

SUMMARY: This Rule outlines the procedures and standards governing the inspection and examination, licensing, permitting, testing, labeling and sanitation of milk and milk product production and distribution.

STATUTORY AUTHORITY: 7 M.R.S.A. §2910

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Please contact the Department of Agriculture, Conservation and Forestry, 28 State House Station, Augusta, ME 04333, phone 207/287-3841, for copies of the following attachments:

ATTACHMENTS

MILK PLANT INSPECTION REPORT

DAIRY FARM INSPECTION REPORT

MANUFACTURING PLANT INSPECTION REPORT

MILK PLANT EQUIPMENT TESTS REPORT

BULK MILK PICKUP TANKER, HAULER REPORT AND SAMPLER EVALUATION FOR

SECTION I - GENERAL

Any person, firm or corporation required to hold a valid permit or license under 7 MRS, Chapter 601, Milk and Milk Products, §2901-C or §2902-A must comply with this rule and in addition any person, firm or corporation which participates in the State/United States Public Health Service/Food and Drug Administration (USPHS/FDA) voluntary Cooperative Program for the Certification of Interstate Milk Shippers (IMS program) must comply with all requirements and is subject to the administrative procedures outlined in the 2019 USDA Grade “A” Pasteurized Milk Ordinance herein referred to as the “PMO”. All further references to “PMO” in this Rule mean the 2019 edition of the PMO. LINK: <https://www.fda.gov/food/milk-guidance-documents-regulatory-information/national-conference-interstate-milk-shipments-ncims-model-documents>

A. DEFINITIONS

1. ABNORMALITIES OF MILK: The following types of lacteal secretions are not suitable for sale for human consumption:
 - (a) Abnormal Milk: Milk that is visibly changed in color, odor, and/or texture.
 - (b) Undesirable Milk: Milk that, prior to the milking of the animal, is expected to be unsuitable for sale, such as milk containing colostrum.
 - (b) Contaminated Milk: Milk that is un-saleable or unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements, or treatment with medicines or insecticides not approved for use on dairy animals by FDA or the Environmental Protection Agency (EPA).
2. ACIDIFIED MILK -
 - (a) “Acidified milk” is the food produced by souring one or more of the optional dairy ingredients specified in paragraph (c) of this Section with one or more of the acidifying ingredients specified in paragraph (d) of this Section, with or without the addition of characterizing microbial organisms. One or more of the other optional ingredients specified in paragraph (b) and (e) of this Section may also be added. When one or more of the ingredients specified in paragraph (e)(i) of this Section are used, they must be included in the souring process. All ingredients used are safe and suitable. Acidified milk contains not less than 3.25 percent milk fat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and may be pasteurized or ultra-pasteurized prior to the addition of the microbial culture and, when applicable, the addition of flakes or granules of butterfat or milk fat.
 - (b) Vitamin addition requirements (optional)
 - (i) If added, vitamin A must be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2,000

International Units thereof, within limits of good manufacturing practice.

- (ii) If added, vitamin D must be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.
- (c) Optional dairy ingredients: Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.
- (d) Optional acidifying ingredients: Acetic acid, adipic acid, citric acid, fumaric acid, glucono-delta-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, and tartaric acid.
- (e) Other optional ingredients.
 - (i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, must not be decreased as a result of adding such ingredients.
 - (ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract; dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweeteners listed in 21 CFR Part 168 (2016), except table syrup.
 - (iii) Flavoring ingredients.
 - (iv) Color additives that do not impart a color simulating that of milk fat or butterfat.
 - (v) Stabilizers.
 - (vi) Butterfat or milk fat, which may or may not contain color additives, in the form of flakes or granules.
 - (vii) Aroma- and flavor-producing microbial culture.
 - (viii) Salt.
 - (ix) Citric acid, in a maximum amount of 0.15 percent by weight of the dairy ingredients used, or an equivalent amount of sodium citrate, as a flavor precursor.

3. ACIDIFIED SOUR CREAM -

- (a) “Acidified sour cream” is the result of the souring of pasteurized cream with safe and suitable acidifiers, with or without addition of lactic acid producing bacteria. Acidified sour cream contains not less than 18 percent milk fat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milk fat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milk fat. Acidified sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.
- (b) Optional ingredients.
 - (i) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.
 - (ii) Rennet.
 - (iii) Safe and suitable nutritive sweeteners.
 - (iv) Salt.
 - (v) Flavoring ingredients, with or without safe and suitable coloring as follows:
 - (a) Fruit and fruit juice, including concentrated fruit and fruit juice.
 - (b) Safe and suitable natural and artificial food flavoring.

