WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Agriculture

RULE TYPE: Legislative TITLE-SERIES: 61-04B

RULE NAME: Frozen Desserts and Imitation Frozen Desserts

CITE AUTHORITY: §19-11B-10

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Norman Bailey -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 61
LEGISLATIVE RULE
DEPARTMENT OF AGRICULTURE

SERIES 04B
FROZEN DESSERTS AND IMITATION FROZEN DESSERTS

§61-4B-1. General.

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

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

1.3. Filing Date. -- ~~April 21, 2015~~

1.4. Effective Date. -- ~~July 1, 2015.~~

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect on August 1, 2033.

§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 Chapter 1 Part 135 Frozen Desserts (April 1, 2003).

2.1.b. Title 40 Code of Federal Regulations Chapter 1 Subchapter N Part N Part 405 (July 1, 2002).

2.1.c. 17th edition of the "Standard Methods for the Examination of Dairy Products" published by the American Public Health Association, 1015 Fifteenth Street, N.W., Washington, D.C. 20005.

~~2.1.d. 17th Edition and supplements to the Official Methods of Analysis of AOAC International (formerly known as the Association of Official Analytical Chemists), published by AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877-2417.~~

~~2.1.e.~~ 2.1.d. 8th Edition and supplements to the "U.S. Food and Drug Administration Bacteriological Analytical Manual" published by AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877-2417.

~~2.1.f.~~ 2.1.e. Grade "A" Pasteurized Milk Ordinance, ~~2001~~ 2019, published by the Food and Drug Administration 200 "C" Street, SW, Washington, D.C. 20204.

2.1.f. Title 7 Code of Federal Regulations Subtitle B Chapter 1 Subchapter C Part 58 Subpart B Requirements for Finished Products Bearing USDA Official Identification § 58.648 Microbiological Requirements for Ice Cream.

§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~~ 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~~, or other milk-producing mammal, as described in W. Va. Code §19~~-1B~~-11B-2(p).

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 ~~sterilants~~ sterilant(s) or other treatment considered appropriate by the commissioner that renders the product or equipment free of viable microorganisms.

3.7. "Validation of Cleaning Procedure (VCP)" means the commissioner, or his or her designee, will enter a frozen dessert manufacturer's ~~place of business~~ place of operation to observe, evaluate, and to make recommendations; such recommendations are to assist the ~~place of business~~ manufacturer and to provide educational opportunities, for example, proper cleaning of the frozen dessert unit. Any samples collected during a VCP will be considered "unofficial," or, in other words, will be part of the educational and informational component (part of the VCP only).

§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 trench 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~~ thermophilus. Fruit, ~~nuts~~ 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~~ because 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~~ 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. The ~~Commissioner~~ commissioner shall issue a 'frozen desserts manufacturer permit' to each manufacturer of frozen desserts or imitation frozen desserts. Permits shall be issued for each place of operation and are not transferable with respect to persons or locations. The permit may be applied to the operation of several freezers at one location. Each freezer will be registered with the commissioner on forms provided and will inform the commissioner of the addition or removal of freezer(s) from a ~~place of business~~ place of operation. Each mobile unit shall be considered as operating at one location.

5.2. Individuals, churches, fraternal ~~organizations~~ organizations, and other groups or 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.

5.3. A manufacturer shall apply on forms supplied by the commissioner and provide any information considered necessary by the commissioner. A manufacturer shall apply for the permit at least fifteen days before the date that the current permit expires or within fifteen days of the date that the person intends to engage in business. A fee ~~of thirty-five dollars ($35.00)~~ set by Appendix 1, Schedule of Fees shall accompany the application. ~~The Commissioner shall add an~~ An additional ~~penalty~~ fee of ~~$100.00~~ $2 shall be ~~chargedto all permits that are not applied for~~ charged when a permit is not sought or renewed within ~~this~~ the above-stated time ~~limit~~. Resample fee(s) and fines must be paid with the registration fee(s) before a permit will be issued. All fees will be collected at the start of the renewal period or at a time or interval otherwise determined by the commissioner. All fees may be paid before the renewal period if such pre-renewal period payments are approved by the commissioner. ~~The permits expire of the thirty-first day of March following the date of issue.~~ Permits will expire on March 31st of each year and must be renewed annually.

