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DHEC Draft Proposed Changes to Regulation
61-36, ~~FROZEN DESSERTS~~

Manufactured Grade Dairy Products

January 2020

61-36. Manufactured Grade Dairy Products.

Statutory Authority: S.C. Code Sections 44-1-140, 44-1-150, and 39-37-120

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SECTION I. DEFINITIONS

The following definitions shall apply in the interpretation and the enforcement of this regulation:

A. ADULTERATED - a MANUFACTURED GRADE DAIRY PRODUCT is deemed to be ADULTERATED if the product:

1. Bears or contains any poisonous or deleterious substance in a quantity that may render it injurious to health;

2. Bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by state or federal regulation, or in excess of such tolerance if one has been established;

3. Consists, in whole or in part, of any substance unfit for human consumption;

4. Has been produced, processed, prepared, packaged, or held under unsanitary conditions;

5. Is packaged in a container which is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

6. Has any substance added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;

7. Is in violation of Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 342); or

8. Contains any animal DRUG residues.

B. ALCOHOL INFUSED FROZEN DESSERT- any FROZEN DESSERT that contains five percent (5%) or more alcohol by volume.

C. APPROVED - acceptable to the DEPARTMENT based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

D. ASEPTICALLY PROCESSED MIX - a MANUFACTURED GRADE DAIRY PRODUCT that is hermetically sealed in a container and so thermally processed in conformance with 21 CFR Part 113 and the provisions of this regulation so as to render the product free of MICROORGANISMS capable of reproducing in the product under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable MICROORGANISMS (including spores) of public health significance.

E. ASEPTIC PROCESSING - a process whereby the MANUFACTURED GRADE DAIRY PRODUCT has been subjected to sufficient heat processing, and packaged in a HERMETICALLY SEALED CONTAINER, to conform to the applicable requirements of 21 CFR Part 113 and the provisions of Section VII A.1.c. of this regulation and maintain the commercial sterility of the product under normal non-refrigerated conditions.

F. BUSINESS DAY - every official work day of the week excluding weekends and state holidays.

G. BUTTER - the FOOD product usually known as BUTTER that is made exclusively from MILK or cream, or both, with or without salt, and with or without additional coloring matter, and which contains not less

than eighty percent (80%) by weight of MILK fat. BUTTER may contain: (a) MILK solids; (b) APPROVED bacterial culture; (c) salt; (d) air or inert gas; and (e) APPROVED FOOD color. BUTTER also includes the following MANUFACTURED GRADE DAIRY PRODUCTS:

1. BUTTER WITH (NAMING THE FRUIT, VEGETABLE, OR RELISH) - BUTTER to which any fruit, vegetable, or relish, or any combination thereof, has been added. It may contain less than eighty percent (80%) MILK fat if the percentage of MILK fat is reduced by the amount of the product added, but the resulting MILK fat content must be at least seventy-five (75%).

2. BUTTER WITH (NAMING THE SEASONING OR FLAVOR) - BUTTER to which a seasoning or a flavor other than that of BUTTER, or both, has been added. It must contain at least eighty percent (80%) MILK fat.

3. CALORIE-REDUCED BUTTER - the FOOD product usually known as calorie-reduced BUTTER that is prepared from MILK or MILK products or a combination thereof, and which contains at least thirty-nine (39%) MILK fat and not more than fifty percent (50%) of the calories that would normally be present in BUTTER. CALORIE-REDUCED BUTTER may contain: (a) MILK solids; (b) APPROVED bacterial culture; (c) salt; (d) air or inert gas; (e) APPROVED FOOD color; (f) APPROVED emulsifying and stabilizing agents; (g) APPROVED preservatives; and (h) not more than one percent (1%) added edible casein, edible caseinates, or any combination thereof.

4. LIGHT BUTTER OR LITE BUTTER - FOOD product usually known as LIGHT BUTTER or LITE BUTTER, which is prepared from MILK or MILK products or a combination thereof, and which contains at least thirty-nine (39%) MILK fat and not more than sixty percent (60%) MILK fat. LIGHT BUTTER or LITE BUTTER may contain: (a) MILK solids; (b) APPROVED bacterial culture; (c) salt; (d) air or inert gas; and (e) APPROVED FOOD color.

5. WHEY BUTTER - FOOD product usually known as WHEY BUTTER that is prepared from MILK or MILK products or a combination thereof, and which contains at least eighty percent (80%) MILK fat that is recovered from whey, by weight. WHEY BUTTER may contain: (a) MILK solids; (b) APPROVED bacterial culture; (c) salt; (d) air or inert gas; and (e) APPROVED FOOD color.

H. CODE OF FEDERAL REGULATIONS (CFR) - a codification of the general and permanent rules and regulations (administrative LAW) published in the Federal Register by the executive departments and agencies of the federal government of the United States. Citations to the CFR in this regulation refer sequentially to the Title, Part, and Section numbers (e.g., 21 CFR 117.10 refers to Title 21, Part 117, Section 117.10).

I. CHEESE - the fresh or matured product obtained by draining after coagulation of MILK, cream, skimmed or partly skimmed MILK, or a combination of some or all of these products, including any CHEESE that conforms to the requirements of 21 CFR 133, as amended.

J. DEPARTMENT - the South Carolina Department of Health and Environmental Control and its authorized representatives.

K. DRUG - shall mean:

1. articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

2. articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

3. articles (other than FOOD) intended to affect the structure of any function of the body of man or other animals; and

4. articles intended for use as a component of any articles specified in clauses 1, 2, or 3, but does not include devices or their components, parts, or accessories.

