

WEST VIRGINIA  
SECRETARY OF STATE

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #1

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OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

NOTICE OF PUBLIC HEARING ON A PROPOSED RULE

AGENCY: West Virginia Department of Agriculture TITLE NUMBER: 61

RULE TYPE: Legislative; CITE AUTHORITY 19-11B

AMENDMENT TO AN EXISTING RULE: YES\_\_\_ NO\_\_XX

IF YES, SERIES NUMBER OF RULE BEING AMENDED: \_\_\_\_\_

TITLE OF RULE BEING AMENDED: \_\_\_\_\_

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

TITLE OF RULE BEING PROPOSED: Frozen Desserts and Imitation

Frozen Desserts

DATE OF PUBLIC HEARING: Monday, July 29, 1991 TIME: 10:00 a.m.

LOCATION OF PUBLIC HEARING: West Virginia Department of Agriculture

J. T. Johnson Conference Room, Building 2

Guthrie Agricultural Center

Charleston, West Virginia 25312

COMMENTS LIMITED TO: ORAL\_\_\_, WRITTEN\_\_\_, BOTH\_\_XX

COMMENTS MAY ALSO BE MAILED TO THE FOLLOWING ADDRESS: Barbara J. Smith, Director  
Compliance Division  
WV Dept. of Agriculture

The Department requests that persons wishing to make comments at the hearing make an effort to submit written comments in order to facilitate the review of these comments.

1900 Kanawha Blvd., E

Charleston, WV 25305-0170

The issues to be heard shall be limited to the proposed rule.

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL



3.60

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APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Frozen Desserts and Imitation Frozen Desserts

Legislative Rule

West Virginia Department of Agriculture  
1900 Kanawha Boulevard East  
Charleston, West Virginia 25305-0170

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 and Alterations	0	0	0	0	0
Equipment	0	0	0	0	0
Other	0	0	0	0	0

2.) Explanation of the above estimates:

There is no anticipated increase to the cost to the state with the implementation of these rules because no significant changes to the current program are proposed. These rules primarily move the current program to the status of regulations.

It is expected that the development of the independent laboratories in this state for bacteriological testing will allow for a reduction in the cost to the state. It is expected that this development will take at least 2 years, therefore the reduction in cost is not shown in these figures.

3.) Objectives of these rules:

The objective of these rules are to develop the operating procedures for implementing the new Frozen Desserts and Imitation Frozen Desserts Law. The rules specify the manufacturing requirements, specify the enforcement policy, set parameters for the approval of laboratories, and adds conditions for adulteration, misbranding and prohibited acts in addition to those specified by law.

Frozen Desserts and Imitation Frozen Desserts

4.) Explanation of Overall Economic Impact of Proposed Rule.

A.) Economic Impact on State Government:

The initial implementation of this program will not be radically different than the current program. Therefore the initial costs to state government are not expected to be different. The costs involved with the approval of laboratories are to be reimbursed to the agency, therefore there will be no costs involved to the government with this process. As laboratories are approved and used by the industry, the cost to state government will decrease, as fewer inspections and samples will be taken by the agency.

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

The economic impact on the frozen dessert industry will involve the costs to obtain independent lab tests on a biannual basis. The estimated cost is between \$18 and \$30 per sample.

Several freezers (approximately 10) currently in use are believed to be not able to meet the standards for equipment specified in these regulations and will need to be replaced within the next 5 years.

A few operators will need to change their formulation for mix as these rules will prohibit the use of unpasteurized eggs for health considerations. There will be no substantial cost involved in this change.

The provisions for animal health are those currently in effect for the Grade A milk program and are not expected to have an effect on the industry.

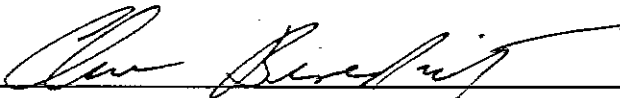
C.) Economic Impact on Citizens/Public at Large:

The public at large will be not be impacted to a significant degree. The increased costs that each operator bears for independent lab tests may involve an insignificant increase in the cost of the product to the customer.

Date:

June 26, 1991

Signature of Agency Head or Authorized Representative



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1991 JUN 26 AM 9:00

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 - §19-11B

1.3. Filing Date -

1.4. Effective Date -

1.5. This regulation is a new legislative rule.

§61-4B-2. Incorporation by Reference

2.1. Title 21 Code of Federal Regulations (April 1, 1991)

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

2.3. 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.

2.4. 15th edition of the "Standard Methods for the Examination of Dairy Products" published by the American Public Health Association, 1015 Eighteenth Street, N.W., Washington, D.C. 20036.

