule, the product must meet all requirements of that definition, except that the product must meet the milkfat requirements as herein specified for "lowfat". However, in no case may the term "lowfat" be used as a qualifier for the product "ice cream".

6.5. No manufacturer or distributor may use the term "nonfat" to describe a product unless that product contains less than 0.5% milkfat. If a product has a definition or standard of identity specified in section 4 of this rule, the product must meet all requirements of that definition, except that the product must meet the milkfat requirements herein specified for "nonfat". However, in no case may the term "nonfat" be used as a qualifier for the product "ice cream".

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

6.6.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 §19-11B-4 and of this section for quantity and for the name and address of the manufacturer, packer or distributor.

6.6.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 §19-11B-4 and of this section of the rule.

6.6.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 §19-11B-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 §19-11B-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.

6.6.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 W. Va. Code §19-11B-4 and of this section of the rule.

§61-4B-7. Misbranded.

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

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

7.1.b. it purports to be or is represented as a food for which a definition or standard of identity has been prescribed in section 4 of this rule and its quality does not meet the requirements of the definition or standard of identity; or

7.1.c. it purports to be or is represented as a food for special dietary uses, unless its label bears such information concerning its dietary properties as is necessary to fully inform purchaser as to its value for such uses.

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§61-4B-8. Adulteration.

8.1. A product is adulterated if:

8.1.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;

8.1.b. 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;

8.1.c. the bacterial counts except for sterile hermetically sealed products, exceed a count of 50,000 per gram for the standard plate count and 10 per gram for the coliform group count;

8.1.d. the bacterial counts for sterile hermetically sealed product exceed <1 per gram for standard plate count and <1 per gram for the coliform group;

8.1.e. the manufacturing conditions designated by these rules are not met;

8.1.f. the zone shown in the Bacillus sterothermophilus test is greater than or equal to 16mm, indicating adulteration with beta-lactam antibiotics; or

8.1.g. pathogenic bacteria are in the product.

8.2. 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. Laboratory tolerances for the method used will be added to these tolerances.

§61-4B-9. Manufacturing conditions.

9.1. The entire manufacturing establishment, including fixtures, furnishings, machinery, apparatus, implements, utensils, receptacles and all equipment used to manufacture, store, keep, handle, distribute or serve product shall be maintained, operated and stored in a clean and sanitary manner by the manufacturer.

9.2. All equipment, utensils, containers and piping used by a manufacturer shall be constructed of a smooth, nontoxic, impervious, corrosion-resistant material and fabricated in such a manner that there could be no contamination of the products handled therein. All equipment shall be capable of being easily sanitized. All equipment shall be designed, installed and operated in accordance with the criteria set forth in Standard 6 adopted by the NSF Board of Trustees, in the document adopted

by reference in section 2 of these rules, or as otherwise approved by the commissioner.

9.2.a. If equipment does not meet the standards outlined above, the manufacturer of the equipment or the manufacturer of the product may petition the commissioner to allow for the use of the equipment. The petition should outline the materials used in the manufacture of the equipment and their resistance to wear and corrosion under the conditions of intended use, the ability of the machine to be completely sanitized when assembled for use, the ability of sanitizer to be self draining after complete assembly, and the procedures for cleaning the equipment, including the procedures for disassembly. The commissioner may ask for additional information, if necessary, to determine the suitability of the equipment for its intended purpose.

9.2.b. The commissioner will allow any manufacturer to continue to use any equipment for five years from the effective date of this rule that does not meet the conditions set forth in this subsection, if the equipment was in use on the effective date of this rule.

9.3. The manufacturer shall keep all equipment in good working order and condition at all times that the equipment is used to manufacture a product.

9.4. The manufacturer shall install all equipment so that no solution used in cleaning or sanitizing will remain inside the equipment in substantial amounts after the draining process.

9.5. The manufacturer shall completely disassemble and clean all equipment that contains product or residues of product within two hours of the time that the equipment has reached or exceeded a temperature of 45°F or when any condition causing, or likely to cause, adulteration of the product has occurred. Equipment designed to achieve a daily heat treatment for reduction of viable bacteria is exempt from the provisions of this subsection regarding temperature but not the provision of

section 8 of these rules regarding any condition that has caused or is likely to cause adulteration.

9.6. The manufacturer shall provide wash tanks of adequate size to wash and sanitize all equipment parts and utensils at the location where the manufacturing takes place or in reasonable proximity to it. The condition of the wash tanks shall not cause adulteration of the equipment parts or the utensils placed in it.

