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STATE OF WEST VIRGINIA

SECRETARY OF STATE

Charleston 25305

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Director, Corporations

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Special Assistant

(Plus all the volunteer
help we can get)

August 12, 1991

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Agriculture

RULE: Amendments, Series 4B, Frozen Desserts

DATE ORIGINALLY FILED AS AN EMERGENCY RULE: June 26, 1991

FILED AS FIRST EMERGENCY AMENDMENT: August 8, 1991

DECISION NO. 71-91

Following review under WV Code 29A-3-15a, it is the decision of the Secretary of State that the above emergency rule be approved. A copy of the complete decision with required findings is available from this office.

A handwritten signature in cursive script that reads "Ken Hechler".

KEN HECHLER
Secretary of State

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Aug 12, 1991
ADMINISTRATIVE LAW DIVISION

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STATE OF WEST VIRGINIA

SECRETARY OF STATE

Charleston 25305

DECISION EMERGENCY RULE DECISION (ERD 71-91)

AGENCY: Agriculture
RULE: New Rule, Series 4B, Frozen Desserts
ORIGINALLY FILED AS AN EMERGENCY RULE: June 26, 1991
FILED AS EMERGENCY AMENDMENT: August 8, 1991

- par. 1 The Department of Agriculture (Department) has filed the above new rule as an emergency.
- par. 2 West Virginia Code 29A-3-a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine if the agency filing such emergency rule: 1) has complied with the procedures for adopting an emergency rule; 2) exceeded the scope of its statutory authority in promulgating the emergency rule; or 3) can show that an emergency exists justifying the promulgation of an emergency rule.
- par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [(29A-3-a(a))].
- par. 4 (A) Procedural Compliance: WV Code 29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).
- par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the forty-two day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.

par. 6 The Department filed this emergency rule with supporting documents with the Secretary of State August 8, 1991 and with the LRMRC August 8, 1991.

par. 7 It is the determination of the Secretary of State that the Department has complied with the procedural requirements of WV Code §29A-3-15 for adoption of an emergency rule.

par. 8 (B) Statutory Authority -- WV Code §19-11-10(a) reads:

(a) Adopt, promulgate and enforce rules to carry out the purpose of this article.

par. 9 It is the determination of the Secretary of State that the Department has not exceeded its statutory authority in promulgating this emergency rule.

par. 10 (C) Emergency WV Code 29A-3-15(g) defines "emergency" as follows:

(g) For the purposes of this section, an emergency exists when the promulgation of a rule is necessary for the immediate preservation of the public peace, health, safety or welfare or is necessary to comply with a time limitation established by this code or by a federal statute or regulation or to prevent substantial harm to the public interest.

par. 11 There are essentially three classes of emergency broadly presented with the above provision: 1) immediate preservation; 2) time limitation; and 3) substantial harm. An agency need only document to the satisfaction of the Secretary of State that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.

par. 12 The facts and circumstances as presented by the Department are as follows:

The Agency has modified the rule that was in effect as an emergency due to the comments received during the public hearing period.

The agency modified provisions of the definitions, permits, labeling, manufacturing conditions, prohibited acts, approved laboratories and the enforcement policy.

The agency wishes to enforce the rule as currently in front of the Legislative Rule Making Review committee.

par. 13 It is the determination of the Secretary of State that this proposal qualifies under the definition of an emergency as defined in §29A-3-15(g). . . "prevent substantial harm to public interest."

par. 14 This decision shall be cited as Emergency Rule Decision 71-91 or ERD 71-91 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Department of Agriculture, the Attorney General and the Legislative Rule Making Review Commission.