5.4. The manufacturer shall place the permit prominently at the place of operation.

§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~~ 6.4 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~~ 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~~ packer, or distributor. The address shall include the city, ~~state~~ state, and zip code. A street address is required to identify the firm ~~place of business~~ 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 ~~place of business~~ whose name appears on the label, the name shall be qualified by a phrase that reveals the firm's ~~place of business'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. In addition, if the name on the label is not the manufacturer, the lot designation or code date shall identify the manufacturer.

6.1.d.A. In the case of mix being sold to a retailer, the product shall have a ~~use by date~~ sell by date or expiration 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. 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 §61-48-2.1.a. of this rule.

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

6.4.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~~ packer, or distributor;

6.4.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;

6.4.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~~ 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,

6.4.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, labeled 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;

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, or

7.1.d. It does not meet the minimum labeling requirements for 21 CFR Part 101 "Nutritional Labeling".

§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~~ 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; or

8.1.f. Pathogenic bacteria are in the ~~product~~ product.

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

§61-4B-9. Manufacturing Conditions.

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

9.2. All equipment, utensils, ~~containers~~ 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 always 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 41°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~~ parts, or the utensils placed in it.

9.7. The manufacturer shall, at all times, 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~~ suitable, and adequate toilets ~~and~~ and/or 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 clean and 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 perishables or non-perishables in locker rooms, toilet rooms or their vestibules, garbage rooms or mechanical rooms.

9.12. The manufacturer shall have a written cleaning and sanitizing guide for the type of equipment used to manufacture product at its facility.

~~9.13. The manufacturer manufacturing products which permit the self service of frozen desserts by the customer shall comply with the following provisions to protect the product from contamination by the public:~~

~~9.13.a. Hoppers, reservoirs and similar frozen dessert mix holding devices to which the public has easy access shall be secured by a method acceptable to the Department to prevent entry by the public; and~~

~~9.13.b. Dispensing nozzles on dispensing freezers shall be protected from incidental contact by the customer by installation of a barrier or shield in front of the nozzle.~~

§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~~ after the addition of the eggs or egg products.

10.2. No person may offer for sale, ~~transport~~ 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 41°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~~ if that product temperature is not allowed to exceed 41°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 41°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 (4) 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~~ if the corrosion caused by such use is minimal.

~~10.10~~ 10.10. ~~No person may offer for sale a~~ A mix product or ~~a~~ frozen dessert manufactured from an expired mix product ~~a mix product having an expired~~ (e.g., one that is past the expiration date or sell-by date) ~~or use-by code date~~ may not be offered for sale.

10.11 Unless the product is pasteurized after the addition of the milk or milk products, a product that contains unpasteurized milk shall not be made or used.

§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, Modified Accredited Advanced Tuberculosis Area or a Tuberculosis Free Area as determined by the U.S. Department of Agriculture, Provided, that herds located in an area that fails to maintain 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 ninety (90) day intervals, and any herd where any animal has a positive milk ring test shall have all animals that are producing milk, or that have recently produced milk, tested with the milk ring test within thirty (30) days from the date of the laboratory ring tests; or

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 to be official product samples unless such samples are collected as part of a VCP.

12.3.a. The commissioner may have service samples taken of frozen desserts or imitation frozen desserts, and such service samples are ~~which would be~~ considered to be unofficial. A manufacturer ~~place of business~~ must contact the commissioner to conduct a VCP, and, upon approval of the commissioner, the VCP will be scheduled ~~with the place of business~~ at the manufacturer's place of business. Those in attendance at a VCP can include owners, management, and/or other necessary individuals. A VCP is not to be used as a replacement for proper training of employees of a ~~place of business~~ manufacturer and is solely intended for educational and/or informational purposes. A VCP fee will apply as set forth in Appendix 1, excluding travel time. No resample fee will be assessed for a VCP. A VCP shall not be conducted more than once every 2 years, unless approved or recommended by the commissioner.

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 Part 135, 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 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~~ low-fat and nonfat products are ~~±,.15%.Tolerances~~ ±.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~~ Section 2 of this rule.

13.4. The testing of products for drug residues shall include any of those residues listed in 21 CFR Part ~~556,~~ 556 and shall use methods adopted by reference in ~~section~~ Section 2 of this rule.

§61-4B-14. Enforcement Policy for Mix Manufacturers or Distributors.