9.7. The manufacturer shall provide a hand washing facility with running hot and cold water, soap and individual towels or a mechanical hand dryer at all times in the vicinity of the freezer when it is producing a product, except for those manufacturers operating at fairs, outings, carnivals and other affairs of short duration, who may use single service cleaning towels.

9.8. The manufacturer shall make available to each person involved in the manufacturing operation proper, suitable and adequate toilets and lavatories for each person involved in the manufacturing operation.

9.9. The manufacturer shall not employ any person that has any contagious or infectious disease in or about the manufacturing operation. The clothing habits and conduct of the employees shall be conducive to and promote cleanliness and sanitization.

9.10. The manufacturer shall sanitize all intermediate containers, such as pails or pouring containers in which mix comes in contact immediately prior to their use.

9.11. The manufacturer shall not store non-perishables in locker rooms, toilet rooms or their vestibules, garbage rooms or mechanical rooms.

§61-4B-10. Prohibited acts.

10.1. 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.

10.2. No person may offer for sale, transport or distribute frozen product that has been allowed to exceed a temperature of 0°F, except that;

10.2.a. a manufacturer may offer for sale at the point of manufacture a soft-serve type frozen product whose temperature has not exceeded 45°F at any time.

10.2.b. a person may offer for sale at retail any frozen product that is held in small quantities for the purpose of softening the product so that it can be dipped as long as that product temperature is not allowed to exceed 45°F at any time.

10.3. No person may produce any product in equipment that has not been sanitized.

10.4. No person may use a product that is drained from the freezer at the end of a production run, called rerun, that has been allowed to exceed a temperature of 45°F or that is likely to cause adulteration of the product produced when it is used.

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

10.6. No person may reconstitute powdered mixes with non-potable water or in an unsanitary manner. Such product shall be cooled to a temperature of 35-40°F within 4 hours after reconstituting.

10.7. No person may thaw frozen mixes in such a manner that any portion of the product will be above 40°F for more than thirty minutes.

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

10.9. 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.

§61-4B-11. Animal Health.

11.1. 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.

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11.2. 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:

11.2.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;

11.2.b. the herd meets the U.S. Department of Agriculture requirements for an individually certified Brucellosis-free herd;

11.2.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

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

§61-4B-12. Powers and Duties of the Commissioner.

12.1. The commissioner shall inspect and sample product from all frozen desserts and imitation frozen desserts manufacturers within the limits of his or her resources.

12.2. The commissioner recommends that each frozen dessert and imitation frozen dessert manufacturer supplement the sampling performed by the commissioner with independent tests by an approved laboratory.

12.3. All products from frozen dessert and imitation frozen dessert manufacturers taken by a sampler employed by an approved laboratory and all products taken by the commissioner for testing are considered official product samples. All test results on official product samples will be considered when applying the enforcement policy.

§61-4B-13. Approved sampling and testing methods.

13.1. 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, or procedures referenced in 21CFR, all adopted by reference in section 2 of these rules, whichever method is applicable to the product being tested.

13.2. 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.

13.2.a. Milkfat tolerances for lowfat and nonfat products are \pm .15%. Tolerances for the method will be added to this tolerance.

13.3. 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.

13.4. The testing methods for drug residues in product are those listed in 21CFR Part 556, as adopted by reference in section 2 of these rules, where applicable.

§61-4B-14. Approved laboratories.

14.1. Laboratories wishing to be approved under provisions of W. Va. Code §19-11B-9 shall apply by letter to the commissioner. The application shall list the name and address of the laboratory, the owners of the laboratory, the laboratory director, and the names of the individuals that will be collecting the official product samples. In addition, the application shall specify the methods for analysis of products, give a listing of the equipment used in the analysis, the quality control and quality assurance measures for sample collection, handling and testing, and methods of record keeping and notification. Other information supporting the application may be submitted as supporting documents.

14.1.a. The commissioner has sixty days to review the application, make an inspection of the facility, if necessary, and approve or deny the application.

14.1.b. The approval shall be for a two year period, however the commissioner may request information supporting the continued approval of the laboratory in the interim.

14.1.c. The laboratory may make amendments to their application at any time. Amendments are subject to review by the commissioner.

14.2. The commissioner may make inspections of the approved laboratory at any time when he suspects that the laboratory may not be following the provisions of W. Va. Code §19-11B-1 et seq. or these rules.

