

FILED

TITLE 61
LEGISLATIVE RULE
DEPARTMENT OF AGRICULTURE

MAR 26 2 53 PM '95

SERIES 4B
FROZEN DESSERTS AND IMITATION FROZEN DESSERTS
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

§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. --

1.4. Effective Date. --

§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, 1995).

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

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.

§61-4B-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 require 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 6.5 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 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 firm whose name appears on the label, the name shall be qualified by a phrase that reveals the firm'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.d.A. In the case of mix being sold to a retailer, the product shall have a use by date on the container or the retailer shall be advised in writing by the distributor of how to calculate the use by date from the manufacture date or lot code on the containers; and

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. A manufacturer or distributor may use descriptors, such as "free," "light," "reduced," "less," "lower," etc., in conjunction with a standard of identity listed in section 4 of this rule and as outlined in 21 CFR, Part 101 adopted by reference in §61-4B-2.1.a. of this rule.

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

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

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

6.5.c. Product sold in a container from which product is dipped, and commonly known as a "bulk container," and where the product is not offered for sale to the ultimate consumer in the bulk container. This product is exempt from the label requirements of W. Va. Code, §19-11B-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; or,

6.5.d. Product packaged in units sold in a multi-unit container, provided that each individual unit remains within the multi-unit container during distribution and the multi-unit container is labeled according to the requirements of W. Va. Code, §19-11B-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 the 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/or 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/or <1 per gram for the coliform group;

8.1.e. The manufacturing conditions designated by this rule 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 this rule. Tolerances for the presence of antibiotics are those tolerances designated in 21 CFR, Part

556, as adopted by reference in section 2 of this rule. Tolerances for unavoidable poisonous or deleterious substances are those tolerances designated in 21 CFR, Part 109.30, as adopted by reference in section 2 of this rule. 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.

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 this rule 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; and,

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/or leaked products in manufacturing any other product.

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

10.7. No person may thaw frozen mixes in such a manner that any portion of the product exceeds 50°F.

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.

10.10 No person may offer for sale a mix product or a frozen dessert manufactured from a mix product having an expired sell-by or use-by code date.

§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 U.S. 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 have 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 two 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 tests by an independent laboratory.

12.3. All products from frozen dessert and imitation frozen dessert manufacturers taken by the commissioner for testing are considered official product samples.

12.3.a. The commissioner may have service sample(s) taken of frozen desserts or imitation frozen desserts, which would be considered unofficial.

12.4. The commissioner will consider only official samples 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 with the standards set forth in the Standard Methods for the Examination of Dairy Products, the Official Methods of Analysis or procedures referenced in 21 CFR, all adopted by reference in section 2 of this rule, or other methods as approved by the commissioner, 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 this rule.

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

§61-4B-14. Enforcement Policy.

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

14.2. 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 ten days from the mailing of the notice of violation.

14.3. 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 this rule and the enforcement policy established by this section of the rule.

14.4. 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.

14.4.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.

14.5. 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.

14.5.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 Third Notice.

14.6. 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 commissioner will normally issue a "Shut-Down Order" 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.

14.6.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.

14.6.b. The manufacturer or distributor are responsible for causing all operations covered by the Shut-Down Order to cease and for following 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.

14.7. If after a Shut-Down Order has been issued the commissioner finds that effective corrective action has not been taken, he or she 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.

14.7.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.

14.7.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.

14.7.c. The commissioner has seven days from the date of receipt of a written plan of correction and a request for the reinstatement of the permit 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 this rule. The commissioner will accept or deny the application for a reinstatement of the permit and will give the terms and conditions under which the permit will be reinstated.

14.8. 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 shall hold a hearing to determine if the Frozen Desserts Manufacturer Permit should be revoked.

14.9. 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 this rule.

14.10. 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.

14.11. 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.

14.12. 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 this rule.

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

14.14. The commissioner will only collect resamples 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:

14.14.a. After a First Notice and one non-violative sample, resamples will be taken 5 to 6 months after the non-violative sample.

14.14.b. After a Second Notice and one non-violative sample, resamples will be taken 3 to 4 months after the non-violative sample.

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

§61-4B- 15. Cleaning and Sanitizing.

15.1. 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.

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

15.1.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.

15.1.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.

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

15.1.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.