L. EMPLOYEE - permit holder, PERSON in charge, PERSON having supervisory or managerial duties, PERSON on the payroll, family member, volunteer, PERSON performing work under a contractual agreement, or any other PERSON working in a MANUFACTURED GRADE DAIRY PRODUCTS plant or distribution station.

M. EXCLUSION - prevention of a PERSON from working as an EMPLOYEE in a MANUFACTURED GRADE DAIRY PRODUCTS plant or distribution station or entering a MANUFACTURED GRADE DAIRY PRODUCTS plant or distribution station as an EMPLOYEE.

N. FDA - United States Food and Drug Administration.

O. FD&C - United States Food, Drug, and Cosmetic Act, the federal LAWS giving authority to FDA to oversee the safety of FOOD, DRUGS, medical devices and cosmetics, as set forth in 21 U.S.C. Section 301 et seq.

P. FOOD - means FOOD as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C) and includes raw materials and ingredients.

Q. FROZEN DESSERT - as used in this regulation is defined in S.C. Code Ann. Section 39-37-10. They shall also include MIXES used for FROZEN DESSERT manufacturing and products such as gelato and sorbetto made in semblance of those products defined in Section 39-37-10.

R. HERMETICALLY SEALED CONTAINER - 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.

S. IMITATION MILK AND IMITATION MILK PRODUCTS, SYNTHETIC MILK AND SYNTHETIC MILK PRODUCTS, MILK DERIVATIVES, AND ANY OTHER PRODUCTS MADE IN SEMBLANCE OF MILK OR MILK PRODUCTS - Products made in semblance of MILK and MILK products are products that are made to resemble in form and are intended to be used in substitution for MILK and/or MILK products and that are determined not to be nutritionally inferior to MILK and/or MILK products.

T. IMMINENT HEALTH HAZARD - a significant threat or danger to health that is considered to exist when there is sufficient evidence to show that a product, practice, circumstance, or event creates a situation requiring immediate correction or cessation of operation to prevent illness or injury based on the number of potential illnesses or injuries, and the nature, severity, and duration of the anticipated illness or injury.

U. LAW - applicable local, state, and federal statutes, regulations, and ordinances.

V. MANUFACTURED GRADE DAIRY PRODUCT(S) - refers to all types of dairy based manufactured FOOD products to include CHEESES, BUTTERS, FROZEN DESSERTS (including MIX), and IMITATION MILK and IMITATION MILK PRODUCTS, SYNTHETIC MILK AND SYNTHETIC MILK PRODUCTS, MILK DERIVATIVES, and ANY OTHER PRODUCTS MADE IN SEMBLANCE OF MILK OR MILK PRODUCTS.

W. MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION - any place or PREMISES, except MANUFACTURED GRADE DAIRY PRODUCTS RETAILERS, where MANUFACTURED GRADE DAIRY PRODUCTS are received, stored, and dispensed to retailers (may also be referred to as "Distribution Station").

X. MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR - any PERSON, except a MANUFACTURED GRADE DAIRY PRODUCTS RETAILER, who receives, stores, and dispenses MANUFACTURED GRADE DAIRY PRODUCTS to retailers (may also be referred to as "Distributor").

Y. MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER - any PERSON, except a MANUFACTURED GRADE DAIRY PRODUCTS RETAILER, who manufactures, processes, or freezes MANUFACTURED GRADE DAIRY PRODUCTS for distribution or sale.

Z. MANUFACTURED GRADE DAIRY PRODUCTS PLANT - any place or PREMISES, except MANUFACTURED GRADE DAIRY PRODUCTS RETAILERS, where MANUFACTURED GRADE DAIRY PRODUCTS are manufactured, processed, or frozen for distribution or sale.

AA. MANUFACTURED GRADE DAIRY PRODUCTS RETAILER - any PERSON who sells, serves, or dispenses MANUFACTURED GRADE DAIRY PRODUCTS at retail which have been processed in an APPROVED MANUFACTURED GRADE DAIRY PRODUCTS PLANT.

BB. MICROORGANISMS - means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are PATHOGENS. The term "undesirable MICROORGANISMS" includes those MICROORGANISMS that are PATHOGENS, that subject FOOD to decomposition, that indicate that FOOD is contaminated with filth, or that otherwise may cause FOOD to be ADULTERATED.

CC. MILK (HOOVED MAMMALS' MILK) - Hooved mammals' MILK is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. Hooved mammals for the purpose of this regulation include, but are not limited to, the members of the Order Cetartiodactyla, such as: Family Bovidae (cattle, water buffalo, sheep, goats, yaks, etc.), Family Camelidae (llamas, alpacas, camels, etc.), Family Cervidae (deer, reindeer, moose, etc.), and Family Equidae (horses, donkeys, etc.).

DD. MIX - the unfrozen combination of ingredients of FROZEN DESSERTS except such fruits, nuts, flavors, color, and other ingredients as may be exempted by the DEPARTMENT. MIX shall be PASTEURIZED.

EE. NUISANCE - for purposes of this regulation, a public health NUISANCE, meaning whatever is dangerous to human life or detrimental to health; or whatever structure or PREMISES is not sufficiently ventilated, sewerred, drained, cleaned, or lighted with respect to its intended occupancy.