2.5. 15th edition and supplements to the "Official Methods of Analysis" published by the Association of Official Analytical Chemists, Suite 400, 2200 Wilson Boulevard, Arlington, Virginia 22201.

2.6. 6th edition and supplements to the "U.S. Food and Drug Administration Bacteriological Analytical Manual" published by the Association of Official Analytical Chemists, Suite 400, 2200 Wilson Boulevard, Arlington, Virginia 22201.

§61-4B-3. Definitions

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

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

3.3. "Milk products" shall include products made from the milk products from a 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 deemed 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 establishes standards of identity for ice cream, frozen custard, french ice cream, french custard ice cream, goat's milk ice cream, goat's milk frozen custard, goat's milk french ice cream, ice milk, goat's milk ice milk, mellorine, fruit sherbet and non-fruit sherbet.

4.2. Frozen yogurt is the food which is prepared by freezing while stirring a mix consisting of the ingredients permitted in ice cream. All dairy ingredients shall be pasteurized or ultrapasteurized. Safe and suitable sweetening agents may be used. Such ingredients are cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. Fruit, nuts or other flavoring materials may be added before or after the mix is pasteurized and cultured. The standard plate count requirement for frozen desserts shall only apply to the mix prior to culturing. Frozen yogurt, exclusive of any flavoring, contains not less than 3.25% milkfat, not less than 8.25% milk solids not fat, and has 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.

4.3.b. If the product contains saccharine, the statement "Contains \_\_\_\_\_% saccharine (or sodium salt of saccharine if the case may be) shall be placed prominently on the label. The blank shall be filled in with the percentage of saccharine 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, contains not less than 3.25% milkfat and 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 frozen desserts or imitation frozen desserts to members of their group or their guests on an intermittent and infrequent basis are exempt from the requirement to obtain a permit when the product is given away.

5.2. Beginning one year from the effective date of this rule, it shall be a requirement for the application for a frozen dessert manufacturers permit that the applicant show proof that he or she has contracted with an approved laboratory for the testing of standard plate count and coliform from each barrel of the machine at least two times a year.

5.2.a. The commissioner may allow exemptions to applicants for this requirement on a case by case basis for up to three years from the effective date of these regulations in areas where no approved laboratory is operating in order to allow frozen desserts to be manufactured in areas where this industry is not yet operating.

#### §61-4B-6. Labeling

6.1. Any package, of whatever form, shall have a complete label attached whenever distributed.

6.1.a. Product sold at the place of manufacturing in packages that are not completely closed at the time of sale are exempt from the label requirements for quantity and for the name and address of the manufacturer, packer or distributor.

6.1.b. Product sold at the place of manufacturing in packages that are placed in packages when the customer orders it is exempt from all labeling requirements.

6.2. Each product that is labeled on the outside of a multi-unit container shall not require labeling of each individual package inside the container, as long as each individual package remains within the labeled multi-unit container during distribution.

6.3. The use of the term "home made" or "farm made" is limited to those products that are actually manufactured in the home or on the farm.

6.4. The use of the term "lowfat" shall be used in the name of the product to indicate that the product meets all requirements for the food as defined or contained in a standard of identity except that the product contains not less than 0.5% nor more than 2.0% milkfat. This designation may not be used as a qualifier for the product "ice cream".

6.5. The use of the term "nonfat" shall be used in the name of the product to indicate that the product meets all requirements for the food as defined or in a standard of identity except that the product contains less than 0.5% milkfat. This designation may not be used as a qualifier for the product "ice cream".

6.6. The label shall contain the following information:

6.6.a. The brand name, if any, and the product name. The product name shall be the name established in the definition or the standard of identity 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.

6.6.b. Quantity 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.

6.6.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 \_\_\_\_\_".

6.6.d. A lot designation or code date to provide identification of the product with a specific production time-period. 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.

6.7. The name of the product on a menu, sign or any other advertising shall clearly reflect the accurate name of the product.

6.8. If ingredient statements or nutritional claims are made on the product label or in labeling, the requirements of 21 CFR Part 101 must be met.

#### §61-4B-7. Misbranded

7.1. Any frozen dessert or imitation frozen dessert referred to in this article shall be considered misbranded if:

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

7.1.b. it purports to be or is represented as a food for which a definition or standard of identity has been prescribed by this article or rule and its quality falls below such standard; 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 necessary to fully inform purchasers as to its value for such uses.

#### §61-4B-8. Adulteration

8.1. A frozen dessert or imitation frozen dessert shall be deemed adulterated if:

8.1.a. any substance has been added thereto or mixed or packed therewith 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 other chemical with these properties. The presence of any sanitizer residue caused as a normal consequence of sanitizing the equipment when standard industry practices are used shall not be considered an adulterant;

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

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

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

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

8.1.g. pathogenic bacteria are in the product.