14.1. The commissioner may assess a ~~violation~~ fee as set forth by ~~of~~ W. Va. Code §§19-11B-1 et seq. or ~~of~~ by this rule against the manufacturer of ~~product~~ mix(es) 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 mix manufacturer and/or 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~~ ~~place of business~~ ~~manufacturer~~ mix manufacturer or distributor 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 samples taken on separate days ~~within a one year period~~ are found to be adulterated or misbranded, the commissioner shall send a written "First Notice" to the mix manufacturer or distributor whichever is appropriate. This notice shall notify the mix 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 samples taken on separate days ~~within a one year period~~ are found to be adulterated or misbranded, the commissioner shall send a written "Second Notice" to the mix manufacturer or distributor whichever is appropriate.

14.4.a. The commissioner ~~shall~~ may collect additional official mix ~~product~~ samples after the Second Notice has been sent to the manufacturer or distributor. ~~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 seven (7) days from the sending of a Second Notice.~~

14.5. Whenever three of the last five consecutive official mix ~~product~~ samples taken on separate days ~~within a one year period~~ are found to be adulterated or misbranded the commissioner shall send a written "Third Notice" to the mix manufacturer or distributor whichever is appropriate.

14.5.a. The commissioner ~~shall~~ may collect additional official mix ~~product~~ samples ~~within 21 days~~ after 15 business days of the sending of the Third Notice to the manufacturer or distributor~~, but shall not collect additional product samples before the lapse of seven (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 twenty-four (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.~~ A ~~manufacturer~~ mix manufacturer or distributor will be assessed a fee of $100 with the issuance of a "Third Notice." All fees will be paid to the department.

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~~ safety, or welfare. In these cases, the mix manufacturer or distributor will be given the opportunity to request an informal hearing before the commissioner after the notification of the Order is received by the mix manufacturer or distributor. All Shut-Down Orders issued due to non-compliance with subdivisions 8.1.c., 8.1.d. or ~~8.1.g.~~ 8.1.f. of this rule are considered to involve a risk to the public health, safety or welfare.

14.6.b. The mix 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 mix 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~~ the commissioner may issue a suspension of the ~~Frozen Desserts Manufacturer~~ Dairy Distributor Permit. The suspension shall state the time that the suspension will become effective, give the reasons for the ~~suspension~~ 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 mix manufacturer or distributor the opportunity to request a hearing in this matter ~~subsequent to~~ after 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.~~ 8.1.f. of this rule are summary suspensions.

14.7.b. A suspension of the ~~Frozen Desserts Manufacturer~~ Dairy Distributors Permit remains in effect until the mix manufacturer or distributor submits and the commissioner accepts a written plan of correction and a request for a reinstatement of the permit. A mandatory course on cleaning and sanitation must be completed, as determined by the commissioner, before the suspension will be lifted.

14.7.c. The commissioner has ~~seven (7)~~ 10 business 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.~~ 8.1.f. of this rule and ~~fourteen~~ 15 business days to respond for all other violations of W. Va. Code §§19-11B-1 et seq. ~~or~~ of this rule. The commissioner shall accept or deny the application for a reinstatement of the permit and shall 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, shall 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.~~ 14.8. Whenever an antibiotic or pesticide residue test is found to be above tolerance, the commissioner shall notify the mix 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.~~ 14.9. 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~~ deciding on an exemption.

~~14.12.~~ 14.10. The commissioner may apply the enforcement policy in a liberal manner in cases where all ~~official product~~ mix 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.~~ 14.11. The commissioner may suspend the standard enforcement policy in cases where such action is necessary to protect the public health, ~~safety~~ safety, or welfare.

~~14.14. The commissioner will only collect resamples from machines that were shown to be producing violative product the during 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 five (5) to six (6) months after the non-violative sample.~~

~~14.14.b. After a Second Notice and one non-violative sample, resamples will be taken three (3) to four (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.~~

~~14.15.~~ 14.12. Hearings.

~~14.15.a. If a violator requests an informal hearing, the compliance officer shall schedule a hearing in accordance with the following procedures:~~

~~14.15.a.1. The compliance officer shall notify any authorized representative of the Commissioner who was involved in the inspection which discovered the violation which is the subject of the hearing, and the violator of the time and place of the informal hearing. In scheduling the location of the informal hearing, the compliance officer shall consider the location of the violation and the violator. The compliance officer may schedule the hearing anywhere in the State of West Virginia.~~

~~14.15.a.2. The compliance officer shall notify the parties at least fifteen (15) calendar days prior to the time of the hearing; and~~

~~14.15.a.3. The compliance officer may continue the informal hearing only for good cause shown.~~