FF. OFFICIALLY DESIGNATED LABORATORY - a commercial laboratory authorized to do official work by the DEPARTMENT, or a MILK industry laboratory officially designated by the DEPARTMENT for the examination of producer samples of Grade "A" RAW MILK for PASTEURIZATION and commingled MILK tank truck samples of RAW MILK for antibiotic residues and bacterial limits.

GG. OFFICIAL LABORATORY - a biological, chemical, or physical laboratory that is under the direct supervision of the DEPARTMENT.

HH. PASTEURIZATION - the process of heating every particle of MANUFACTURED GRADE DAIRY PRODUCT in properly designed and operated equipment to one of the temperatures given in the following table, and holding the product continuously at or above that temperature for at least the corresponding specified time:

Batch (Vat) PASTEURIZATION	
Temperature	Time
145°F (63°C)*	30 minutes
Continuous Flow (HTST and HHST) PASTEURIZATION	
Temperature	Time
161°F (72°C)*	15 seconds
191°F (89°C)	1.0 second
194°F (90°C)	0.5 second
201°F (94°C)	0.1 second
204°F (96°C)	0.05 second
212°F (100°C)	0.01 second

*If the fat content of the dairy product is ten percent (10%) or greater, or a total solids of eighteen percent (18%) or greater, or if it contains added sweeteners, the specified temperature shall be increased by 5°F (3°C).

Provided, that FROZEN DESSERTS shall be heated to at least the following temperature and time specifications:

Batch (Vat) PASTEURIZATION	
Temperature	Time
155°F (69°C)	30 minutes
Continuous Flow (HTST) PASTEURIZATION	
Temperature	Time
175°F (80°C)	25 seconds
180°F (83°C)	15 seconds

Provided, that MILK for CHEESE making shall be heated to at least the following temperature and time specification:

Batch (Vat) PASTEURIZATION	
Temperature	Time
145°F (63°C)	30 minutes
Continuous Flow (HTST) PASTEURIZATION	
Temperature	Time
161°F (72°C)	15 seconds

Provided, that cream for BUTTER making shall be heated to at least the following temperature and time specifications:

Batch (Vat) PASTEURIZATION	
Temperature	Time
165°F (74°C)	30 minutes
Continuous Flow (HTST) PASTEURIZATION	
Temperature	Time
185°F (85°C)	15 seconds

Provided further that nothing in this definition shall be construed as barring any other process found equivalent to PASTEURIZATION for dairy products, which has been recognized by the FDA as provided in Section 403(h)(3) of the FD&C (21 U.S.C. Section 343(h)(3)), as amended, and which is APPROVED by the DEPARTMENT.

II. PATHOGEN - a microorganism of public health significance.

JJ. PERMIT - the document issued by the DEPARTMENT that authorizes a PERSON or entity to operate a MANUFACTURED GRADE DAIRY PRODUCTS PLANT or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION.

KK. PERMIT HOLDER - the entity, such as the owner, the owner's agent, or other PERSON, that possesses a valid PERMIT to operate a MANUFACTURED GRADE DAIRY PRODUCTS PLANT or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION and is legally responsible for its operation.

LL. PERSON - any individual, plant operator, partnership, corporation, company, firm, trustee, association, or institution.

MM. PEST - any objectionable animals or insects including but not limited to birds, rodents, flies, and larvae.

NN. PASTEURIZED MILK ORDINANCE (PMO) - a set of minimum standards and requirements that are established by the FDA for regulating the production, processing, and packaging of Grade "A" MILK.

OO. PREMISES -

1. The physical facility, its contents, its land, and any adjacent or bordering contiguous land or property under the control of the PERMIT HOLDER; or

2. The physical facility, its contents, and land or property not described in (a) of this definition if the facilities and contents are under the control of the PERMIT HOLDER and may impact the MANUFACTURED GRADE DAIRY PRODUCTS PLANT or distribution station personnel, facilities, or operations, and the MANUFACTURED GRADE DAIRY PRODUCTS PLANT or distribution station is only one component of a larger operation such as a healthcare facility, hotel, motel, school, recreational camp, or prison.

PP. RAW MILK - MILK that has not been PASTEURIZED.

QQ. RESTRICTION - limitation of the activities of an EMPLOYEE so that there is no RISK of transmitting a disease that is transmissible through MANUFACTURED GRADE DAIRY PRODUCTS or ingredients and the EMPLOYEE does not work with exposed MANUFACTURED GRADE DAIRY PRODUCTS or ingredients, clean equipment, utensils, linens, or unwrapped single-service or single-use articles.

RR. RETAIL FOOD ESTABLISHMENT - an establishment that sells FOOD products directly to consumers as its primary function. RETAIL FOOD ESTABLISHMENTS include, but are not limited to, grocery stores, convenience stores, roadside stands, farmers markets, and community supported agriculture (CSA) operations. Any business making FOOD (including a farm business) with at least 50.1 percent in direct to individual consumer FOOD sales satisfies the definition of a RETAIL FOOD ESTABLISHMENT and is exempt from the Bioterrorism Act registration regulations under the 2002 Bioterrorism Act (21 CODE OF FEDERAL REGULATIONS [C.F.R.] 1.225) as a RETAIL FOOD ESTABLISHMENT. The term "consumers" does

not include businesses. A RETAIL FOOD ESTABLISHMENT also includes certain farm-operated businesses selling FOOD directly to consumers as their primary function.

SS. RISK - the likelihood that an adverse health effect will occur within a population as a result of a hazard in a FOOD.