KEN HECHLER
Secretary of State

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Aug 12, 1991
ADMINISTRATIVE LAW DIVISION

Entered _____

**WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION**

Form #8

Do Not Mark In This Box
Filing Date

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Aug. 7, 1991
ADMINISTRATIVE LAW DIVISION

Effective Date

Aug. 12, 1991

NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE

AGENCY: Agriculture TITLE NUMBER: 61

DATE EMERGENCY RULE WAS ORIGINALLY FILED: June 26, 1991

IS THIS THE FIRST EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:

yes

IS THIS THE SECOND EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:

DATE OF FIRST EMERGENCY AMENDMENT: _____

SERIES NUMBER OF RULE: 4B TITLE OF RULE: Frozen Desserts and
Imitation Frozen Desserts

THE ATTACHED IS AN EMERGENCY AMENDMENT TO AN EXISTING EMERGENCY RULE. THIS EMERGENCY AMENDMENT BECOMES EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 35TH DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY AMENDMENT ARE AS FOLLOWS:

See attached sheet

Use Additional Sheets If Necessary.


Signature

FROZEN DESSERTS AND IMITATION FROZEN DESSERTS

STATEMENT OF THE FACTS AND CIRCUMSTANCES CONSTITUTING
AN EMERGENCY AMENDMENT TO THE RULE

The agency has modified the rule that was in effect as an emergency due to the comments received during the public hearing period.

The agency modified provisions of the definitions, permits, labeling, manufacturing conditions, prohibited acts, approved laboratories, and the enforcement policy.

The agency wishes to enforce the rule as currently in front of the Legislative Rule Making Review Committee.

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: 6-26-91

Signature of Agency Head or Authorized Representative

Clare Bessie

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, 1990)

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 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 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.

4.4. 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.

§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.

6.1.c. Product sold in containers used for dipping product to consumers where the product will not be offered for sale to the ultimate consumer is exempt from the label requirements for name and address of the packer, manufacturer and distributor if the product is identified by plant number or other system to the place where manufactured. The product is also exempt from the requirements for brand name and quantity, if the quantity is clearly indicated on the invoice.

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, except that the word "Homemade" may be used as a brand name.

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 containing frozen desserts, imitation frozen desserts or residues of these products 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 and rinsed prior to use 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 any 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 0F 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 any frozen dessert or imitation frozen dessert.

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 milk ring 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 frozen desserts and imitation frozen desserts 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 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 product 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 during the time that the approval is suspended.

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 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.

13.5. Approved laboratories shall report all official 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 or misbranded, 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 or misbranded 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, give the reasons for the suspension and offer the person concerned an opportunity to request a hearing in this matter. If the violation can be identified with one part of a manufacturing operation, then the suspension will cover only that part of the operation and will be specified in the suspension order.

14.4.a. A Level 1 suspension order shall remain in effect for the time period specified in the order, beginning from the time when the order is received by the permittee. After this time period, the permit will be automatically reinstated.

14.4.a.A. The Level 1 suspension order will remain in effect for three working days (96 hours) except that the order will remain in effect for one working day (24 hours) if there is an official sample result in the permittee's file that has been taken by an approved laboratory within the 7 months previous to taking the sample resulting in the suspension order, as demonstration of the permittee's good faith efforts to comply with the law.

14.4.a.B. Until April 1, 1992 all Level 1 suspension orders will be for 24 hours. This will give time for laboratories to become approved and for permittee to arrange for testing to be performed.

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 or misbranded the commissioner shall send a written notice thereof to the person concerned. This notice shall notify the person concerned that a Suspension of the Frozen Desserts Manufacturers Permit is contemplated or in effect, the length of the suspension, give the reasons for the suspension and offer the person concerned an opportunity to request a hearing in this matter.

14.5.a. A Suspension of the Frozen Desserts Manufacturers Permit 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.

14.11 The commissioner may apply the enforcement policy in a liberal manner in cases where no product served to the public has been found to be violative.

14.12 The commissioner may suspend the standard enforcement policy in cases where such action is necessary to protect the public health.

§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

KEN HECHLER
Secretary of State

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SECRETARY OF STATE

Charleston 25305

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Special Assistant

(Plus all the volunteer
help we can get)

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Agriculture

RULE: New Rule, Series 4B, Frozen Desserts

ORIGINALLY FILED AS AN EMERGENCY RULE: June 26, 1991

FIRST EMERGENCY AMENDMENT: August 8, 1991

SECOND EMERGENCY AMENDMENT: October 2, 1991

DECISION NO. 91-91

Following review under WV Code 29A-3-15a, it is the decision of the Secretary of State that the above emergency rule be approved. A copy of the complete decision with required findings is available from this office.