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

4235

H. B. 4235

(By Delegates Douglas, Gallagher, Faircloth, Compton,
Linch and Riggs)

(Introduced January 29, 1996; referred to the
Committee on the Judiciary)

61-4B

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

16 Be it enacted by the Legislature of West Virginia:

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

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

23 **§64-9-1. Commissioner of agriculture.**

1 (a) The legislative rules filed in the state

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1 register on the fifteenth day of August, one thousand nine
2 hundred ninety-four, authorized under the authority of
3 section one, article twenty-nine, chapter nineteen, of this
4 code, modified by the commissioner of agriculture to meet
5 the objections of the legislative rule-making review
6 committee and refiled in the state register on the
7 fourteenth day of October, one thousand nine hundred
8 ninety-four, relating to the commissioner of agriculture
9 (West Virginia aquaculture farm rules, 61 CSR 23), are
10 authorized with the amendments set forth below:

11 On page 1, section 61-23-1, by striking out section
12 1.1 and substituting in lieu thereof the following:

13 "1.1 The Commissioner will inspect aquaculture
14 production on a voluntary basis for a period of three
15 years. At the end of this three year period the
16 Aquaculture Farm Rule shall be reviewed to determine
17 whether the rule should become mandatory. Aquaculture
18 producers wishing to participate in the voluntary
19 inspection program must apply in writing to the
20 Commissioner. Once a producer enters the voluntary program
21 they will be required to produce fish according to all of
22 the provisions of this rule for the remaining portion of
23 the three year period. The inspections will be conducted
24 on a risk assessment basis with the purpose of educating

1 farmers and assuring the production of wholesome, unspoiled
2 and unadulterated fish and fishery products."

3 On page 4, section 61-23-3, by striking out section
4 3.1 and substituting in lieu thereof the following:

5 "3.1 All producers of fish participating in the
6 voluntary inspection program outlined in this rule shall
7 have and implement a written Hazard Analysis Critical
8 Control Point Plan, approved by the commissioner, for each
9 location where fish are grown. The commissioner shall
10 furnish a model Hazard Analysis Critical Control Point Plan
11 to the producers for them to follow."

12 On page 5, section 61-23-3, by striking out section
13 3.4.

14 On page 6, section 61-23-4, by striking out all of
15 section 4.6 and substituting in lieu thereof the following:

16 "4.6 Septic tanks, home aeration units, vault privy,
17 or other sewage tanks shall not be located within 50 feet
18 of a well or groundwater supply used as an aquaculture
19 water source, or aquaculture production areas in order to
20 prevent fecal and other contamination of water where fish
21 are raised for human consumption, except that tanks or
22 other aquaculture production systems with a barrier
23 preventing possible contamination may be located closer."

24 On page 8, section 61-23-7, by striking out section

1 7.1 and substituting in lieu thereof the following:

2 "7.1 All fish transported for sale and/or processing
3 by producers participating in this voluntary program shall
4 be:"

5 On page 8, section 61-23-7, by striking out section
6 7.5 and substituting in lieu thereof the following:

7 "7.5 All shipments of human food fish to other
8 producers, wholesalers, retailers, and/or processors
9 required to operate under a HACCP plan shall be accompanied
10 by a written notification stating that any and all drugs,
11 feed and color additives, pesticides and/or medicated feeds
12 have been legally administered and withdrawal periods have
13 been followed. This notification shall include the name,
14 address, and telephone number of the grower; date of sale;
15 and the lot number of fish. This notification shall be
16 signed by the grower. Except that:"

17 On page 8, section 61-23-7, by striking out section
18 7.5.a. and substituting in lieu thereof the following:

19 "7.5.a. Shipments of fish to other producers before
20 the completion of a required withdrawal period shall be
21 accompanied by a written notification including the name
22 and dose of the drug, feed, color additive, pesticide,
23 and/or medicated feed; date administered and length of
24 required withdrawal period; date of sale; and lot number of

1 the fish. This notification shall be signed by the
2 grower."

3 On page 9, section 61-23-9, by striking out section
4 9.1 and substituting in lieu the following:

5 "9.1 It is prohibited to:"

6 On page 10, section 61-23-10, by striking out section
7 61-23-10 in its entirety, and renumbering the remaining
8 sections.