TT. SANITIZE - to adequately treat cleaned surfaces by a DEPARTMENT-accepted process that is effective in destroying vegetative cells of PATHOGENS, and in substantially reducing numbers of other undesirable MICROORGANISMS, but without adversely affecting the product or its safety for the consumer.

UU. ULTRA-PASTEURIZED - MANUFACTURED GRADE DAIRY PRODUCT that has been thermally processed at or above 280°F (138°C) for at least two (2) seconds, either before or after packaging, so as to produce a product that has an extended shelf life under refrigerated conditions.

VV. UNEXPOSED PACKAGED FOOD - packaged FOOD that is not exposed to the environment.

Additional definitions related to this regulation are found in 21 CFR 117.3, as amended.

SECTION II. ADULTERATED OR MISBRANDED MANUFACTURED GRADE DAIRY PRODUCTS

A. No PERSON within South Carolina, or its jurisdiction, shall produce, provide, sell, offer, or expose for sale, or have in possession with intent to sell, any MANUFACTURED GRADE DAIRY PRODUCT that is ADULTERATED or misbranded. Any MANUFACTURED GRADE DAIRY PRODUCT that may contain any unwholesome substance, or that does not conform with an applicable standard of identity or other requirement under Section I for that particular MANUFACTURED GRADE DAIRY PRODUCT, shall be deemed ADULTERATED and/or misbranded.

B. The DEPARTMENT issues PERMITS for the manufacturing of ALCOHOL INFUSED FROZEN DESSERTS. The DEPARTMENT does not regulate the distribution or sale of ALCOHOL INFUSED FROZEN DESSERTS. Compliance with DEPARTMENT requirements under this regulation does not exempt PERSONS engaged in the production, distribution, or sale of ALCOHOL INFUSED FROZEN DESSERTS from any other applicable LAWS governing the sale or distribution of alcoholic products.

C. The DEPARTMENT may place a hold order on a MANUFACTURED GRADE DAIRY PRODUCT that it determines or has reason to believe:

1. Originated from an unAPPROVED source;
2. May be unsafe, unwholesome, ADULTERATED, misbranded, or not honestly presented;
3. Is not labeled according to LAW; or
4. Is otherwise not in compliance with this regulation.

D. The DEPARTMENT may suspend a PERSON's PERMIT for violating a hold order.

E. The DEPARTMENT may impound, condemn, forbid the sale of, or cause to be removed or destroyed, any FOOD that is determined to be in violation of this regulation, unwholesome, contaminated, ADULTERATED, misbranded, or from an unAPPROVED source.

F. The DEPARTMENT may issue a hold order to a PERMIT HOLDER or to a PERSON who owns or controls the FOOD, as specified above, without prior warning, notice of a hearing, or a hearing on the hold order.

G. The DEPARTMENT may examine MANUFACTURED GRADE DAIRY PRODUCTS as often as necessary to determine freedom from ADULTERATION or misbranding. Under a hold order, MANUFACTURED GRADE DAIRY PRODUCTS shall be suitably stored. It shall be unlawful for any PERSON to remove or alter a hold order, notice, or tag placed on MANUFACTURED GRADE DAIRY PRODUCTS by the DEPARTMENT, and neither such MANUFACTURED GRADE DAIRY PRODUCTS nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the DEPARTMENT, except on order by a court of competent jurisdiction.

H. Whenever MANUFACTURED GRADE DAIRY PRODUCTS are ADULTERATED by DRUGS, pesticides, herbicides, or other poisonous substances, the PERSON or entity in possession of the product shall remove the product from the market, dispose of the product, and stop sale of the product until analysis provides the product to be free from ADULTERATION.

SECTION III. COMPLIANCE PROCEDURES

A. PERMIT.

1. It shall be unlawful for any PERSON to manufacture or distribute any MANUFACTURED GRADE DAIRY PRODUCT without a valid PERMIT issued by the DEPARTMENT for the specific MANUFACTURED GRADE DAIRY PRODUCTS PLANT or DISTRIBUTION STATION. Grocery stores, restaurants, and similar establishments where MANUFACTURED GRADE DAIRY PRODUCTS are served or sold at retail, but not processed (other than fountain freezing of APPROVED pasteurized MIX for FROZEN DESSERTS), may be exempt from the requirements of this section.

2. Every MANUFACTURED GRADE DAIRY PRODUCTS PLANT and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION must obtain a PERMIT. PERMITS are nontransferable with respect to PERSONS and/or locations.

B. Suspension of PERMIT.

1. The DEPARTMENT may suspend a PERMIT whenever:

- a. it has reason to believe that a public health hazard exists;
- b. the PERMIT HOLDER has violated any of the requirements of this regulation;
- c. the PERMIT HOLDER has violated its PERMIT or an order of the DEPARTMENT, including but not limited to, a hold order; or
- d. the PERMIT HOLDER has interfered with the DEPARTMENT in the performance of its duties.

A suspension shall remain in effect until the violation has been corrected to the satisfaction of the DEPARTMENT.

2. The DEPARTMENT may without prior warning or notice, suspend summarily a PERMIT to operate a MANUFACTURED GRADE DAIRY PRODUCTS PLANT or DISTRIBUTION STATION when the DEPARTMENT determines that the operation of the MANUFACTURED GRADE DAIRY PRODUCTS PLANT or DISTRIBUTION STATION, including but not limited to a willful refusal to permit authorized inspection, constitutes an IMMEDIATE HEALTH HAZARD. Upon summary PERMIT suspension, all manufacturing and distribution operations shall immediately cease. During the process, the PERMIT shall remain suspended unless the IMMEDIATE HEALTH HAZARD has been corrected.