A handwritten signature in cursive script that reads "Ken Hechler".

KEN HECHLER
Secretary of State

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Oct. 21, 1991
ADMINISTRATIVE LAW DIVISION

KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

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DECISION EMERGENCY RULE DECISION
(ERD 91-91)

AGENCY: Agriculture
RULE: New Rule, Series 4B, Frozen Desserts
ORIGINALLY FILED AS AN EMERGENCY RULE: June 26, 1991
FILED AS FIRST EMERGENCY AMENDMENT: August 8, 1991
FILED AS SECOND EMERGENCY AMENDMENT: October 2, 1991

- par. 1 The Department of Agriculture (Department) has filed the above new rule as an emergency.
- par. 2 West Virginia Code 29A-3-a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine if the agency filing such emergency rule: 1) has complied with the procedures for adopting an emergency rule; 2) exceeded the scope of its statutory authority in promulgating the emergency rule; or 3) can show that an emergency exists justifying the promulgation of an emergency rule.
- par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [(29A-3-a(a))].
- par. 4 (A) Procedural Compliance: WV Code 29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).
- par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the forty-two day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.

par. 6 The Department filed this emergency rule with supporting documents with the Secretary of State October 2, 1991 and with the LRMRC October 2, 1991.

par. 7 It is the determination of the Secretary of State that the Department has complied with the procedural requirements of WV Code §29A-3-15 for adoption of an emergency rule.

par. 8 (B) Statutory Authority -- WV Code §19-11-10(a) reads:

(a) Adopt, promulgate and enforce rules to carry out the purpose of this article.

par. 9 It is the determination of the Secretary of State that the Department has not exceeded its statutory authority in promulgating this emergency rule.

par. 10 (C) Emergency WV Code 29A-3-15(g) defines "emergency" as follows:

(g) For the purposes of this section, an emergency exists when the promulgation of a rule is necessary for the immediate preservation of the public peace, health, safety or welfare or is necessary to comply with a time limitation established by this code or by a federal statute or regulation or to prevent substantial harm to the public interest.

par. 11 There are essentially three classes of emergency broadly presented with the above provision: 1) immediate preservation; 2) time limitation; and 3) substantial harm. An agency need only document to the satisfaction of the Secretary of State that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.

par. 12 The facts and circumstances as presented by the Department are as follows:

This rule was modified and passed by the Legislative Rule Making Review committee. Most of the changes involve changes in language to create an "active" tense rather than a "passive" tense and do not involve substantive changes. Section 12 Powers and Duties of the Commissioner was added to clarify the responsibilities of the commissioner and the role of independent laboratory testing. Section 15 Enforcement Policy (formerly section number 14) was extensively rewritten for clarity. What was formerly called a "Level 1 suspension order" is now called a "Shut-Down order". What was formerly called a "Level 2 suspension order" is now called a "Suspension of the Frozen Desserts Manufacturers Permit".

This agency requests approval of this amendment so that we can enforce the version of the rule approved by the LRMRC committee.

par. 13 It is the determination of the Secretary of State that this proposal qualifies under the definition of an emergency as defined in §29A-3-15(g). . . "prevent substantial harm to public interest."

par. 14 This decision shall be cited as Emergency Rule Decision 91-91 or ERD 91-91 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Department of Agriculture, the Attorney General and the Legislative Rule Making Review Commission.



KEN HECHLER
Secretary of State

Entered _____

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Oct. 21, 1991
ADMINISTRATIVE LAW DIVISION

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Form #8

Effective Date

Oct 21, 1991 *J*

NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE

AGENCY: Agriculture TITLE NUMBER: 61

DATE EMERGENCY RULE WAS ORIGINALLY FILED: June 26, 1991

IS THIS THE FIRST EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:

No

IS THIS THE SECOND EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:

Yes

DATE OF FIRST EMERGENCY AMENDMENT: August 8, 1991

SERIES NUMBER OF RULE: 4B TITLE OF RULE: Frozen Desserts and
Imitation Frozen Desserts

THE ATTACHED IS AN EMERGENCY AMENDMENT TO AN EXISTING EMERGENCY RULE. THIS EMERGENCY AMENDMENT BECOMES EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 35TH DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY AMENDMENT ARE AS FOLLOWS:

"See attached sheet"

3.80

Use Additional Sheets If Necessary.