4. ACIDIFIED SOUR HALF-AND-HALF -

- (a) “Acidified sour half-and-half” is the result of the souring of pasteurized half-and-half with safe and suitable acidifiers, and with or without addition of lactic acid producing bacteria. Acidified sour half-and-half contains not less than 10.5 percent but less than 18 percent milk fat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milk fat is not less than 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milk fat. Acidified sour half-and-half has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.
- (b) Optional ingredients.
 - (i) Safe and suitable ingredients to improve texture, prevent syneresis, or extend the shelf life of the product.

- (ii) Rennet.
- (iii) Safe and suitable nutritive sweeteners.
- (iv) Salt.
- (v) Flavoring ingredients, with or without safe and suitable coloring, as follows:
 - (c) Fruit and fruit juice, including concentrated fruit and fruit juice.
 - (d) Safe and suitable natural and artificial food flavoring.

5. ADULTERATED MILK AND MILK PRODUCTS -

Any milk or milk product shall be deemed to be adulterated:

- (a) If it bears or contains any poisonous or deleterious substance (such as an emerging contaminant) which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or
- (b) If it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) any animal drug) which is unsafe within the meaning of Section 406 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. section 342(a)(1) (2005)) (hereinafter referred to as FD&C), or
- (c) If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a) of the FD&C (21 U.S.C. section 346a (2019)); or
- (d) If it is, or it bears or contains, any food additive which is unsafe within the meaning of Section 409 of the FD&C (21 U.S.C. section 348 (2018)): provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under Section 408 of the FD&C (21 U.S.C. section 346a (2019)) and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of Section 406 and 409 of the FD&C (21 U.S.C. section 346a (2019) and 21 U.S.C. section 348 (2018)), not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or

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- (e) If it is, or it bears or contains, any animal drug (or conversion product thereof) which is unsafe within the meaning of Section 512 of the FD&C(21 U.S.C. section 360b (2018)) ; or
 - (f) If it consists in whole or in part of any filthy, putrid or decomposed substance, or if it is otherwise unfit for food; or
 - (g) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or
 - (h) If it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or
 - (i) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
 - (j) If it has been intentionally subjected to radiation, unless the use of radiation was in conformity with a regulation or exemption in effect pursuant to Section 409 of the FD&C (21 U.S.C. section 348 (2018)); or
 - (k) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (ii) if any substance has been substituted wholly or in part therefor; or (iii) if damage or inferiority has been concealed in any manner; or (iv) if any substance has been added thereto or mixed or packed 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; or
 - (l) If it is, or it bears or contains, a color additive which is unsafe within the meaning of Section 706(a) of the FD&C (21 U.S.C. section 379e (1993)); or
 - (m) If it is confectionery, and - (i) has partially or completely imbedded therein any non-nutritive object: provided, that this clause shall not apply in the case of any non-nutritive object if such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health; (ii) bears or contains any alcohol other than alcohol not in excess of one-half of 1 percent by volume derived solely from the use of flavoring extracts; or (iii) bears or contains any non-nutritive substance: provided, that this clause shall not apply to a safe non-nutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this rule: and provided further that the Commissioner may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular non-nutritive substances; or

- (n) (n) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.
6. AND/OR - Where the term “and/or” is used, “and” shall apply where appropriate; otherwise “or” shall apply.
7. ASEPTIC PROCESSING - “Aseptic processing”, when used to describe a milk product, means that the product has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of Title 21 CFR 113 and the provisions of Section V and maintain the commercial sterility of the product under normal non-refrigerated conditions.
8. ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS - “Aseptically processed milk and milk products” are products that have been subjected to sufficient heat processing and packaged in a hermetically sealed container, to conform to the applicable requirements of Title 21 CFR 113 and the provisions of Section V and to maintain the commercial sterility of the product under normal non-refrigerated conditions.
9. AUTOMATIC MILKING INSTALLATION (AMI) - The term “automatic milking installation” covers the entire installation of one or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning and sanitation.
10. BULK MILK HAULER/SAMPLER - A “bulk milk hauler/sampler” is any person who collects official samples and/or transports raw milk from a farm and/or raw milk products to or from a farm, milk plant, receiving station or transfer station and has in their possession a permit from any state to sample such products.
11. BULK MILK PICKUP TANKER - A “bulk milk pickup tanker” is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by the bulk milk hauler/sampler or milk tank truck driver to transport bulk raw milk for pasteurization or processing from a dairy farm to a milk plant, receiving station or transfer station.
12. BUTTER - “Butter” means the food product which is made exclusively from milk or cream or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80% by weight of milk fat.
13. BUTTERMILK - “Buttermilk” is a fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8 1/4 percent of milk solids not fat.
- (a) Dry Buttermilk: Grade "A" dry buttermilk means dry buttermilk, which complies with the applicable provisions of this Rule.