8.2. Tolerances for the presence of pesticide residues shall be those designated in 40CFR Part 185; for the presence of antibiotics shall be those designated in 21CFR Part 556 and for unavoidable poisonous or deleterious substances shall be those designated in 21CFR 109.30. Laboratory tolerances for the method used will be added to these tolerances.

#### §61-4B-9. Manufacturing conditions

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

9.2. The equipment, utensils, containers and piping shall be constructed of a smooth, nontoxic, impervious, corrosion-resistant material and fabricated in such a manner that there is no contamination of the products handled therein. Such equipment shall be easily sanitized. Freezers shall be designed, installed and operated in accordance with the criteria set forth in Standard 6 adopted by the NSF Board of Trustees or as otherwise approved by the commissioner.

9.2.a. If equipment does not meet the standards outlined above, the permittee or manufacturer may petition the commissioner to allow for the use of the equipment. The petition will 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, 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. All equipment put in use after the effective date of this rule shall comply with these standards. Equipment in use on the effective date of this rule that does not meet the conditions set forth in this subsection shall be allowed to be used for five years from the effective date of this rule.

9.3. All equipment shall be kept in good working order and condition at all times that it is used to manufacture product.

9.4. All equipment shall be installed so that no solution used in cleaning or sanitizing shall remain inside the equipment in substantial amounts after the draining process.

9.5. Manufacturing equipment shall be completely disassembled and cleaned 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 has occurred. Equipment designed to achieve a daily heat treatment for reduction of viable bacteria shall be exempt from this provision regarding temperature but not the provision regarding adulteration.

9.6. Wash tanks adequate to wash and sanitize all equipment parts and utensils shall be provided 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 freezer or the utensils placed in it.

9.7. A hand washing facility with running hot and cold water, soap and individual towels or a mechanical hand dryer shall be available at all times in the vicinity of the freezer when producing product, except for those manufacturers operating at fairs, outings, carnivals and other affairs of short duration, where the use of single service cleaning towels will be allowed.

9.8. Proper, suitable and adequate toilets and lavatories will be available for each person involved in the manufacturing operation.

9.9. No person having any contagious or infectious disease shall be employed 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. Intermediate containers, such as pails or pouring containers in which mix comes in contact shall be washed, rinsed and sanitized immediately before use.

9.11. Storage of non-perishables shall not be 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 product unless the product is pasteurized subsequent to the addition of the eggs or egg products.

10.2. No person may be prohibited from offering for sale at the point of manufacture any soft-serve frozen desserts or imitation frozen desserts due to the product temperature exceeding 0°F as long as the temperature of the product has not exceeded a temperature of 45°F.

10.3. No person may be prohibited from offering for sale at retail any frozen dessert or imitation frozen dessert that exceeds a temperature of 0°F as long as that product is held in small quantities for the purpose of softening the product for dipping purposes and the product has not exceeded a temperature of 45°F at any time.

10.4. No person may be prohibited from using 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 is minimal.

10.5. No person may produce any frozen desserts and imitation frozen desserts in equipment that has not been sanitized.

10.6. 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.

10.7. No person may use any spilled, overflowed and leaked products in manufacturing equipment.

10.8. 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.

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

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

§61-4B-11. Animal Health

11.1. All frozen desserts or imitation frozen desserts shall be made from milk products or milk-derived ingredients from herds which are located in a Modified Accredited Tuberculosis 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.

11.2. All frozen desserts or imitation frozen desserts 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. Located in a Certified Brucellosis-free Area as defined by the U.S. Department of Agriculture and enrolled in the testing program for such areas;

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

11.2.c. Participating in a milkring testing program at least four times per year at approximately 90 day intervals, and all herds with positive milk ring test results shall have the entire herd blood tested within 30 days from the date of the laboratory ring tests; or

11.2.d. Have an individual blood agglutination test annually with an allowable maximum grace period not exceeding 2 months.

#### §61-4B-12. Approved sampling and testing methods

12.1. Procedures for the collection and holding of official 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 Standard Methods for the Examination of Dairy Products, the Official Methods of Analysis, or procedures referenced in 21CFR whichever is applicable to the product being tested.

12.2. The Roesse-Gottlieb Fat Extraction Method of testing for milkfat is adopted as the approved method for determining milkfat content of dairy products and is approved for all milkfat testing.

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

12.3. Aseptically processed milk and milk 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.

12.4. The testing methods for drug residues in food shall be those listed in 21CFR Part 556 where applicable.

§61-4B-13. Approved laboratories

13.1. Laboratories wishing to be approved under provisions of this article shall make application by letter to the commissioner. The application shall list the name and address of the laboratory, the owners, the laboratory director, and the names of the individuals that will be collecting the official samples. In addition, the application shall specify the methods for analysis, 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 given as supporting documents.