Chas. Beshear
Signature

FROZEN DESSERTS AND IMITATION FROZEN DESSERTS

STATEMENT OF FACTS AND CIRCUMSTANCES CONSTITUTING
AN EMERGENCY AMENDMENT TO THE RULE

This rule was modified and passed by the Legislative Rule Making Review Committee. Most of the changes involve changes in language to create an "active" tense rather than a "passive" tense and do not involve substantive changes.

Section number 12 Powers and Duties of the Commissioner was added to clarify the responsibilities of the commissioner and the role of independent laboratory testing.

Section number 15 Enforcement policy (formerly section number 14) was extensively rewritten for clarity. What was formerly called a "Level 1 suspension order" is now called a "Shut-Down order". What was formerly called a "Level 2 suspension order" is now called a "Suspension of the Frozen Desserts Manufacturers Permit".

This agency requests approval of this amendment so that we can enforce the version of the rule approved by the LRMRC committee.

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-10

1.3. Filing Date -

1.4. Effective Date -

1.5. This regulation is a new legislative rule.

§61-4B-2. Incorporation by Reference

2.1. The following documents are adopted in their entirety:

2.1.a. Title 21 Code of Federal Regulations (April 1, 1990)

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

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

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

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

2.1.f. 6th edition and supplements to the "U.S. Food and Drug Administration Bacteriological Analytical Manual" published by

the Association of Official Analytical Chemists, Suite 400, 2200 Wilson Boulevard, Arlington, Virginia 22201.

§61-4B-3. Definitions

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

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

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

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

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

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

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

4.1. The provisions of 21 CFR Part 135 establish standards of identity for ice cream, frozen custard, french ice cream, french custard ice cream, goat's milk ice cream, goat's milk frozen custard, goat's milk french ice cream, ice milk, goat's milk ice milk, mellorine, fruit sherbet and non-fruit sherbet.

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

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

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

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

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

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

5.1. Individuals, churches, fraternal organizations and other organizations manufacturing product for members of their group or their guests on an intermittent and infrequent basis are exempt from the permitting requirements of WV Code 19-11B-3.

§61-4B-6. Labeling

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

6.1.a. The brand name, if any, and the product name. The product name is the name established in the definition or the standard of identity, as described in section 4 of this rule, or a name that accurately identifies and describes the product. The name shall not be so similar to the name of any other food so as to be confusing to the average consumer.

6.1.b. The quantity of the product in the container shall be expressed in pounds, ounces, gallons, pints, quarts or fluid ounces. A combination of numerical count and weight may be used for multi-unit packages. In addition to these units, metric

declarations may be used. All statements of quantity shall be accurate with reasonable variations due to packaging allowed.

6.1.c. The name and address of the manufacturer, packer or distributor. The address shall include the city, state and zip code. A street address is required to identify the firm when there are several firms of that name in that city or if the street address is not available through a city or telephone directory. When the product is not manufactured by the company whose name appears on the label, the name shall be qualified by a phrase that reveals the company's connection with the food; such as "Manufactured for _____", or "Distributed by _____".

6.1.d. A lot designation or code date to provide identification of the product with a specific production time-period. In addition, if the name on the label is not the manufacturer, the lot designation or code date shall identify the manufacturer in addition to a specific production time-period.

6.1.e. If ingredient statements or nutritional claims are made on the product label or in labeling, the requirements of 21 CFR Part 101, as incorporated by reference in section 2 of this rule, must be met.

6.2. No person may use a product name on a menu, sign or any other advertising unless that name clearly reflects the accurate name of the product.

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

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

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

6.6. A manufacturer or distributor shall not distribute any

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

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

6.6.b. product sold at the place of manufacturing that is placed in a package after the customer orders the product. This product is exempt from all labeling requirements of WV Code 19-11B-4 and of this section of the rule.