- (b) **Dry Buttermilk Products: Grade "A" dry buttermilk products** means dry buttermilk products, which comply with the applicable provisions of this Rule.
 - (c) **Concentrated (Condensed) Buttermilk:** Concentrated (condensed) buttermilk means the product resulting from the removal of a considerable portion of water from buttermilk.
 - (d) **Concentrated (Condensed) and Dry Buttermilk and Buttermilk Products: Grade "A" concentrated (condensed) and dry buttermilk and buttermilk products** means concentrated (condensed) or dry buttermilk and buttermilk products, which comply with the applicable provisions of this Rule. The words "concentrated (condensed) and dry milk products" shall be interpreted to include concentrated (condensed) and dry buttermilk and buttermilk products.
14. **CHEESE** - "Cheese" is the consolidated curd of milk used as an article of food.
15. **CLEAN** - "Clean" means that direct product contact surfaces have had the effective and thorough removal of product and/or contaminants.
16. **CLEAN-IN-PLACE (CIP) CLEANING** - "Clean-in-place (CIP) cleaning" means the removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Components of the equipment, which are not designed to be cleaned-in-place, are removed from the equipment to be cleaned out-of-place (COP) or manually cleaned. Product contact surfaces must be inspectable, except when the cleanability by CIP has been documented and accepted by the Department. In such accepted equipment, all product and solution contact surfaces do not have to be readily accessible for inspection, i.e., permanently installed pipelines and silo tanks.
17. **COMMISSIONER** - "Commissioner" means the Commissioner of the Maine Department of Agriculture, Conservation and Forestry or his/her duly authorized agent.
18. **COMMON NAME** - "Common name" means the generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, etc.
19. **CONCENTRATED (CONDENSED) MILK** - "Concentrated (condensed) milk" means a fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which, when combined with potable water in accordance with instructions printed on the container, results in a product conforming with the milk fat and milk solids not fat levels of milk as defined in this section.
- (a) **Concentrated (Condensed) Milk Products:** "Concentrated (condensed) milk products" means and includes homogenized concentrated (condensed) milk, concentrated (condensed) skim milk, concentrated (condensed) reduced fat or low-fat milk, and similar concentrated (condensed) products made from concentrated (condensed) milk or

concentrated (condensed) skim milk, which when combined with potable water in accordance with instructions printed on the container label, conform with the definitions of the corresponding milk products in this Section.

- (b) Grade "A" Concentrated (Condensed) Skim Milk: "Grade "A" concentrated (condensed) skim milk" means concentrated (condensed) skim milk, which complies with the applicable provisions of the PMO.
20. COOLING POND - "Cooling Pond" means a man-made structure designed for the specific purpose of cooling cows.
21. COTTAGE CHEESE -
- (a) "Cottage cheese" means the soft uncured cheese prepared by mixing cottage cheese dry curd with a creaming mixture as provided in paragraph (b) of this Section. The milk fat content is not less than 4 percent by weight of the finished food, within limits of good manufacturing practice. The finished food contains not more than 80 percent of moisture.
 - (b) The creaming mixture is prepared from safe and suitable ingredients including, but not limited to, milk or substances derived from milk. Any ingredients used that are not derived from milk must serve a useful function other than building the total solids content of the finished food and shall be used in a quantity not greater than is reasonably required to accomplish their intended effect. The creaming mixture may be pasteurized; however, heat labile ingredients, such as bacterial starters, may be added following pasteurization.
 - (c) The name of the food consists of the following two phrases which must appear together:
 - (i) The words "cottage cheese" which must appear in type of the same size and style.
 - (ii) The statement "not less than ... percent milk fat" or "... percent milk fat minimum", the blank being filled in with the whole number that is closest to, but does not exceed, the actual fat content of the product. This statement of fat content must appear in letters not less than one-half of the height of letters in the phrase specified in paragraph (c)(i) of this Section, but in no case less than one-eighth of an inch in height.
 - (d) When the optional process described in Title 21 CFR 133 (2019) is used to make the cottage cheese dry curd, the label must bear the statement "directly set" or "Curd set by direct acidification". Wherever the name of the food appears on the label so conspicuously as to be seen under customary conditions of purchase, the statement specified in this paragraph, showing the optional process used must immediately and

conspicuously precede or follow such name without intervening written, printed, or graphic matter.