9 On page 11, section 61-23-12, by striking out section
10 12.1.a and substituting in lieu thereof the following:

11 "12.1.a. Enter and inspect, during reasonable hours,
12 any aquaculture production area participating in the
13 voluntary inspection program, where fish are produced,
14 sold, stored, or transported. The inspection includes, but
15 is not limited to, photographing, video taping, verifying,
16 copying and auditing computer files, records and papers
17 relating to the production of fish, as is necessary to
18 determine compliance with this rule and to investigate
19 consumer complaints. The inspection also includes, but is
20 not limited to, photographing, video taping, observing and
21 verifying the premises, vehicles, personnel and
22 activities;"

23 On page 12, section 61-23-12, by striking out section
24 12.1.i.

1 On page 13, section 61-23-13, by striking out section
2 13.3.

3 And,

4 On page 13, section 61-23-13, by striking out section
5 13.4.

6 (b) The legislative rules filed in the state register
7 on the twenty-second day of July, one thousand nine hundred
8 ninety-four, authorized under the authority of section two,
9 article nine, chapter nineteen, of this code, modified by
10 the commissioner of agriculture to meet the objections of
11 the legislative rule-making review committee and refiled in
12 the state register on the ninth day of August, one thousand
13 nine hundred ninety-four, relating to the commissioner of
14 agriculture (animal disease control, 61 CSR 1), are
15 authorized.

16 (c) The legislative rules filed in the state register
17 on the fifteenth day of August, one thousand nine hundred
18 ninety-four, authorized under the authority of section
19 four, article twenty-nine, chapter nineteen, of this code,
20 modified by the commissioner of agriculture to meet the
21 objections of the legislative rule-making review committee
22 and refiled in the state register on the eleventh day of
23 October, one thousand nine hundred ninety-four, relating to
24 the commissioner of agriculture (inspection of

1 nontraditional, domesticated animals, 61 CSR 23D), are
2 authorized.

3 (d) The legislative rules filed in the state register
4 on the fifteenth day of August, one thousand nine hundred
5 ninety-four, authorized under the authority of section ten,
6 article eleven-a, chapter nineteen, of this code, modified
7 by the commissioner of agriculture to meet the objections
8 of the legislative rule-making review committee and refiled
9 in the state register on the fourteenth day of October, one
10 thousand nine hundred ninety-four, relating to the
11 commissioner of agriculture (labeling of dairy products for
12 rBST or rBGH, 61 CSR 4D), are authorized.

13 (e) The legislative rules filed in the state register
14 on the fifteenth day of August, one thousand nine hundred
15 ninety-four, authorized under the authority of section one,
16 article twenty-nine, chapter nineteen, of this code,
17 modified by the commissioner of agriculture to meet the
18 objections of the legislative rule-making review committee
19 and refiled in the state register on the fourteenth day of
20 October, one thousand nine hundred ninety-four, relating to
21 the commissioner of agriculture (West Virginia fish
22 processing rules, 61 CSR ~~23D~~ 23A), are authorized.

23 (f) The legislative rules filed in the state register
24 on the thirty-first day of July, one thousand nine hundred

1 ninety-five, authorized under the authority of section ten,
2 article eleven-b, chapter nineteen, of this code, modified
3 by the commissioner of agriculture to meet the objections
4 of the legislative rule-making review committee and refiled
5 in the state register on the twentieth day of December, one
6 thousand nine hundred ninety-five, relating to the
7 commissioner of agriculture (frozen desserts and imitation
8 frozen desserts, 61 CSR 4B), are authorized.

9

10 NOTE: The purpose of this bill is to authorize the
11 Commissioner of Agriculture to promulgate legislative rules
12 relating to the frozen desserts and imitation frozen
13 desserts.

14
15 Strike-throughs indicate language that would be
16 stricken from the present law, and underscoring indicates
17 new language that would be added.

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SENATE BILL NO. 166

(By Senators Ross, Anderson, Boley,
Buckalew, Grubb and Macnaughtan)

[Introduced January 29, 1996; referred
to the Committee on

AGRICULTURE

THE JUDICIARY

61-4B

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

1 register on the fifteenth day of August, one thousand nine
2 hundred ninety-four, authorized under the authority of
3 section one, article twenty-nine, chapter nineteen, of this
4 code, modified by the commissioner of agriculture to meet
5 the objections of the legislative rule-making review
6 committee and refiled in the state register on the
7 fourteenth day of October, one thousand nine hundred
8 ninety-four, relating to the commissioner of agriculture
9 (West Virginia aquaculture farm rules, 61 CSR 23), are
10 authorized with the amendments set forth below:

11 On page 1, section 61-23-1, by striking out section
12 1.1 and substituting in lieu thereof the following:

13 "1.1 The Commissioner will inspect aquaculture
14 production on a voluntary basis for a period of three
15 years. At the end of this three year period the
16 Aquaculture Farm Rule shall be reviewed to determine
17 whether the rule should become mandatory. Aquaculture
18 producers wishing to participate in the voluntary
19 inspection program must apply in writing to the
20 Commissioner. Once a producer enters the voluntary program
21 they will be required to produce fish according to all of
22 the provisions of this rule for the remaining portion of
23 the three year period. The inspections will be conducted
24 on a risk assessment basis with the purpose of educating

1 farmers and assuring the production of wholesome, unspoiled
2 and unadulterated fish and fishery products."