6.6.c. product sold in a container from which product is dipped, and commonly known as a "bulk container", and where the product is not offered for sale to the ultimate consumer in the bulk container. This product is exempt from the label requirements of WV Code 19-11B-4 and of this section for the name and address of the packer, manufacturer or distributor, provided that the product label identifies the manufacturing location by means of a plant number or other means. The product is also exempt from the label requirements of WV Code 19-11B-4 for the product name and quantity of the contents, provided that the quantity of contents of the size container(s) sold and the product name(s) are clearly indicated on the invoice.

6.6.d. product packaged in units sold in a multiunit container, provided that each individual unit remains within the multi-unit container during distribution and the multiunit container is labeled according to the requirements of WV Code 19-11B-4 and of this section of the rule.

§61-4B-7. Misbranded

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

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

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

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

§61-4B-8. Adulteration

8.1. A product is adulterated if:

8.1.a. any substance has been added to the product or mixed or packed with the product so as to make it appear of greater value than it is, and the substance is not clearly noted in the ingredient statement or by other means on the label;

8.1.b. any bactericidal substance has been added to the product, such as a sanitizer, preservative or any other chemical with bactericidal properties. A product is not adulterated due to the presence of any sanitizer residue where the residue is caused as a normal consequence of sanitizing the equipment while using standard industry practices;

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

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

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

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

8.1.g. pathogenic bacteria are in the product.

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

§61-4B-9. Manufacturing conditions

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

9.2. All equipment, utensils, containers and piping used by a manufacturer shall be constructed of a smooth, nontoxic, impervious, corrosion-resistant material and fabricated in such a manner that there could be no contamination of the products handled therein. All equipment shall be capable of being easily sanitized. All equipment shall be designed, installed and operated in accordance with the criteria set forth in Standard 5 adopted by the NSF Board of Trustees, in the document adopted by reference in section 2 of these rules, or as otherwise approved by the commissioner.

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

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

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

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

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

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

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

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

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

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

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

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

§61-4B-10. Prohibited acts

10.1. No person may use non-pasteurized eggs or egg products in any product unless the product is pasteurized subsequent to the addition of the eggs or egg products.

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

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

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

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

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

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

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

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

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

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

10.9. No person may use any method for sanitizing that adversely affects the equipment, dairy product or the health of the consumers consuming the product. However, the commissioner will not prohibit the use of chemicals commonly used in the industry for cleaning and sanitizing dairy equipment using normal industry practices due to the causing of corrosion of the equipment as long as the corrosion caused by such use is minimal.

§61-4B-11. Animal Health

11.1. All products shall be made from milk products or milk-derived ingredients from herds which are located in a Modified Accredited Tuberculosis Area or a Tuberculosis Free Area as determined by the U.S. Department of Agriculture, Provided, that herds located in an area that fails to maintain such accredited status shall have been accredited by the U.S. Department of Agriculture as tuberculosis free, or shall have passed an annual tuberculosis test that is performed by a veterinarian accredited by the United States Department of Agriculture, Animal and Plant Health Inspection Service.

11.2. All products shall be made from milk products or milk-derived ingredients from herds which are under a brucellosis eradication program which meets one of the following conditions:

11.2.a. the herd is located in a Certified Brucellosis-free Area as defined by the U.S. Department of Agriculture and enrolled in the testing program for such area;

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

11.2.c. the herd is participating in a milk ring testing program at least four times per year at approximately 90 day intervals, and any herd where any animal has a positive milk ring test shall all animals that are producing milk, or that have recently produced milk, tested with the milk ring test within 30 days from the date of the laboratory ring tests; or

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

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

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

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

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

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

13.1. Procedures for the collection and holding of official product samples, the selection and preparation of apparatus, media and reagents, and the analytical procedures, incubation, reading and reporting of results, shall be in compliance the standards set forth in the Standard Methods for the Examination of Dairy Products, the Official Methods of Analysis, or procedures referenced in 21CFR, all adopted by reference in section 2 of these rules, whichever method is applicable to the product being tested.

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

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

13.3. Aseptically processed products packaged in hermetically sealed containers shall be opened in accordance with procedures published in the U.S. Food and Drug Administration Bacteriological Analytical Manual, as adopted by reference in section 2 of these

rules.