- (e) The common or usual name of each of the ingredients used in the food must be declared on the label as required by the applicable sections. Except that:
 - (i) Concentrated milk, dried milk, and reconstituted milk prepared by addition of water to concentrated milk or dried milk may be declared as “milk”.
 - (ii) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as “skim milk”.
 - (iii) Bacterial cultures may be declared by the word “cultured” followed by the name of the substrate, e.g., “made from cultured skim milk”.
 - (iv) Milk-clotting enzymes may be declared by the word “enzymes”.

22. CREAM - “Cream” means the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milk fat.

23. CULTURED MILK -

- (a) “Cultured milk” is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this Section with characterizing microbial organisms. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this Section may also be added. When one or more of the ingredients specified in paragraph (d)(i) of this Section are used, they must be included in the culturing process. All ingredients used are safe and suitable. Cultured milk contains not less than 3.25 percent milk fat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and may be pasteurized or ultra-pasteurized prior to the addition to the microbial culture, and when applicable, the addition of flakes or granules of butterfat or milk fat.
- (b) Vitamin addition requirements (optional).
 - (i) If added, vitamin A must be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.

- (ii) If added, vitamin D must be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof, within limits of good manufacturing practice.
 - (c) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.
 - (d) Other optional ingredients.
 - (i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, must not be decreased as a result of adding such ingredients.
 - (ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweetener listed in 21 CFR Part 168, except table syrup.
 - (iii) Flavoring ingredients.
 - (iv) Color additives that do not impart a color simulating that of milk fat or butterfat.
 - (v) Stabilizers.
 - (vi) Butterfat or milk fat, which may or may not contain color additives, in the form of flakes or granules.
 - (vii) Aroma- and flavor-producing microbial culture.
 - (viii) Salt.
 - (ix) Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.
24. DAIRY FARM - "Dairy farm" means any place or premises where one (1) or more cows, goats, sheep, water buffalo, or other hooved mammal are kept for milking purposes, and from which a part or all of the milk or milk product(s) is provided, sold or offered for sale to a milk plant, receiving or transfer station. (Refer to the **NOTE**: at the end of Section XIII)

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25. DAIRY PLANT SAMPLER - “Dairy plant sampler” means an individual responsible for the collection of official samples for regulatory purposes outlined in this Rule. This person is an employee of the Department or an official designee of the Department and is evaluated every two years by the State Sample Surveillance Officer. Sampling Surveillance Officers or properly delegated Sampling Surveillance Regulatory Officials are not required to be evaluated for sampling collection procedures.
26. DEPARTMENT - “Department” means the Maine Department of Agriculture, Conservation & Forestry.
27. DRUG - The term “drug” means:
- (a) 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
 - (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and
 - (c) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
 - (d) Articles intended for use as a component of any articles specified in clause (a), (b) or (c), but does not include devices or their components, parts or accessories.
28. DRY CURD COTTAGE CHEESE -
- (a) “Dry curd cottage cheese” is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this Section. The finished food contains less than 0.5 percent milk fat. It contains not more than 80 percent of moisture.
 - (b) Preparation Procedures:
 - (i) One or more of the dairy ingredients specified in paragraph (b)(ii) of this section is pasteurized; calcium chloride may be added in a quantity of not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the mix; thereafter one of the following methods is employed:
 - (a) Harmless lactic-acid-producing bacteria, with or without rennet and/or other safe and suitable milk clotting enzyme that produces equivalent curd formation, are added and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd may be washed with water and further drained; it may be pressed, chilled, worked, seasoned with salt; or

- (b) Food grade phosphoric acid, lactic acid, citric acid, or hydrochloric acid, with or without rennet and/or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, is added in such amount as to reach a pH of between 4.5 and 4.7; coagulation to a firm curd is achieved while heating to a maximum of 48.9°C (120°F) without agitation during a continuous process. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is washed with water, stirred, and further drained. It may be pressed, chilled, worked and seasoned with salt.
 - (c) Food grade acids as provided in paragraph (b)(i)(b) of this Section, D-Glucono- delta-lactone with or without rennet, and/or other safe and suitable milk clotting enzyme that produces equivalent curd formation, are added in such amounts as to reach a final pH value in the range of 4.5-4.8, and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is then washed with water, and further drained. It may be pressed, chilled, worked, and seasoned with salt.
- (ii) The dairy ingredients referred to in paragraph (b)(i) of this Section are sweet skim milk, concentrated skim milk, and nonfat dry milk. If concentrated skim milk or nonfat dry milk is used, water may be added in a quantity not in excess of that removed when the skim milk was concentrated or dried.
 - (iii) For the purposes of this Section the term “skim milk” means the milk of cows from which the milk fat has been separated, and “concentrated skim milk” means skim milk from which a portion of the water has been removed by evaporation.
- (c) The name of the food consists of the following two phrases which must appear together:
 - (i) The words “cottage cheese dry curd” or alternatively “dry curd cottage cheese” which must all appear in type of the same size and style.
 - (ii) The words “less than 1/2% milk fat” which must all appear in letters not less than one-half of the height of the letters in the phrase specified in paragraph (c)(i) of this Section, but in no case less than one-eighth of an inch in height.
- (d) When either of the optional processes described in paragraph (b)(i) (b) or (c) of this Section is used, the label must bear the statement “Directly set” or “Curd set by direct acidification”. Wherever the name of the food appears on the label so conspicuously as to be seen under customary conditions of purchase, the statement specified in this paragraph,

showing the optional process used, must immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