14.3. The commissioner may suspend the approval of the laboratory at any time when he finds that the laboratory is not in compliance with W. Va. Code §19-11B-1 et seq. or these rules. The laboratory may not test official product samples under the provisions of W. Va. Code §19-11B-1 et seq. or this rule during the time that the approval is suspended.

14.4. All official product samples collected under the authority of W. Va. Code §19-11B-1 et seq. or these rules shall be randomly scheduled and collected by a sampler who is listed in the application for approval of the laboratory. The laboratory has a variance of four weeks from when a sample is requested in order to schedule a sample collection in a random manner. Evidence of collection of samples in a randomly scheduled manner will be submitted to the commissioner when requested in order to substantiate this requirement.

14.5. Approved laboratories shall report all official analytical test results to the commissioner and to the manufacturer of the product no later than five working days after the test was completed for non-adulterated products, and within twenty-four hours for adulterated products.

14.5.a. All reports shall contain, the time and date when the product was sampled, the temperature of the product when collected, the name of the person collecting the official product sample, the place where the sample was collected, the test results, analytical information to support the quality control procedures, the name of the laboratory performing the work, and the signature of the laboratory director.

14.6. The manufacturer and the approved laboratory will keep on file all test results of official product samples for at least two years.

§61-4B-15. Enforcement policy.

15.1. The commissioner may assess a violation of W. Va. Code §19-11B-1 et seq. or of these rules against the manufacturer of product

and/or the distributor of the mix used to manufacture the product.

15.2. The commissioner will assess any violations of W. Va. Code §19-11B-1 et seq. or of this rule to the distributor for mix sampled from unopened containers. The company will not be assessed additional cumulative notices of violations until the commissioner has determined that the firm has had adequate notice of the previous notice, generally 10 days from the mailing of the notice of violation.

15.3. 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 or distributor whichever is appropriate. This notice shall notify the manufacturer or distributor of the violation of W. Va. Code §19-11B-1 et seq. or of these rules and the enforcement policy established by this section of the rule.

15.4. 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 or distributor whichever is appropriate.

15.4.a. The commissioner shall collect additional official product sample(s) within 21 days of the sending of a Second Notice to the manufacturer or distributor, but shall not collect product samples before the lapse of 7 days from the sending of a Second Notice.

15.5. 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 or distributor whichever is appropriate.

15.5.a. The commissioner shall collect additional official product sample(s) within 21 days of the sending of the Third Notice to the

manufacturer or distributor, but shall not collect additional product samples before the lapse of 7 days from the date of sending of the notice.

15.6. The commissioner will issue a "Shut-down Order" for a period of 24 hours to a manufacturer or distributor when the record of the firm indicates that effective action has not been taken to correct the causes of the violations, for instance when three out of the last five samples from the same machine are violative. The "Shut-down Order" will normally be issued with the "Third Notice". The "Shut-down Order" will give the reasons for the order, state the portion of the manufacturing or distributing operation that is prohibited from operating while the order is in effect, give conditions of the order, state the length of time that the Shut-down Order will be in effect and specify a time and place for a hearing to be held in this matter. Except that in the case where the public health, safety or welfare is at risk, the commissioner will issue an immediate Shut-down Order and give notice to the manufacturer or distributor under the provisions of subdivision 15.6.a. of this rule.

15.6.a. The commissioner will issue an immediate Shut-down Order without giving the manufacturer or distributor the opportunity to be heard where there is a hazard to the public health, safety or welfare. In these cases, the manufacturer or distributor will be given the opportunity to request a hearing before the commissioner after the notification of the order is received by the manufacturer or distributor. All Shut-down Orders issued due to non-compliance with subdivisions 8.1.c., 8.1.d., or 8.1.g. of this rule are considered to involve a risk to the public health, safety or welfare.

15.6.b. The manufacturer or distributor will be responsible for causing all operations covered by the Shut-down Order to cease and follow all other conditions of the order. At the end of the period of the order, the manufacturer or distributor may resume operations without further action by the commissioner.

15.7. If after a Shut-down Order has been issued the commissioner finds that effective corrective action has not been taken, he may issue a suspension of the Frozen Desserts Manufacturer 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 manufacturer the opportunity to request a hearing in this matter subsequent to the notification of the suspension.

15.7.a. All suspensions due to non-conformance to subdivisions 8.1.c., 8.1.d. or 8.1.g. of this rule are summary suspensions.