~~14.15.b.~~ 14.12.a. Informal Hearing Procedures. An informal hearing, as provided in this subsection, is intended to be an informal discussion of the facts which gave rise to the issuance of a notice of violation. A hearing can be requested at any time by the commissioner or by the permittee. ~~The hearing officer shall conduct the hearing in the following manner:~~

~~14.15.b.1. The hearing officer shall not discuss the case "ex parte" with either the~~

~~compliance officer or other department employees involved in the case;~~

~~14.15.b.2. The hearing officer shall not strictly apply The West Virginia Rules of Civil Procedure and West Virginia Rules of Evidence~~

~~14.15.b.3. All testimony and evidence at a hearing shall be recorded by mechanical means, which may include the use of tape recordings. The mechanical record shall be maintained for ninety(90) days from the date of the hearing and the Department shall make a transcript of the hearing available to the aggrieved party.~~

~~14.15.b.4. Within thirty (30) calendar days following the informal hearing, the hearing officer shall issue and furnish a written decision affirming or dismissing the initial notice of violation and give reasons for his or hers decision.~~

~~14.15.a.4.~~ 14.12.b. A party seeking to challenge the suspension, revocation, or denial order of a permit may appeal within sixty (60) days to the West Virginia Intermediate Court of Appeals. ~~Any party who feels aggrieved of the suspension, revocation or denial order of a license may appeal within sixty (60) days to the circuit court of the county in which the violator has located its principal place of business.~~

~~14.15.a.5.~~ 14.12.c. At any formal review proceedings which may occur later, any evidence, as to any statement made by one party at the informal hearing, may not be introduced as evidence by another party, nor may any statement be used to impeach a witness, unless the statement is or was available as competent evidence independent of its introduction during the informal hearing.

14.12.d. A hearing (other than an informal hearing) may take place at the request of the commissioner in instances of extenuating circumstance. The commissioner will state the cause for this hearing, set a time and date, and will set forth the responsibilities of each party. Notice of such hearings will be provided 15 business days in advance of the date set by the commissioner.

§61-4B-15. Enforcement Policy for Frozen Dessert or Imitation Frozen Dessert Manufacturers

15.1. The commissioner may assess a violation or fee as set forth by W. Va. Code §§19-11B-1 et seq., or as provided by this rule, against the manufacturer of product made in the state.

15.1.a. A resample fee of $45 will be collected for each collection day after the issuance of a "First Notice".

15.2. Whenever official product samples taken are found to be adulterated or misbranded, the commissioner shall send a written "First Notice" to the manufacturer. This notice shall notify the manufacturer 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. Resamples may be taken after 20 business days of the sending of the "First Notice".

15.3. Whenever official product samples taken are found to be adulterated or misbranded after the issuance of a "First Notice", the commissioner shall send a written "Second Notice" to the manufacturer. This notice shall notify the manufacturer 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. Resamples may be taken after 20 business days of the sending of the "Second Notice".

15.4. Whenever official product samples taken are found to be adulterated or misbranded after the issuance of a "Second Notice", the commissioner shall send a written "Third Notice" to the manufacturer. This notice shall notify the manufacturer 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. Resamples may be taken after 20 business

days of the sending of the "Third Notice". A manufacturer will be assessed a fee of $100 with the issuance of a "Third Notice". All fees will be paid to the department.

15.5. The commissioner will issue a "Shut-Down Order" for a period of twenty-four (24) hours to a manufacturer when the record of the ~~place of business~~ manufacturer indicates that effective action has not been taken to correct the causes of the violation. All violations will be assessed when the same machine(s) are violative. The commissioner may 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 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. 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 under the provisions of subdivision 15.5.a. of this rule.

15.5.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.f. of this rule are considered to involve a risk to the public health, safety, or welfare.

15.5.b. The manufacturer is 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 may resume operations without further action by the commissioner.

15.6. If after a "24 Hour Shut-Down Order" has been issued and the commissioner finds that the manufacturer has not complied with the Shut-Down Order, the commissioner 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 an informal 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 an informal hearing in this matter after the notification of the suspension to explain the failure to follow the Shut-Down Order.

15.7. Whenever official product samples taken are found to be adulterated or misbranded after the issuance of a "Third Notice", the commissioner shall send a written "Fourth Notice" to the manufacturer. This notice shall notify the manufacturer 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. A manufacturer will be assessed a fee of $200 with the issuance of a "Fourth Notice". All fees will be paid to the department. A suspension of the Frozen Desserts Manufacture Permit will be issued at this time of the "Fourth Notice", and all manufacturing operation is prohibited from operating while the suspension is in effect. After the issuance of a "Fourth Notice" the manufacturer must submit, and the commissioner accepts a written plan of correction. The manufacturer must state the actions to be taken to correct the problem. A mandatory course on cleaning and sanitation must be completed, as determined by the commissioner before the suspension will be released.