3. Any MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR whose PERMIT has been suspended may make written application for the reinstatement of the PERMIT.

4. Within seven (7) BUSINESS DAYS of receiving the written application, the DEPARTMENT shall make inspections and/or collect samples for analysis to determine whether the conditions cited in the notice of suspension no longer exist. If conditions warrant, the DEPARTMENT may reinstate the PERMIT.

C. Revocation of PERMIT.

1. The DEPARTMENT may revoke a PERMIT for repeated violations of any of the requirements of this regulation, the PERMIT, or an order of the DEPARTMENT, or for interference with the DEPARTMENT or its staff in the performance of its duties. Notwithstanding any other provisions of this regulation, the PERMIT may be revoked if the DEPARTMENT is threatened with bodily harm or physical interference in the performance of inspectional duties.

2. The DEPARTMENT may deny a new PERMIT based upon past noncompliance, including previous enforcement, suspension, or revocation history.

3. Any PERSON whose PERMIT is revoked shall not be eligible to apply for re-permitting within one (1) year from the date of revocation. Any PERSON whose PERMIT has previously been revoked and who obtains a subsequent PERMIT and violates the provisions of this regulation, resulting in revocation of the PERMIT for a second time, shall not be granted another PERMIT for a period of five (5) years.

SECTION IV. LABELING

MANUFACTURED GRADE DAIRY PRODUCTS must be labeled according to the requirements in 21 CFR Part 101, as amended.

SECTION V. INSPECTION OF MANUFACTURED GRADE DAIRY PRODUCTS PLANTS, AND MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS

A. Each MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER whose MANUFACTURED GRADE DAIRY PRODUCTS are intended for consumption within South Carolina or its jurisdiction shall be inspected by the DEPARTMENT prior to the issuance of a PERMIT.

B. Following the issuance of a PERMIT, the DEPARTMENT will inspect each MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and DISTRIBUTOR at a frequency determined by the RISK level assigned to the product(s) being manufactured or distributed, or as otherwise deemed necessary by the DEPARTMENT to determine compliance with this regulation.

C. When the DEPARTMENT finds a critical processing element violation involving:

1. Improper PASTEURIZATION, whereby every particle of a MANUFACTURED GRADE DAIRY PRODUCT may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment; or

2. cross contamination whereby direct contamination of a PASTEURIZED MANUFACTURED GRADE DAIRY PRODUCT is occurring; or

3. conditions whereby direct contamination of a MANUFACTURED GRADE DAIRY PRODUCT is occurring, the DEPARTMENT shall take immediate action to prevent further processing of such MIX or MANUFACTURED GRADE DAIRY PRODUCT until all violations of critical processing element(s) have been corrected. Should correction of such critical processing elements not be accomplished immediately, the DEPARTMENT will take prompt action to suspend the PERMIT as provided for in Section III of this regulation.

D. In the case of a plant producing ASEPTICALLY PROCESSED MIX, when an inspection of the plant or its records reveal that the process used has been less than the required scheduled process, as per the PMO, it shall be considered an IMMINENT HEALTH HAZARD and the DEPARTMENT shall take immediate action to suspend the PERMIT of the plant for the sale of aseptically processed MANUFACTURED GRADE DAIRY PRODUCTS in conformance with Section III of this regulation.

E. A copy of the inspection report will be provided either electronically or in paper form to the PERMIT HOLDER, manager, or other duly authorized representative.

F. Every MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and DISTRIBUTOR shall, upon request of a DEPARTMENT representative, permit the DEPARTMENT access to all parts of the establishment or facilities to determine compliance with the provisions of this regulation. A PERMIT HOLDER, manager, or other duly authorized representative shall furnish the DEPARTMENT, upon request and for official use only, a true statement of the actual quantities of MANUFACTURED GRADE DAIRY PRODUCT purchased and sold, and a list of all sources of such MANUFACTURED GRADE DAIRY PRODUCT, records of inspections, records of tests, and PASTEURIZATION time and temperature records.

G. It is unlawful for any PERSON who, in an official capacity, obtains any information under the provisions of this regulation which is entitled to protection as a trade secret, to use such information to his or her own advantage or to reveal it to any unauthorized PERSON.

SECTION VI. THE EXAMINATION OF MANUFACTURED GRADE DAIRY PRODUCTS

A. Sampling criteria.

1. Samples of MANUFACTURED GRADE DAIRY PRODUCTS shall be collected by the manufacturer or the DEPARTMENT, as directed, at a frequency that is deemed appropriate by the DEPARTMENT based on the level of RISK of the product.

2. Samples may be taken while in the possession of the manufacturer and/or distributor, retail stores, cafes, restaurants, and other places where MANUFACTURED GRADE DAIRY PRODUCTS are sold and shall be taken and examined as often as the DEPARTMENT may require.