3 On page 4, section 61-23-3, by striking out section
4 3.1 and substituting in lieu thereof the following:

5 "3.1 All producers of fish participating in the
6 voluntary inspection program outlined in this rule shall
7 have and implement a written Hazard Analysis Critical
8 Control Point Plan, approved by the commissioner, for each
9 location where fish are grown. The commissioner shall
10 furnish a model Hazard Analysis Critical Control Point Plan
11 to the producers for them to follow."

12 On page 5, section 61-23-3, by striking out section
13 3.4.

14 On page 6, section 61-23-4, by striking out all of
15 section 4.6 and substituting in lieu thereof the following:

16 "4.6 Septic tanks, home aeration units, vault privy,
17 or other sewage tanks shall not be located within 50 feet
18 of a well or groundwater supply used as an aquaculture
19 water source, or aquaculture production areas in order to
20 prevent fecal and other contamination of water where fish
21 are raised for human consumption, except that tanks or
22 other aquaculture production systems with a barrier
23 preventing possible contamination may be located closer."

24 On page 8, section 61-23-7, by striking out section

1 7.1 and substituting in lieu thereof the following:

2 "7.1 All fish transported for sale and/or processing
3 by producers participating in this voluntary program shall
4 be:"

5 On page 8, section 61-23-7, by striking out section
6 7.5 and substituting in lieu thereof the following:

7 "7.5 All shipments of human food fish to other
8 producers, wholesalers, retailers, and/or processors
9 required to operate under a HACCP plan shall be accompanied
10 by a written notification stating that any and all drugs,
11 feed and color additives, pesticides and/or medicated feeds
12 have been legally administered and withdrawal periods have
13 been followed. This notification shall include the name,
14 address, and telephone number of the grower; date of sale;
15 and the lot number of fish. This notification shall be
16 signed by the grower. Except that:"

17 On page 8, section 61-23-7, by striking out section
18 7.5.a. and substituting in lieu thereof the following:

19 "7.5.a. Shipments of fish to other producers before
20 the completion of a required withdrawal period shall be
21 accompanied by a written notification including the name
22 and dose of the drug, feed, color additive, pesticide,
23 and/or medicated feed; date administered and length of
24 required withdrawal period; date of sale; and lot number of

1 the fish. This notification shall be signed by the
2 grower."

3 On page 9, section 61-23-9, by striking out section
4 9.1 and substituting in lieu the following:

5 "9.1 It is prohibited to:"

6 On page 10, section 61-23-10, by striking out section
7 61-23-10 in its entirety, and renumbering the remaining
8 sections.

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12 any aquaculture production area participating in the
13 voluntary inspection program, where fish are produced,
14 sold, stored, or transported. The inspection includes, but
15 is not limited to, photographing, video taping, verifying,
16 copying and auditing computer files, records and papers
17 relating to the production of fish, as is necessary to
18 determine compliance with this rule and to investigate
19 consumer complaints. The inspection also includes, but is
20 not limited to, photographing, video taping, observing and
21 verifying the premises, vehicles, personnel and
22 activities;"

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10 the commissioner of agriculture to meet the objections of
11 the legislative rule-making review committee and refiled in
12 the state register on the ninth day of August, one thousand
13 nine hundred ninety-four, relating to the commissioner of
14 agriculture (animal disease control, 61 CSR 1), are
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16 (c) The legislative rules filed in the state register
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19 four, article twenty-nine, chapter nineteen, of this code,
20 modified by the commissioner of agriculture to meet the
21 objections of the legislative rule-making review committee
22 and refiled in the state register on the eleventh day of
23 October, one thousand nine hundred ninety-four, relating to
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1 nontraditional, domesticated animals, 61 CSR 23D), are
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7 by the commissioner of agriculture to meet the objections
8 of the legislative rule-making review committee and refiled
9 in the state register on the fourteenth day of October, one
10 thousand nine hundred ninety-four, relating to the
11 commissioner of agriculture (labeling of dairy products for
12 rBST or rBGH, 61 CSR 4D), are authorized.

13 (e) The legislative rules filed in the state register
14 on the fifteenth day of August, one thousand nine hundred
15 ninety-four, authorized under the authority of section one,
16 article twenty-nine, chapter nineteen, of this code,
17 modified by the commissioner of agriculture to meet the
18 objections of the legislative rule-making review committee
19 and refiled in the state register on the fourteenth day of
20 October, one thousand nine hundred ninety-four, relating to
21 the commissioner of agriculture (West Virginia fish
22 processing rules, 61 CSR ~~23D~~ 23A), are authorized.