- (e) The common or usual name of each of the ingredients used in the food must be declared on the label as required in Section XIV of this rule, except that:
 - (i) Concentrated skim milk, nonfat dry milk, and reconstituted skim milk prepared by addition of water to concentrated skim milk or nonfat dry milk may be declared as “skim milk”.
 - (ii) Bacterial cultures may be declared by the word “cultured” followed by the name of the substrate, e.g., “made from cultured skim milk”.
 - (iii) Milk-clotting enzymes may be declared by the word “enzymes”.

29. EGGNOG -

- (a) “Eggnog” is the food containing one or more of the optional dairy ingredients specified in paragraph (b), one or more of the optional egg yolk-containing ingredients specified in paragraph (c) of this Section, and one or more of the optional nutritive carbohydrate sweeteners specified in paragraph (d) of this Section. One or more of the optional ingredients specified in paragraph (e) of this Section may also be added. All ingredients used are safe and suitable. Eggnog contains not less than 6 percent milk fat and not less than 8.25 percent milk solids not fat. The egg yolk solids content is not less than 1 percent by weight of the finished food. The food must be pasteurized or ultra-pasteurized and may be homogenized. Flavoring ingredients and color additives may be added after the food is pasteurized or ultra-pasteurized.
- (b) Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.
- (c) Egg Yolk-containing ingredients. Liquid egg yolk, frozen egg yolk, dried egg yolk, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one or more of the foregoing ingredients with liquid egg whites or frozen egg whites. Whenever eggs or egg yolk solids are used as an ingredient, they must be pasteurized or, if not, the mix must be pasteurized after the eggs or egg yolk solids are added.
- (d) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner’s syrup; molasses (other than blackstrap); high fructose corn syrup; fructose, fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any of the sweeteners listed in 21 CFR Part 168, except table syrup.
- (e) Other optional ingredients.

- (i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, must not be decreased as a result of adding such ingredients.
 - (ii) Salt.
 - (iii) Flavoring ingredients.
 - (iv) Color additives that do not impart a color simulating that of egg yolk, milk fat or butterfat.
 - (v) Stabilizers.
30. FDA - Food & Drug Administration, an agency with the United States Department of Health and Human Services. The core functions of this agency are oversight of Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations.
31. FD&C - Food, Drug, and Cosmetic Act: A set of laws passed by Congress in 1938 giving authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs, and cosmetics.
32. FALSE POSITIVE - In reference to antibiotic screening of bulk tanker milk and bulk tank milk, "false positive" means that, on subsequent testing by high pressure chromatograph (HPLC), antibiotic residue was not found to be present.
33. FALSE VIOLATIVE - In reference to antibiotic screening of bulk tanker milk or bulk tank milk, "false violative" means that on subsequent testing by high pressure liquid chromatograph, antibiotic residue was found to be present at below the FDA-established safe or tolerance level.
34. FOOD ALLERGENS - Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than 90 % of all food allergies: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.
35. FROZEN MILK CONCENTRATE - "Frozen milk concentrate" is a frozen milk product with a composition of milk fat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milk fat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported and sold in the frozen state.
36. FROZEN YOGURT -