15.7.b. A suspension of the Frozen Desserts Manufacturer Permit remains in effect until the manufacturer submits and the commissioner accepts a written plan of correction and a request for a reinstatement of the permit.

15.7.c. The commissioner has seven days from the date of receipt of this application to respond to a suspension in the case of violations of subdivisions 8.1.c., 8.1.d. or 8.1.g. of this rule and fourteen days to respond for all other violations of W. Va. Code §19-11B-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.

15.8. If the commissioner finds that after the firm has resumed production following a suspension of their Frozen Desserts Manufacturer Permit that effective corrective action has not been taken, then the commissioner will hold a hearing to determine if the Frozen Desserts Manufacturer Permit should be revoked.

15.9. Persons who manufacture a product on an intermittent or infrequent basis, so that the standard enforcement policy cannot apply, will enter into a consent agreement with the commissioner for correction of all items found to

be not in conformance with W. Va. Code §19-11B-1 et seq. or these rules.

15.10. 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.

15.11. 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.

15.12. 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 §19-11B-1 et seq. or these rules.

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

15.14. Resamples will only be taken from machines that were shown to be producing violative product the previous visit, except for resamples needed to check that the non-violative status is being maintained according to the following schedule:

15.14.a. After a first notice and one non-violative sample, resamples will be taken between 5 to 6 months after the non-violative sample.

15.14.b. After a second notice and one non-violative sample, resamples will be taken

between 3-4 months after the non-violative sample.

15.14.c. Other resamples may be considered necessary to determine that the non-violative status is being maintained.

§61-4B-16. Cleaning and sanitizing.

16.1. Procedures used for cleaning and sanitizing equipment and utensils that come in contact with product shall substantially comply with the guidelines set forth in this section.

16.1.a. The manufacturer shall thoroughly rinse all equipment used during the manufacturing process with lukewarm water until the water runs clear.

16.1.b. The manufacturer shall use a suitable detergent designed to remove the product from all surfaces of the equipment, including inside the freezer. The cleaning process must be sufficient to remove all product and lubricant residues and should be performed in hot (approximately 120°F) water.

16.1.c. The manufacturer shall sanitize all clean surfaces that are likely to come in contact with product with a suitable bactericidal chemical before use for manufacturing or storage of a product.

16.1.d. Prior to use, the manufacturer will not handle or expose to the air any portion of equipment or containers that have been sanitized.

16.1.e. When adding mix to the freezer after sanitizing, the manufacturer will hold the freezer draw tube open to allow all remaining sanitizer to be removed from the machine. *space*

16.1.f. The manufacturer is encouraged to use an acidic milkstone remover occasionally.

Bill Agri, Frozen Desserts 61-4B

H. B. 4257

(By Delegate Grubb)

(Introduced January 27, 1992)

; referred to the
Committee on Health and Human Resources then the
Judiciary

A BILL to amend and reenact section one, article nine, chapter
sixty-four of the code of West Virginia, one thousand nine
hundred thirty-one, as amended, relating to authorizing the
commissioner of agriculture to promulgate legislative rules
relating to frozen desserts and imitation frozen desserts.

Be it enacted by the Legislature of West Virginia:

That section one, article nine, chapter sixty-four of the
code of West Virginia, one thousand nine hundred thirty-one, as
amended, be amended and reenacted, to read as follows:

ARTICLE 9. AUTHORIZATION FOR MISCELLANEOUS AGENCIES AND BOARDS
TO PROMULGATE LEGISLATIVE RULES.

§64-9-1. Commissioner of Agriculture.

(a) The legislative rules filed in the state register on the
sixth day of April, one thousand nine hundred eighty-three,

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1 relating to the commissioner of agriculture (schedule of charges
2 for inspection services: fruit), are authorized.

3 (b) The legislative rules filed in the state register on the
4 third day of August, one thousand nine hundred eighty-three,
5 relating to the commissioner of agriculture (licensing of
6 auctioneers), are authorized.

7 (c) The legislative rules filed in the state register on the
8 eighth day of February, one thousand nine hundred eighty-four,
9 relating to the commissioner of agriculture (conduct of beef
10 industry self-improvement assessment program referendum), are
11 authorized.

12 (d) The legislative rules filed in the state register on the
13 fourth day of June, one thousand nine hundred eighty-four,
14 relating to the commissioner of agriculture (feeding untreated
15 garbage to swine), are authorized.