23 (f) The legislative rules filed in the state register
24 on the thirty-first day of July, one thousand nine hundred

1 ninety-five, authorized under the authority of section ten,
2 article eleven-b, chapter nineteen, of this code, modified
3 by the commissioner of agriculture to meet the objections
4 of the legislative rule-making review committee and refiled
5 in the state register on the twentieth day of December, one
6 thousand nine hundred ninety-five, relating to the
7 commissioner of agriculture (frozen desserts and imitation
8 frozen desserts, 61 CSR 4B), are authorized.

9

10 NOTE: The purpose of this bill is to authorize the
11 Commissioner of Agriculture to promulgate legislative rules
12 relating to the frozen desserts and imitation frozen
13 desserts.

14

15 Strike-throughs indicate language that would be
16 stricken from the present law, and underscoring indicates
17 new language that would be added.

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

STEPHEN N. REED
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

Telephone: (304) 558-6000
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FILED

WILLIAM H. HARRINGTON
Chief of Staff

APR 10 10 15 AM '96 JUDY COOPER
Director, Administrative Law

PENNEY BARKER
Supervisor, Corporations

STATE OF WEST VIRGINIA OFFICE OF WEST VIRGINIA
SECRETARY OF STATE SECRETARY OF STATE

SECRETARY OF STATE
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

(Plus all the volunteer
help we can get)

TO: John Liggett

AGENCY: Agriculture

FROM: JUDY COOPER, DIRECTOR, ADMINISTRATIVE LAW DIVISION

DATE: April 3, 1996

THE ATTACHED RULE 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: 4B TITLE: 61 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: [Signature]

TITLE OF PERSON SIGNING: Assistant Director, Regulatory Protection Div.

DATE: April 8, 1996

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

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

STEPHEN N. REED
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

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Supervisor, Corporations

STATE OF WEST VIRGINIA

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Charleston, WV 25305-0770

(Plus all the volunteer
help we can get)

March 12, 1996

John E Liggett
Agriculture
Regulatory Protection Division
1900 Kanawha Blvd East
Charleston, WV 25305

SB 162 authorizing, Title 61, Series 04B, Frozen Desserts & Imitation Frozen Desserts passed the Legislature on **March 9, 1996**. It is now awaiting the Governor's signature.

You have sixty (60) days after the Governor signs **SB 162** to final file the legislative rule with the Secretary of State's office. To final file your legislative rule, fill in the blanks on the enclosed form #6, the "Final Filing" form and file the form with our office with a promulgation history of the rule. Authorization for your legislative rule is cited in **SB 162 Section 64-9-1(e)**. The agency may set the effective date of the legislative rule up to ninety (90) days from the date the legislative rule is final filed with the Secretary of State's office. Please have an authorized signature on the bottom line.

*****IMPORTANT: IF YOUR AGENCY HAS COMPLETED THE LEGISLATIVE RULE ON A WORD PERFECT OR WORD PERFECT COMPATIBLE COMPUTER SYSTEM THAT USES A 3 1/2" DISK, YOU MUST SUBMIT A CLEAN COPY WITH ALL UNDERLINING AND STRIKE-THROUGHS, HEADERS OR FOOTERS REMOVED, TO OUR OFFICE WHEN FINAL FILING THE RULE. REMEMBER, THE TEXT OF THE COMPUTER FILED RULE MUST BE IDENTICAL - WORD FOR WORD, COMMA FOR COMMA, WITH ALL UNDERLINING, STRIKE-THROUGHS, HEADERS OR FOOTERS REMOVED, AS THE HARD COPY AUTHORIZED BY THE LEGISLATURE. NOTICE: ALL ELECTRONIC FILINGS NOT COMPLYING WITH THIS WILL BE REJECTED AND SENT BACK TO THE AGENCY TO BE RESUBMITTED!**

After the final rule is entered into the data base, the rule will be sent back to the agency for review and proofing. The agency has ten (10) working days to send a confirmation or corrections to the Secretary of States. If the agency fails to return this within ten (10) working days, the rule will be filed in the data base with a disclaimer attached stating that the agency failed to review the rule. Following confirmation, corrections or failure to review, as the case may be, the Secretary of State shall submit to the agency a final version of the rule for their records.

If you have any questions or need any assistance, please do not hesitate to contact our office.

Thank you,
Administrative Law Division