- (a) “Frozen yogurt” is the food which is prepared by freezing while stirring a pasteurized mix consisting of the ingredients identified for ice cream. 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*, provided, however, 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 apply to the mix prior to culturing. Frozen yogurt, exclusive of any flavoring contains not less than 3.25 percent milk fat, not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.3 percent expressed as lactic acid. Where the titratable acidity of the frozen yogurt is less than 0.3 percent, the manufacturer may establish compliance with this section by disclosing to the Department its quality control records that demonstrate as a result of bacterial culture fermentation, at least a 0.15 percent increase in titratable acidity calculated as lactic acid, above the apparent titratable acidity of the uncultured dairy ingredients in the frozen yogurt mix. The direct addition of food grade acids or other acidogens for the purpose of raising the titratable acidity of the frozen yogurt mix to comply with the prescribed minimum is not permitted; and no chemical preservative treatment or other preservation process, other than refrigeration, may be utilized that results in reduction of the live culture. Sweetener(s), flavoring(s) and/or other characterizing food ingredients may be added to the mix before or after pasteurization or ultra-pasteurization is done in accordance with good manufacturing practice. The finished yogurt must weigh not less than 4 pounds per gallon. Any dairy ingredients added after pasteurization or ultra-pasteurization must have been pasteurized.
- (b) The name of the food is “frozen yogurt”. In addition to all other required information, the label must contain a complete list of ingredients, in accordance with the provisions of 21 CFR 101.4, and comply with the provisions of subdivisions (h) and (i) of 21 CFR 101.22. On the label of frozen yogurt the strains of bacteria may be collectively referred to as yogurt culture.
37. GOAT MILK - “Goat milk” is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages must contain not less than 2.5 percent milk fat and not less than 7.5 percent milk solids not fat. Goat milk and goat milk food products must be produced according to the sanitary standards of this rule.
38. GOAT’S MILK ICE CREAM -
- (a) “Goat’s milk ice cream” is the food prepared in the same manner prescribed in 21 CFR 135, and complies with all the provisions of 21 CFR 135, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this Section; caseinates and hydrolyzed milk proteins may not be used; and paragraph (f)(1) and (g) of Sec. 135.110 shall not apply.

- (b) Optional dairy ingredients. The optional dairy ingredients referred to in paragraph (a) of this Section are goat's skim milk, goat's milk, and goat's cream. These optional dairy ingredients may be used in liquid, concentrated, and/or dry form.
 - (c) If eggs or egg yolk solids are used as an ingredient, they must be pasteurized or, if not, the mix must be pasteurized after the eggs or egg yolk solids are added.
- 39. GRADE A MILK AND MILK PRODUCTS "Grade A milk and milk products" are products that have been manufactured under and comply with all applicable provisions of the PMO. All such products are pasteurized or are destined for pasteurization.
- 40. GRADE A DRY MILK AND WHEY PRODUCTS - "Grade A dry milk and whey products" are products which have been produced for use in Grade A pasteurized or aseptically processed milk products and which have been manufactured under the provisions of the Grade A Condensed and Dry Milk Products and Condensed and Dry Whey-Supplement to comply with all applicable provisions of the PMO.
- 41. GRAS - "GRAS" means generally recognized as safe as defined by 21 CFR Part 184 (2016).
- 42. HACCP - "HACCP" means Hazard Analysis and Critical Control Point. It is a food safety control system based on technical and scientific principles that assure safe food.
- 43. HALF-AND-HALF -
 - (a) "Half-and-half" is the food consisting of a mixture of milk and cream which contains not less than 10.5 percent but less than 18 percent milk fat. It may be homogenized.
 - (b) Optional ingredients. The following safe and suitable optional ingredients may be used.
 - (i) Emulsifiers.
 - (ii) Stabilizers.
 - (iii) Nutritive sweeteners.
 - (iv) Characterizing flavoring ingredients (with or without safe and suitable coloring) as follows:
 - (a) Fruit and fruit juice (including concentrated fruit and fruit juice)
 - (b) Natural and artificial food flavoring.

44. HEAT TREATED -

“Heat treated” or “heat-treated” or “heat treatment” means processed by heating every particle of milk to a temperature of 145 degrees Fahrenheit for at least 30 minutes. Other heat treatment processes of differing temperature and time combinations may be acceptable if validated through a heat treatment study by a food processing authority.

45. HEAVY CREAM OR HEAVY WHIPPING CREAM -

- (a) “Heavy cream” is cream which contains not less than 36 percent milk fat. It may be homogenized.
- (b) Optional ingredients. The following safe and suitable optional ingredients may be used:
 - (i) Emulsifiers.
 - (ii) Stabilizers.
 - (iii) Nutritive sweeteners.
 - (iv) Characterizing flavoring ingredients (with or without coloring) as follows:
 - (a) Fruit and fruit juice (including concentrated fruit and fruit juice).
 - (b) Natural and artificial food flavorings.

46. HERMETICALLY SEALED CONTAINER - A “hermetically sealed container” is 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.

47. HOMOGENIZED - The term “homogenized” means that milk or a milk product has been treated to insure breakup of the fat globules to such an extent that, after 48 hours of quiescent storage at 4.4°C (40°F), no visible cream separation occurs in the milk; and the fat percentage of the top 100 milliliters of milk in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than 10 percent from the fat percentage of the remaining milk as determined after thorough mixing.