B. Sampling enforcement.

1. Upon receipt of unsatisfactory samples, as specified in (a) and (b) below, the DEPARTMENT shall send a written notice thereof to the PERMIT HOLDER of the MANUFACTURED GRADE DAIRY PRODUCTS PLANT or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATION.

a. For FROZEN DESSERTS this notice shall be sent when two (2) of the last four (4) consecutive bacterial counts (except those for ASEPTICALLY PROCESSED MIX), coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for FROZEN DESSERTS. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. The DEPARTMENT shall suspend the manufacturer and/or distributor's PERMIT in accordance with Section III and/or take court action as necessary whenever the additional sampling results indicate that three (3) of the last five (5) bacterial counts (except those for ASEPTICALLY PROCESSED MIX), coliform determinations, or cooling temperatures exceed the limit of the standard for FROZEN DESSERTS.

b. For CHEESE and BUTTER, this notice shall be sent when a sample is confirmed to be positive for PATHOGENIC organisms. A positive finding of PATHOGENIC organisms in a sample shall be considered an IMMEDIATE HEALTH HAZARD, and the product involved shall not be offered for sale. The DEPARTMENT shall immediately suspend the PERMIT and the PERMIT shall remain suspended until a minimum of two (2) consecutive representative samples are found to be free of PATHOGENIC organisms.

2. Whenever a phosphatase test is positive, the cause shall be determined by the PERMIT HOLDER. Where the cause is improper PASTEURIZATION, it shall be corrected, and any MANUFACTURED GRADE DAIRY PRODUCT involved shall not be offered for sale.

3. Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the product involved shall not be offered for sale. The cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no MANUFACTURED GRADE DAIRY PRODUCT shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

4. Whenever a DRUG residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provision of Section II of this regulation.

5. Whenever a container or containers of ASEPTICALLY PROCESSED MANUFACTURED GRADE DAIRY PRODUCT is found to be unsterile due to under processing, the DEPARTMENT shall consider this to be an IMMEDIATE HEALTH HAZARD and shall suspend the PERMIT of the MANUFACTURED GRADE DAIRY PRODUCT plant for the sale of ASEPTICALLY PROCESSED MANUFACTURED GRADE DAIRY PRODUCT. No ASEPTICALLY PROCESSED MANUFACTURED GRADE DAIRY PRODUCT shall be sold until it can be shown that the processes, equipment, and procedures used are suitable for consistent production of a sterile product. All products, including MANUFACTURED GRADE DAIRY PRODUCT, manufactured in or from the lot found to contain one (1) or more unsterile units shall be recalled and disposed of as directed by the DEPARTMENT.

C. Sampling methods.

Samples shall be analyzed at an official or appropriate OFFICIALLY DESIGNATED LABORATORY. All sampling procedures and required laboratory examinations shall be in substantial compliance with the Standard Methods for the Examination of Dairy Products of the American Public Health Association, and the certification of sample collectors, and examinations shall be evaluated in accordance with the United States Public Health Service/FDA Evaluation of MILK Laboratories. Aseptically processed MANUFACTURED GRADE DAIRY PRODUCTS packaged in HERMETICALLY SEALED CONTAINERS shall be tested in accordance with the FDA's Bacteriological Analytical Manual. Examinations and tests to detect adulterants, including pesticides, shall be conducted as the DEPARTMENT requires.

SECTION VII. STANDARDS FOR MANUFACTURED GRADE DAIRY PRODUCTS PLANTS AND MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS

A. Temperature, bacteriological and chemical requirements.

1. All frozen dessert MIX shall be produced, processed, and PASTEURIZED, ULTRA-PASTEURIZED, or ASEPTICALLY PROCESSED as specified in the PMO and frozen to conform with the following temperature, bacteriological, and chemical standards and the sanitation requirements of this section:

a. RAW MILK and MILK products obtained by a FROZEN DESSERT manufacturer for future PASTEURIZATION, ULTRA-PASTEURIZATION, or ASEPTIC PROCESSING and use in the production of FROZEN DESSERTS must come from an APPROVED source and must be in compliance with the temperature, bacteriological, and chemical standards in R.61-34, Raw Milk for Human Consumption, or R. 61-34.1, Pasteurized Milk and Milk Products, or the PMO.

b. PASTEURIZED FROZEN DESSERTS and/or Heat-Treated, Bulk-Shipped MILK Products:

(1) Temperature – Cooled to 45°F (7°C) or less and maintained thereat.

(2) Bacterial limits* - 30,000 per mL.

(3) Coliform - Not to exceed 10 per mL: provided that, in the case of bulk MILK transport tank shipments, where contents are to be repasteurized, shall not exceed 100 per mL.

(4) Phosphatase** - Less than 500 milliunits/L by the Fluorometer or Clarion ALP or equivalent.

(5) DRUGS - No positive results on DRUG residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade “A” PMO as amended.

c. ASEPTICALLY PROCESSED MIX:

(1) Temperature - None.

(2) Bacterial limits - No growth by test specified in Section VI.

(3) DRUGS - No positive results on DRUG residue detection methods as referenced in Section 6 – Laboratory Techniques, FDA Grade “A” PMO as amended.

*Not applicable to cultured products.

**Not applicable to bulk shipped heat-treated products.

2. Each type of CHEESE shall conform to the sanitation requirements of this section and be produced and processed and PASTEURIZED, ULTRA-PASTEURIZED, and ASEPTICALLY PROCESSED to conform with the temperature, bacteriological, and chemical standards that are outlined below:

a. Except as provided in paragraph A.2.b. below, all MILK and MILK products used in the production of CHEESE shall meet the requirements in either (1) or (2) below:

(1) Be PASTEURIZED or subjected to equivalent heat treatment by the CHEESE manufacturer in accordance with the applicable specifications under the definition of PASTEURIZATION in Section I of this regulation.

a. PASTEURIZATION achieved by methods other than those described in the current PMO must be achieved in accordance with a written procedure that has been APPROVED by the DEPARTMENT; and

b. has been proven by a phosphatase test to achieve PASTEURIZATION.