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

13.1.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.

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

13.2. The commissioner may make inspections of the approved laboratory at any time for cause.

13.3. The commissioner may suspend the approval of the laboratory at any time for cause. The laboratory may not test official samples under the provisions of this article with a suspended approval.

13.4. All official samples collected under the authority of this article shall be randomly scheduled and collected by a sampler who is listed under the terms of the approval of the laboratory. The laboratory will have a variance of  $\pm$  four weeks from when a resample is due in order to schedule a sample collection in a random manner.

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

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

13.6. Test results reported to the commissioner and the permittee shall be kept on file by these persons for at least two years. Reports shall be available for inspection.

#### §61-4B-14. Enforcement policy

14.1. The commissioner may institute charges against the permittee and/or the distributor of the mix used to manufacture the products.

14.2. If over 30% of the samples of mix from unopened containers are violative for a distributor within a three month period, then all remaining violations for unopened containers of mix shall be charged to the distributor until five official samples taken on different days are all non-violative. No violations will be charged to the distributor until at least 3 samples have been collected from that distributor during the three month period.

14.3. Whenever one of the last five consecutive official sample(s) taken on separate days within a one year period are found to be adulterated, the commissioner shall send a written notice thereof to the person concerned. This notice shall notify the person of the enforcement policy.

14.4. Whenever two of the last five consecutive official sample(s) taken on separate days within a one year period are found to be adulterated the commissioner shall send a written notice thereof to the person concerned. This notice shall notify the person concerned that a Level 1 suspension order is contemplated or in effect, the length of the suspension of the Frozen Desserts Manufacturers Permit, give the reasons for the suspension and offer the person concerned an opportunity to request a hearing in this matter.

14.4.a. A Level 1 suspension order shall remain in effect for three working days after the written notice is received by the permittee. After this time period, the permit will be automatically reinstated.

14.4.b. The commissioner shall collect additional official sample(s) within 21 days of the sending of such notice, but shall not sample before the lapse of 7 days from the sending of such notice.

14.5. Whenever three of the last five consecutive official

sample(s) taken on separate days within a one year period are found to be adulterated the commissioner shall send a written notice thereof to the person concerned. This notice shall notify the person concerned that a Level 2 suspension is contemplated or in effect, the length of the suspension of the Frozen Desserts Manufacturers Permit, give the reasons for the suspension and offer the person concerned an opportunity to request a hearing in this matter.

14.5.a. A Level 2 suspension shall remain in effect until the permittee submits and the commissioner accepts a written plan of correction and request for a reinstatement of the permit.

14.5.b. The commissioner shall have seven days from the date of receipt of this application to respond in the case of bacterial violations and fourteen days if the suspension is for other types of adulteration. The response shall accept or deny the application and will give the terms and conditions under which the permit will be reinstated.

14.5.c. The commissioner shall collect additional official sample(s) within 21 days of the reinstatement of the permit, but shall not sample before the lapse of 3 days from the date of reinstatement.

14.6. If two Level 1 suspensions occur within a twelve month period, then a hearing will be held to determine if the Frozen Desserts Permit should be revoked.

14.7. All suspensions for adulteration due to bacteria shall be summary suspensions.

14.8. Persons who manufacture on an intermittent or infrequent basis, such that the standard enforcement policy cannot apply, will enter into a consent agreement with the commissioner for correction of the violation(s) as a substitute for the standard policy.

14.9. Whenever an antibiotic or pesticide residue test is found to be above tolerance, the interested person(s) shall be notified immediately, an investigation shall be made to determine the cause, and the cause shall be corrected before the manufacturing and distribution of the product may resume.

14.10. 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 will consider the facts of each case when making a decision on an exemption.

§61-4B-15. Cleaning and sanitizing

15.1. Procedures for cleaning and sanitizing equipment and utensils that come in contact with frozen desserts and imitation frozen desserts shall be in substantial compliance with these guidelines.

15.1.a. Thoroughly rinse all equipment used during the manufacturing process with lukewarm water until the water runs clear.

15.1.b. Use a suitable detergent designed to remove the product from the equipment on all surfaces, including inside the freezer. The cleaning process will be sufficient to remove all product and lubricant residues and should be performed in hot (approximately 120°F) water.

15.1.c. 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 product.

15.1.d. Prior to use, do 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, hold the freezer draw tube open to allow all remaining sanitizer to be removed from the machine.

15.1.f. The occasional use of an acidic milkstone remover is highly recommended.

:frozen.reg