48. HOOVED MAMMALS MILK - Hooved mammals milk is the normal lacteal secretion, practically free of colostrums, obtained by the complete milking of one (1) or more healthy hooved mammals. This product must be produced according to the sanitary standards of this Rule. Hooved mammals for the purpose of this Rule, 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.). This product must be produced according to the sanitary standards of this Rule. (Refer to the **NOTE**: at the end of Section XIII)

49. ICE CREAM AND FROZEN CUSTARD -

(a) Ice Cream and Frozen Custard Specifications: These are foods produced by freezing, while stirring, a mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this Section, and may contain one or more of the optional caseinates specified in paragraph (c) of this Section subject to the conditions hereinafter set forth, one or more of the optional hydrolyzed milk proteins as provided for in paragraph (d) of this Section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions.

(i) Ice cream is sweetened with safe and suitable sweeteners and may be characterized by the addition of flavoring ingredients. If eggs or egg yolk solids are used as an ingredient, they must be pasteurized or, if not, the mix must be pasteurized after the eggs or egg yolk solids are added.

(ii) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Ice cream contains not less than 10 percent milk fat, nor less than 10 percent nonfat milk solids, except that when it contains milk fat at 1 percent increments above the 10 percent minimum, it may contain the following milk fat-to-nonfat milk solids levels:

Percent milk fat	Minimum percent non-fat milk solids
10	10
11	9
12	8
13	7
14	6

Except that when one or more bulky flavors are used, the weights of milk fat and total milk solids are not less than 10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of the bulky flavors from the weight of milk fat or total milk solids less than 8 percent and 16 percent, respectively, of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used.

(iii) Frozen custard must contain 1.4 percent egg yolk solids by weight of the finished food: provided, however, that when bulky

flavors are added the egg yolk solids content of frozen custard may be reduced in proportion to the amount of weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12 percent. A product containing egg yolk solids in excess of 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (e)(i) of this Section.

- (iv) When calculating the minimum amount of milk fat and nonfat milk solids required in the finished food, the solids of chocolate or cocoa must be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids, used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.
- (b) Optional dairy ingredients. The optional dairy ingredients referred to in paragraph (a) of this Section are: Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, skim milk in concentrated or dried form which has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate, and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrated) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent calculated as lactic acid. The term "milk" as used in this Section means cow's milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content to be finished food. The modified skim milk, when adjusted with water to a total solids content of 9 percent is substantially free of lactic acid as determined by titration within 0.1N NaOH, and it has a pH value in the range of 8.0 to 8.3.
- (c) Optional caseinates. The optional caseinates referred to in paragraph (a) of this Section that may be added to ice cream mix containing not less than 20 percent total milk solids are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium

caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.

- (d) Optional hydrolyzed milk proteins. One or more of the optional hydrolyzed milk proteins referred to in paragraph (a) of this Section may be added as stabilizers at a level not to exceed 3 percent by weight of ice cream mix containing not less than 20 percent total milk solids provided that any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. Further, when hydrolyzed milk proteins are used in the food, the declaration of these ingredients on the food label must comply with the requirements of Section XIV.
- (e) Nomenclature.
 - (i) The name of the food is "ice cream", except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this Section the name of the food is "frozen custard" or "french ice cream" or "french custard ice cream".
 - (ii) Flavoring Label Requirements
 - (a) If the food contains no artificial flavor, the name on the principal display panel or panels of the label must be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla" in letters not less than one-half the height of the letters used in the words "ice cream".
 - (b) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels must be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream" followed by the word "flavored", in letters not less than one half the height of the letters in the name of the characterizing flavor, e.g. "vanilla flavored", or "peach flavored", or "vanilla flavored and strawberry flavored".
 - (c) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if the artificial flavor is used alone, the name on the principal display panel or panels of the label must be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream", preceded by "artificial" or "artificially flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g. "artificial

vanilla", "artificially flavored strawberry" or "artificially flavored vanilla and artificially flavored strawberry".

- (d) If the food is subject to the requirements of paragraph (e)ii(b) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label must also bear the word "artificial flavor added" or "artificial _____ flavor added", the blank being filled in with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.
- (e) Whenever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph must immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: provided, however, that where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor, and provided further, that if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g. "Vanilla flavored, chocolate and strawberry flavored, artificial flavors added".
- (iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor must, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with subsequently equal prominence, e.g. "strawberry and artificial strawberry flavor".
- (iv) An artificial flavor simulating the characterizing flavor must be deemed to predominate:
 - (a) In the case of vanilla beans or vanilla extracts used in combination with vanillin if the amount of vanillin used

is greater than 1 ounce per unit of vanilla constituent as defined in 21 CFR part 169 (2019).