16 (e) The legislative rules filed in the state register on the
17 fourth day of June, one thousand nine hundred eighty-four,
18 relating to the commissioner of agriculture (registration,
19 taxation and control of dogs), are authorized.

20 (f) The legislative rules filed in the state register on the
21 first day of November, one thousand nine hundred eighty-four,
22 relating to the commissioner of agriculture (public markets), are
23 authorized.

24 (g) The legislative rules filed in the state register on the
25 tenth day of September, one thousand nine hundred eighty-four,

1 relating to the commissioner of agriculture (noxious weed rules),
2 are authorized.

3 (h) The legislative rules filed in the state register on the
4 fourth day of June, one thousand nine hundred eighty-four,
5 relating to the commissioner of agriculture (animal disease
6 control), are authorized.

7 (i) The legislative rules filed in the state register on the
8 fifth day of January, one thousand nine hundred eighty-four,
9 relating to the commissioner of agriculture (use of certain
10 picloram products), are authorized.

11 (j) The legislative rules filed in the state register on the
12 eighth day of March, one thousand nine hundred eighty-five,
13 relating to the commissioner of agriculture (increasing certain
14 fees by rules and regulations), are authorized.

15 (k) The legislative rules filed in the state register on the
16 thirteenth day of January, one thousand nine hundred eighty-six,
17 modified by the commissioner of agriculture to meet the
18 objections of the legislative rule-making review committee and
19 refiled in the state register on the thirty-first day of January,
20 one thousand nine hundred eighty-six, relating to the
21 commissioner of agriculture (licensing of livestock dealers), are
22 authorized.

23 (l) The legislative rules filed in the state register on the
24 eighteenth day of June, one thousand nine hundred eighty-six,
25 modified by the commissioner of agriculture to meet the

1 objections of the legislative rule-making review committee and
2 refiled in the state register on the fifth day of January, one
3 thousand nine hundred eighty-seven, relating to the commissioner
4 of agriculture (West Virginia pesticide use and application act),
5 are authorized.

6 (m) The legislative rules filed in the state register on the
7 eighteenth day of August, one thousand nine hundred eighty-six,
8 modified by the director of the division of forestry of the
9 department of agriculture to meet the objections of the
10 legislative rule-making review committee and refiled in the state
11 register on the fifth day of January, one thousand nine hundred
12 eighty-seven, relating to the director of the division of
13 forestry of the department of agriculture (ginseng), are
14 authorized.

15 (n) The legislative rules filed in the state register on the
16 tenth day of April, one thousand nine hundred eighty-seven,
17 relating to the commissioner of agriculture (schedule of charges
18 for inspection services: fruit), are authorized.

19 (o) The legislative rules filed in the state register on the
20 thirteenth day of August, one thousand nine hundred eighty-seven,
21 modified by the commissioner of agriculture to meet the
22 objections of the legislative rule-making review committee and
23 refiled in the state register on the eighth day of September, one
24 thousand nine hundred eighty-seven, relating to the commissioner
25 of agriculture (animal disease control), are authorized.

1 . . . (p) The legislative rules filed in the state register on the
2 fifteenth day of September, one thousand nine hundred
3 eighty-eight, relating to the commissioner of agriculture (sale
4 and distribution of commercial fertilizer), are authorized.

5 (q) The legislative rules filed in the state register on the
6 fifteenth day of September, one thousand nine hundred
7 eighty-eight, modified by the commissioner of agriculture to meet
8 the objections of the legislative rule-making review committee
9 and refiled in the state register on the twenty-sixth day of
10 October, one thousand nine hundred eighty-eight, relating to the
11 commissioner of agriculture (animal disease control), are
12 authorized.

13 . . . (r) The legislative rules filed in the state register on the
14 fifteenth day of May, one thousand nine hundred eighty-nine,
15 modified by the commissioner of agriculture to meet the
16 objections of the legislative rule-making review committee and
17 refiled in the state register on the twenty-first day of August,
18 one thousand nine hundred eighty-nine, relating to the
19 commissioner of agriculture (production of milk and cream for
20 manufacturing purposes), are authorized.

21 . . . (s) The legislative rules filed in the state register on the
22 seventh day of August, one thousand nine hundred eighty-nine,
23 modified by the commissioner of agriculture to meet the
24 objections of the legislative rule-making review committee and
25 refiled in the state register on the twenty-third day of October,

1 one thousand nine hundred eighty-nine, relating to the
2 commissioner of agriculture (animal disease control), are
3 authorized.