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

§61-4B-14. Approved laboratories

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

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

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

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

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

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

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

substantiate this requirement.

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

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

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

§61-4B-15. Enforcement policy

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

15.2. If over 30% of the samples of product taken from any previously unopened container that have been distributed by a firm do not meet the requirements of this rule within a three month period; then the commissioner will assess all remaining violations of WV Code 19-11B-1 et seq. or of these rules to distributor. The commissioner, however, will not assess any violations of WV Code 19-11B-1 et seq. or of this rule to the distributor until at least three samples of product from unopened containers distributed by that firm have been recorded for that three month period. Once a violation of WV Code 19-11B-1 et seq. or these rules is assessed to a distributor then the commissioner will continue charging the distributor with violations of WV Code 19-11B-1 et seq. or of these rules until there have been five official product samples taken on different days that meet the requirements of WV Code 19-11B-1 et seq. and of this rule.

15.3. Whenever one of the last five consecutive official product sample(s) taken on separate days within a one year period are found to be adulterated or misbranded, the commissioner shall send a written "First Notice" to the manufacturer or distributor whichever is appropriate. This notice shall notify the manufacturer or distributor of the violation of WV Code 19-11B-1 et seq. or of these rules and the enforcement policy established by this section of the rule.

15.4. Whenever two of the last five consecutive official

product sample(s) taken on separate days within a one year period are found to be adulterated or misbranded the commissioner shall send a written "Second Notice" to the manufacturer or distributor whichever is appropriate. The Second Notice shall notify the manufacturer or distributor whichever is appropriate that a "Shut-down Order" is contemplated or in effect, give the reasons for the order, state the portion of the manufacturing or distributing operation covered by the provisions of WV Code 19-11B-1 et seq. or these rules that is prohibited from operating when the Shut-down Order is in effect, 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 paragraph 15.4.c.

15.4.a. 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.

15.4.b. The commissioner will issue a Shut-down Order for the entire manufacturing or distributing operation when the portion of the operation that is in violation of WV Code 19-11B-1 et seq. or these rules cannot be identified.

15.4.c. 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.

15.4.d. The commissioner will issue a Shut-down Order for ninety-six hours except when he finds that the manufacturer or distributor has submitted at least one official product sample result from an approved laboratory within the previous 7 months, in which case the commissioner will consider this as evidence of the firm's good faith effort to comply with the law, and will issue a Shut-down Order for a length of twenty-four hours: Provided that, until April 1, 1992 the commissioner will issue all Shut-down Orders for a twenty-four hour period to give time for laboratories to become approved and for firms to arrange for official product sample testing from these firms.

15.4.e. 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.

15.4.f. All Shut-down Orders issued due to non-compliance with paragraphs 8.1.c., d., or g. of this rule are considered to involve a risk to the public health, safety or welfare.

15.5. Whenever three of the last five consecutive official product sample(s) taken on separate days within a one year period are found to be adulterated or misbranded the commissioner shall send a written "Third Notice" to the manufacturer or distributor whichever is appropriate. The Third Notice shall notify the manufacturer or distributor whichever is appropriate that a Suspension of the Frozen Desserts Manufacturer Permit is contemplated or in effect, 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 suspensions the commissioner will give the manufacturer the opportunity to request a hearing in this matter subsequent to the notification of the suspension.

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

15.5.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.

15.5.b.A. The commissioner has seven days from the date of receipt of this application to respond to a suspension in the case of violations of paragraphs 8.1.c., d. or g. of this rule and fourteen days to respond for all other violations of WV 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.

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

15.6. If two Shut-down Orders for any firm occur within a twelve month period, then the commissioner will hold a hearing to determine if the Frozen Desserts Manufacturer Permit should be revoked.

15.7. 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 WV

Code 19-11B-1 et seq. or these rules.

15.8. 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.

15.9. 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 on an exemption.

15.10. 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 WV Code 19-11B-1 et seq. or these rules.

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

§61-4B-16. Cleaning and sanitizing

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

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

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

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

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

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

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

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