WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION
#2

FILED
JUN 23 4 10 PM '95

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Department of Agriculture TITLE NUMBER: 61

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

AMENDMENT TO AN EXISTING RULE: YES X NO ___

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

TITLE OF RULE BEING AMENDED: Frozen Desserts and Imitation Frozen Desserts

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: ___

TITLE OF RULE BEING PROPOSED: ___

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 24, 1995 AT 8:00 a.m.

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

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

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

Robert L. Maynor

5.80

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

STATEMENT OF CIRCUMSTANCES

Regulatory Protection Division
West Virginia Department of Agriculture

Frozen Desserts and Imitation Frozen Desserts

LEGISLATIVE RULE
§61-4b-1 et seq.

These amendments to the existing rule are necessitated by changes in CFR 21 with regard to the labeling of frozen desserts and the standards of identity of the same. The proposed changes to the rule include removal of requiring NSF approval for frozen dessert equipment, the addition of the requirement of a USE BY date on mix, and the removal of low-fat and non-fat descriptors which are no longer in sync with federal requirements.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Frozen Desserts and Imitation Frozen Desserts

Type of Rule: X Legislative ____Interpretive ____Procedural

Agency: West Virginia Department of Agriculture

Address: Regulatory Protection Division

1900 Kanawha Blvd., East

Charleston, WV 25305

1. Effect of Proposed Rule

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	$ 0	$ 0	$ 0	$ 0	$ 0
PERSONAL SERVICES	0	0	0	0	0
CURRENT EXPENSE	0	0	0	0	0
REPAIRS & ALTERNATIONS	0	0	0	0	0
EQUIPMENT	0	0	0	0	0
OTHER	0	0	0	0	0

2. Explanation of above estimates:

This is an existing rule and the changes being offered are expected to have no fiscal impact.

3. Objectives of these rules:

To align state regulations with Federal guidelines and eliminate sections of the rule that were found to be unworkable.

Rule Title: Frozen Desserts and Imitation Frozen Desserts

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None

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

None

C. Economic Impact on Citizens/Public at Large.

None

Date: 6-23-95

Signature of Agency Head or Authorized Representative

Robert D. Moore

Summary

Frozen Desserts and Imitation Frozen Desserts

§61-4A-1 et seq.

West Virginia Department of Agriculture

Legislative Rule

This is a modification to an existing legislative rule. The existing rule establishes the requirements governing the manufacture and distribution of frozen desserts and imitation frozen desserts. The existing rule includes incorporation by reference of several federal regulations as well as several nationally established standards for the sampling and testing of frozen desserts.

The existing rule also includes standards of identity not defined in the CFR, frozen dessert labeling requirements, misbranding section, adulteration section, manufacturing conditions for frozen desserts, prohibited acts, animal health requirements for the milk being used in frozen desserts, powers and duties of the commissioner, approved sampling and testing methods, a section outlining the requirements for an approved laboratory, an enforcement policy for frozen desserts, and cleaning and sanitizing guide for frozen dessert equipment.

The proposed changes to the rule include: removal of the section requiring NSF approval for frozen dessert equipment, the addition of the requirement of a use by date on mix, the removal of lowfat and nonfat descriptors which are no longer in sync with federal requirements, correction to the frozen mix thawing temperature, the addition of the prohibition of selling outdated mix, and the removal of the approved laboratory section which did not work as originally conceived.

FILED

JUN 23 4 10 PM '95

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

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. --

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, 1990~~ April 1, 1994)

2.1.b. Title 40 Code of Federal Regulations (~~July 1, 1990~~ July 1, 1991)

~~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.c. ~~15th~~ 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. ~~15th~~ 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. ~~6th~~ 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 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 thermophilous. 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~~ 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 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.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 of how to calculate the use by date

from the manufacture date or lot code on the containers.

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% but 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".~~

6.4 Descriptors such as "free", "light", "reduced", "less", "lower", etc. may be used in conjunction with a standard of identity as outlined in 21 CFR Part 101 adopted by reference in §61-4B-2.1.a. of this rule.

~~6.6.~~ 6.5. A manufacturer or distributor shall not distribute any package, of whatever form, without a complete label attached except for:

~~6.6.a.~~ 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.

~~6.6.b.~~ 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.

~~6.6.c.~~ 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.

~~6.6.d.~~ 6.5.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.

§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 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~~ exceed ~~40°F~~ 50°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.

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 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~~ independent 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.~~

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. Only official 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, or other methods as approved by the commissioner 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 ± .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~~ 14. Enforcement policy.

~~15~~ 14.1. 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~~ 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 10 days from the mailing of the notice of violation.

~~15~~ 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 these rules and the enforcement policy established by this section of the rule.

~~15~~ 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.

~~15~~ 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.

~~15~~ 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.

~~15~~ 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 notice.

~~15~~ 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 "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~~ 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.

~~15~~ 14.6.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~~ 14.7. 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~~ 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.

~~15~~ 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.

~~15~~ 14.7.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~~ 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 will hold a hearing to determine if the Frozen Desserts Manufacturer Permit should be revoked.

~~15~~ 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 these rules.

~~15~~ 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.

~~15~~ 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.

~~15~~ 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 these rules.

~~15~~ 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.

~~15~~ 14.14. 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~~ 14.14.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~~ 14.14.b. After a second notice and one non-violative sample, resamples will be taken between 3-4 months after the non-violative sample.

~~15~~ 14.14.c. Other resamples may be considered necessary to determine that the non-violative status is being maintained.

§61-4B-~~16~~ 15. Cleaning and sanitizing.

~~16~~ 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.

~~16~~ 15.1.a. The manufacturer shall thoroughly rinse all equipment used during the manufacturing process with lukewarm water until the water runs clear.

~~16~~ 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.

~~16~~ 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.

~~16~~ 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.

~~16~~ 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.

~~16~~ 15.1.f. The manufacturer is encouraged to use an acidic milkstone remover occasionally.