4 (t) The legislative rules filed in the state register on the
5 tenth day of August, one thousand nine hundred ninety, modified
6 by the commissioner of agriculture to meet the objections of the
7 legislative rule-making review committee and refiled in the state
8 register on the fifth day of October, one thousand nine hundred
9 ninety, relating to the commissioner of agriculture (meat
10 inspection), are authorized.

11 (u) The legislative rules filed in the state register on the
12 tenth day of August, one thousand nine hundred ninety, modified
13 by the commissioner of agriculture to meet the objections of the
14 legislative rule-making review committee and refiled in the state
15 register on the third day of October, one thousand nine hundred
16 ninety, relating to the commissioner of agriculture (agricultural
17 liming materials), are authorized.

18 (v) The legislative rules filed in the state register on the
19 tenth day of August, one thousand nine hundred ninety, modified
20 by the commissioner of agriculture to meet the objections of the
21 legislative rule-making review committee and refiled in the state
22 register on the third day of October, one thousand nine hundred
23 ninety, relating to the commissioner of agriculture (public
24 markets), are authorized.

1 -- (w) The legislative rules filed in the state register on the
2 nineteenth day of September, one thousand nine hundred ninety,
3 modified by the commissioner of agriculture to meet the
4 objections of the legislative rule-making review committee and
5 refiled in the state register on the ninth day of November, one
6 thousand nine hundred ninety, relating to the commissioner of
7 agriculture (animal disease control), are authorized.

8 (x) The legislative rules filed in the state register on the
9 eighth day of August, one thousand nine hundred ninety-one,
10 modified by the commissioner of agriculture to meet the
11 objections of the legislative rule-making review committee and
12 refiled in the state register on the twenty-fourth day of
13 September, one thousand nine hundred ninety-one, relating to the
14 commissioner of agriculture (frozen desserts and imitation frozen
15 desserts) are authorized.

16
17 NOTE: The purpose of this bill is to authorize the
18 ~~Commissioner of Agriculture~~ to promulgate legislative rules
19 relating to frozen desserts and imitation frozen desserts.

20
21 Strike-throughs indicate language that would be stricken from
22 the present law, and underscoring indicates new language that
23 would be added.



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Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

WILLIAM H. HARRINGTON
Chief of Staff

JUDY COOPER
Director, Administrative Law

A. RENEE COE
Deputy Secretary of State

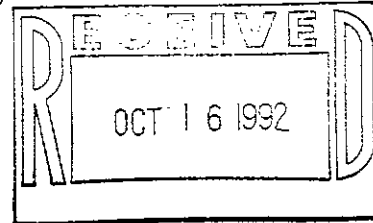
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help we can get)

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TO: Barbara Smith

AGENCY: Department of Agriculture

FROM: JUDY COOPER, DIRECTOR, ADMINISTRATIVE LAW DIVISION

DATE: October 15, 1992

THE ATTACHED RULE RECENTLY FILED BY YOUR AGENCY HAS BEEN ENTERED INTO OUR COMPUTER SYSTEM. PLEASE REVIEW, PROOF AND RETURN IT WITH ANY CORRECTIONS. IF THERE ARE NO CORRECTIONS, PLEASE SIGN THIS MEMO AND RETURN IT TO THIS OFFICE. YOU WILL BE SENT A FINAL VERSION OF THE RULE FOR YOUR RECORDS.

PLEASE RETURN EITHER THE CORRECTED RULE OR THIS FORM WITHIN TEN (10) WORKING DAYS OF THE DATE YOU RECEIVED THIS REQUEST. CALL IF YOU HAVE ANY QUESTIONS.

SERIES: 48 TITLE: 61 Department of Agriculture

* THE ATTACHED RULE HAS BEEN REVIEWED AND IS CORRECT.

SIGNED: _____

TITLE OF PERSON SIGNING: _____

DATE: _____

* THE ATTACHED RULE HAS BEEN REVIEWED AND NEEDS CORRECTING. THE CORRECTIONS HAVE BEEN MARKED.

SIGNED: Barbara J. Smith

TITLE OF PERSON SIGNING: Director of Compliance

DATE: 10-22-92

NOTE: IF YOU ARE NOT THE PERSON WHO HANDLES THIS RULE, PLEASE FORWARD TO THE CORRECT PERSON.