(2) Be made from PASTEURIZED MILK products or from MILK products which have been subjected to equivalent heat treatment as outlined in Section I of this regulation.

b. If made from RAW MILK (CHEESE labeled as “heat treated”, “unPASTEURIZED”, “RAW MILK”, or “for manufacturing”), CHEESE must be aged for no less than sixty (60) days at a temperature greater than or equal to 35°F (1.7°C) in order to control microbial PATHOGENS.

c. RAW MILK and MILK products obtained by a CHEESE manufacturer for future PASTEURIZATION, ULTRA-PASTEURIZATION, or ASEPTIC PROCESSING and use in the production of CHEESE must come from an APPROVED source and be in compliance with the temperature, bacteriological, and chemical standards in R.61-34, Raw Milk for Human Consumption, or R. 61-34.1, Pasteurized Milk and Milk Products., or the PMO.

d. All CHEESE shall be made from ingredients that conform to the quality specifications for raw materials outlined in 21 CFR 58.430 through 58.437, as amended.

e. Each type of CHEESE must meet the specific standards and limits applicable to it under Subpart B of 21 CFR Part 133, as amended.

3. All BUTTERS shall conform to the sanitation requirements of 21 CFR 117.80 and be produced, processed, and PASTEURIZED, ULTRA-PASTEURIZED, or ASEPTICALLY PROCESSED to conform with the temperature, bacteriological, and chemical standards that are outlined below:

a. All BUTTERS shall be manufactured from MILK or MILK products that have been PASTEURIZED or subjected to equivalent heat treatment in accordance with the applicable specifications under the definition of PASTEURIZATION in Section I of this regulation and shall not be made from RAW MILK or RAW MILK products.

(1) PASTEURIZATION achieved by methods other than those described in the current PMO must be achieved in accordance with a written procedure that has been APPROVED by the DEPARTMENT; and

(2) has been proven by a phosphatase test to achieve PASTEURIZATION.

b. All BUTTERS shall be made from ingredients that conform to the quality specifications for raw materials outlined in 7 CFR 58.322 through 58.331, as amended.

c. BUTTER specifications:

(1) Proteolytic count - Not more than 100 per gram.

(2) Yeast and mold count - Not more than 20 per gram.

(3) Coliform count - Not more than 10 per gram.

(4) Enterococci - Not more than 10 per gram.

4. No process or manipulation other than PASTEURIZATION, ULTRA-PASTEURIZATION or ASEPTIC PROCESSING, freezing, processing methods integral therewith, and appropriate refrigeration (freezing) shall be applied to MANUFACTURED GRADE DAIRY PRODUCTS for the purpose of removing or deactivating MICROORGANISMS.

5. All IMITATION MILK, IMITATION MILK PRODUCTS, AND PRODUCTS MADE IN SEMBLANCE OF MILK AND MILK PRODUCTS shall meet the minimum standards for the MILK or MILK product which it imitates or resembles, including those for fat and solids not fat. To each quart of IMITATION MILK, imitation low-fat MILK, imitation skim MILK, and products made in semblance of these products, 400 U.S.P. units of Vitamin D and 2000 U.S.P. units of Vitamin A shall be added.

B. Post-PASTEURIZATION ingredients.

Only the following flavoring ingredients and other ingredients which have been found to be safe and suitable may be added to a MANUFACTURED GRADE DAIRY PRODUCT after PASTEURIZATION:

1. Fresh fruits and vegetables, provided the resultant equilibrium pH level (4.6 or below when measured at 75°F (24°C)) of the finished product is reached without undue delay and is maintained during the shelf life of the product;

2. Ingredients subjected to prior heating or other technology that has been demonstrated to the FDA to be sufficient to destroy or remove PATHOGENIC MICROORGANISMS;

3. Ingredients having a water activity of 0.85% or less;

4. Ingredients having a high acid content (pH level of 4.6 or below when measured at 75°F (24°C)) or high alkalinity (pH level greater than 11 when measured at 75°F (24°C));

5. Roasted nuts;

6. Dry sugars and salts;
7. Safe and suitable bacterial cultures and enzymes;
8. Alcohol;
9. Ingredients that have been found to be safe and suitable by the FDA.

All such additions shall be made in a sanitary manner that prevents the contamination of the added ingredient or the MANUFACTURED GRADE DAIRY PRODUCT.

C. Sanitation of MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS.

1. All MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURERS and DISTRIBUTORS, regardless of exemption status, shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, as amended.

a. In addition to the requirements in Section VII(C)(1) above, BUTTER plants, BUTTER manufacturers, BUTTER distribution stations, and BUTTER distributors shall comply with 7 CFR 58.311 through 58.321, as amended, and 7 CFR 58.332 through 58.344, as amended.

b. In addition to the requirements in Section, VII(C)(1) above, CHEESE plants, CHEESE manufacturers, CHEESE distribution stations, and CHEESE distributors shall comply with 7 CFR 58.406 through 58.429, as amended, and 7 CFR 58.438 through 58.445, as amended.

2. MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and DISTRIBUTION STATIONS that have been granted a Qualified Facility Exemption by the FDA or that are solely engaged in the storage of refrigerated UNEXPOSED PACKAGED FOODS when temperature controls are necessary to prevent PATHOGEN growth shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart D - Modified Requirements, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, and be familiar with Subpart E - Withdrawal of a Qualified Facility Exemption, as amended.