15.8. The commissioner has 10 business days from the date of receipt of a written plan of correction, a completed notice of the mandatory cleaning and sanitation course 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.f. of this rule and 15 business days to respond for all other violations of W. Va. Code §§19-11B-1 et seq. or this rule. The commissioner shall accept or deny the request for a reinstatement of the permit and shall give the terms and conditions under which the permit will be reinstated.

15.9. Whenever official product samples taken are found to be adulterated or misbranded after the issuance of a "Fourth Notice", the commissioner shall issue a Suspension of the Frozen Desserts Manufacturer Permit. This notice shall notify the manufacturer of the violation of W. Va. Code §§19-

11B-1 et seq. of this rule and the enforcement policy established by this section of the rule. The manufacture is to stop all production at the place of business. 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.

15.10. The failure to comply with the Suspension will result with the Frozen Desserts Permit being revoked for one (1) calendar year.

15.11. A hearing as determined by the commissioner will be scheduled by the commissioner. The hearing will determine the status of the Frozen Desserts Manufacturer Permit and how the manufacturer can have the Frozen Desserts Manufacturer Permit reinstated. The commissioner will determine all conditions necessary to reinstate the Frozen Desserts Manufacturer Permit.

15.12. All suspensions due to non-conformance to subdivisions 8.1.c., 8.1.d. or 8.1.f. of this rule are summary suspensions.

15.13. If the commissioner finds that after the ~~place of business~~ manufacturer has resumed production following a suspension of their Frozen Desserts Manufacturer Permit that effective corrective action has not been taken, then the commissioner may determine if the Frozen Desserts Manufacturer Permit should be revoked. Any actions taken will be determined by the commissioner and the place of business will be notified in writing. The ~~place of business~~ manufacturer may request a hearing with the commissioner.

15.14. Persons who manufacture a product on an intermittent or infrequent basis, so that the standard enforcement policy cannot apply, shall 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.

15.15. 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.

15.16. A person who performs a recall by voluntarily removing product from sale and distribution in an effective manner, 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 deciding on an exemption.

15.17. 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.

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

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

15.19.a. After a First Notice and one non-violative sample, resamples may be taken six (6) to twelve (12) months after the non-violative sample.

15.19.b. After a Second Notice and one non-violative sample, resamples may be taken three (3) to six (6) months after the non-violative sample.

15.19.c. After a Third Notice and one non-violative sample, resamples may be taken two (2) to four (4) months after the non-violative sample.

15.19.d. After a Fourth Notice and one non-violative sample, resamples may be taken one (1) to two (2) months after the non-violative sample.

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

15.20. Hearings

15.20.a The commissioner will schedule all hearings. The department shall notify any authorized representative of the non-violative samples. The department shall set the location of the hearing and determine what representatives of each party shall be in attendance. This is to be an informal hearing between the parties.

15.20.b. The department shall notify the parties at least 15 business days prior to the time of the hearing.

15.20.c. The department may continue the informal hearing only for good cause shown.

15.20.d. All decisions as determined by the commissioner shall be final, and all parties must comply with those decisions.

15.20.e. At any formal review proceeding(s) (a hearing other than an informal hearing) which may occur later, any evidence, as to any statement made by one party at the informal hearing, may not be introduced as evidence by another party, nor may any statement be used to impeach a witness, unless the statement is or was available as competent evidence independent of its introduction during the informal hearing.

~~§61-4B-15.~~ §61-4B-16. 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 water temperatures recommended in the machine's owner's manual.~~

~~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.~~

16.1. The manufacturer is responsible for the maintenance, upkeep, cleaning, sanitizing, and overall condition of the machine and product for which that machine produces. This includes the training of staff in the proper maintenance, cleaning, sanitizing, and operation of machine(s) in each permitted establishment. It is encouraged that more than one person be trained in the proper care and cleaning of the machine(s).

APPENDIX 1- Schedule of Fees

Permit Fee	$20
Resample Collection Fee	$45
Third Notice Fee	$100
Fourth Notice Fee	$200
Validation of Cleaning Procedure (VCP)	$50/hr. excluding travel time