3. All MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and DISTRIBUTION STATIONS that have not been granted a Qualified Facility Exemption by the FDA shall comply with the requirements of 21 CFR Part 117, Subpart A - General Provisions, Subpart B - Current Good Manufacturing Practice, Subpart C - Hazard Analysis and Risk-Based Preventive Controls, and Subpart F - Requirements Applying to Records That Must Be Established and Maintained, as amended.

4. MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and DISTRIBUTION STATIONS that are requiring a withdrawal of their Qualified Facility Exemption from the FDA shall be subject to the requirements of 21 CFR Part 117, Subpart E - Withdrawal of a Qualified Facility Exemption, as amended.

5. MANUFACTURED GRADE DAIRY PLANTS and DISTRIBUTION STATIONS that have not been granted a Qualified Facility Exemption by the FDA and have identified a hazard requiring a supply-chain applied control shall comply with the requirements of 21 CFR Part 117, Subpart G - Supply-Chain Program, as amended.

6. There shall be separate rooms for processing and packaging of different types of MANUFACTURED GRADE DAIRY PRODUCTS as determined by the DEPARTMENT.

7. Water Supply.

a. Water used for MANUFACTURED GRADE DAIRY PRODUCTS PLANT purposes shall be from a supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality. Any water used as an ingredient must be obtained from an APPROVED public water system as defined in R.61-58. Water for MANUFACTURED GRADE DAIRY PLANTS that have not been granted a Qualified Facility Exemption by the FDA must be from an APPROVED public water supply.

b. Firms that have been granted a Qualified Facility Exemption by the FDA shall have their water supply tested. Samples for bacteriological testing of individual water supplies may be taken by the DEPARTMENT or by other APPROVED individuals with the results to be submitted to the DEPARTMENT upon the initial approval of the physical structure, annually thereafter, and when any repair or alteration of the water supply system has been made. Examinations shall be conducted in an OFFICIAL LABORATORY at the MANUFACTURED GRADE DAIRY PRODUCT PLANT'S expense. The plant must maintain records of the tested samples.

SECTION VIII. MANUFACTURED GRADE DAIRY PRODUCTS FROM OUT OF STATE OR OUTSIDE THE UNITED STATES

MANUFACTURED GRADE DAIRY PRODUCTS from out of state or outside the United States may be sold in South Carolina only if the DEPARTMENT determines they are manufactured and distributed under provisions substantially equivalent to the requirements of this regulation and adequately enforced.

SECTION IX. PLANS FOR CONSTRUCTION AND RECONSTRUCTION

Properly prepared plans for all MANUFACTURED GRADE DAIRY PRODUCTS PLANTS or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS regulated under this regulation which are to be constructed, reconstructed, or extensively altered shall be submitted to the DEPARTMENT for written approval before work is begun.

SECTION X. EQUIPMENT AND FACILITIES IN OPERATION PRIOR TO JULY 1, 2020

Equipment and physical facilities of MANUFACTURED GRADE DAIRY PRODUCTS PLANTS and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTION STATIONS in operation prior to July 1, 2020

are deemed in compliance even if they do not meet all construction, equipment, and facilities requirements of this regulation if the facilities and equipment:

A. Are in compliance with the regulatory standards in place for such equipment and facilities on January 1, 2020;

B. Are capable of being maintained in a sanitary condition;

C. Are not a public health hazard or NUISANCE; and

D. Are replaced in the normal course of operation with equipment and facilities that meet the requirements of this regulation.

This section shall not apply to equipment installed or construction commenced on or after July 1, 2020.

SECTION XI. PROCEDURE WHEN INFECTION OR HIGH RISK INFECTION IS SUSPECTED

When reasonable cause exists to suspect the possibility of transmission of infection from any PERSON concerned with the handling of MANUFACTURED GRADE DAIRY PRODUCTS, or their ingredients, the DEPARTMENT is authorized to require any or all of the following measures:

A. The immediate EXCLUSION or RESTRICTION of that PERSON from handling MANUFACTURED GRADE DAIRY PRODUCTS, or their ingredients;

B. The immediate removal of the MANUFACTURED GRADE DAIRY PRODUCTS of concern from distribution and use; and/or

C. Adequate medical and bacteriological examination of the PERSON, of their associates, and any of their bodily discharges.

SECTION XII. RECALLS

For MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURERS and DISTRIBUTORS that have not been granted a Qualified Facility Exemption by the FDA, the Recall Plan requirements of 21 CFR 117.139 supersede the requirements of this section.

If 21 CFR 117.139 does not apply, each MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the PERMIT HOLDER or the DEPARTMENT has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the DEPARTMENT determines, based upon representative samples, RISK analysis, information provided by the MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and/or

MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR, and/or other information available to the DEPARTMENT, that the circumstances present an IMMEDIATE HEALTH HAZARD and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the DEPARTMENT may order the MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and/or MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR to initiate a level of product recall or, if appropriate, issue a form of notification to customers. Each MANUFACTURED GRADE DAIRY PRODUCTS MANUFACTURER and MANUFACTURED GRADE DAIRY PRODUCTS DISTRIBUTOR shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION XIII. ENFORCEMENT AND PENALTIES

Any PERSON found to be in violation of this regulation, in non-compliance with the issued PERMIT, or in violation of an order issued by the DEPARTMENT shall be subject to civil monetary penalties, PERMIT suspension, and/or PERMIT revocation. Each day of continued violation shall be a separate offense.

SECTION XIV. SEVERABILITY CLAUSE

Should any section, paragraph, sentence, clause, or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.