- (b) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.
- (c) In the case of nut meats used in combination with artificial nut flavor, if the quantity of the nut meats is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 percent.
- (d) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e)(5)(b) or (c) of this Section. For example, if a combination of ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be “artificially flavored banana-almond ice cream”. However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be banana-almond flavored ice cream”.
- (v) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.
- (vi) Each of the optional ingredients used must be declared on the label as required by the applicable section of 21 CFR 101 (2019), except that sources of milk fat or milk solids not fat may be declared in descending order of predominance either by the use of the terms “milk fat and nonfat milk” when one or any combination of two or more of the ingredients listed in 21 CFR 101 (2019) are used or alternatively as permitted in 21 CFR 101 (2019). Pursuant to the FD & C (artificial colors approved by the FDA), artificial color need not be declared in ice cream except for FD&C Yellow No. 5. However, voluntary declaration of any color in ice cream is recommended.

50. ICE CREAM MIX - “Ice cream mix” is the unfrozen product from which ice

cream is manufactured. When applicable, the ingredient and butterfat standards must be the same for ice cream.

51. INDUSTRY PLANT SAMPLER - A person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Section XIII of this Rule. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two (2) year period by a State Sampling Surveillance Officer or a properly delegated Sampling Surveillance Regulatory Official.
52. LACTOSE-REDUCED MILK - "Lactose-reduced milk" is the product resulting from the treatment of milk, as defined in this rule, by the addition of safe and suitable enzymes to convert sufficient amounts of the lactose to glucose and/or galactose so that the remaining lactose is less than 30 percent of the lactose in milk.
53. LIGHT CREAM -
 - (a) "Light cream" is cream which contains not less than 18 percent but less than 30 percent milk fat. It may be homogenized.
 - (b) Optional ingredients. The following safe and suitable optional ingredients may be used:
 - (i) Stabilizers.
 - (ii) Emulsifiers.
 - (iii) Nutritive Sweeteners.
 - (iv) Characterizing flavoring ingredients (with or without coloring) as follows:
 - (a) Fruit and fruit juice (including concentrated fruit and fruit juice)
 - (b) Natural and artificial food flavorings.
54. LIGHT MILK -
 - (a) "Light milk" is milk that has less than or equal to 4 grams of fat per 8 ounce (240 mL) serving and contains not less than 8.25 percent milk solids not fat.
 - (b) Vitamin requirements.
 - (i) Vitamin A must be present in such quantity that each 946 milliliters (1 quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.

- (ii) Addition of vitamin D is optional. If added, vitamin D must be present in such quantity that each 946 milliliters (1 quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.
55. LIGHT WHIPPING CREAM, MEDIUM CREAM OR WHIPPING CREAM -
- (a) “Light whipping cream, medium cream or whipping cream” is cream which contains not less than 30 percent but less than 36 percent milk fat. It may be homogenized.
 - (b) Optional ingredients. The following safe and suitable optional ingredients may be used:
 - (i) Stabilizers.
 - (ii) Emulsifiers.
 - (iii) Nutritive sweeteners.
 - (iv) Characterizing flavoring ingredients (with or without coloring) as follows:
 - (a) Fruit and fruit juice (including concentrated fruit and fruit juice).
 - (b) Natural and artificial food flavorings.
56. LOW-SODIUM MILK - “Low-sodium milk” is the product resulting from the treatment process of passing milk through an ion exchange resin reducing the sodium content of the product to less than 10 milligrams in 100 milliliters.
57. LOW-FAT MILK -
- (a) “Low-fat milk” is milk that has between 0.5 and 3 grams of fat per 8 ounce (240 mL) serving and contains not less than 8.25 percent milk solids not fat.
 - (b) Vitamin requirements.
 - (i) Vitamin A must be present in such quantity that each 946 milliliters (1 quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.
 - (ii) Addition of vitamin D is optional. If added, vitamin D must be present in such quantity that each 946 milliliters (1 quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.
58. LOW-FAT YOGURT -

- (a) “Low-fat yogurt” is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this Section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. One or more of the other optional ingredients specified in paragraph (b) and (d) of this Section may also be added. When one or more of the ingredients specified in paragraphs (d)(i) of this Section are used, they must be included in the culturing process. All ingredients used are safe and suitable. Low-fat yogurt, before the addition of bulky flavors, contains not less than 0.5 percent nor more than 2 percent milk fat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and may be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, low-fat yogurt may be heat-treated after culturing is completed, to destroy viable microorganisms.
- (b) Optional vitamin addition.
- (i) If added, vitamin A must be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2,000 International Units thereof, within limits of current good manufacturing practice.
- (ii) If added, vitamin D must be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.
- (c) Optional dairy ingredients: Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.
- (d) Other optional ingredients.
- (i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present must not be decreased as a result of adding such ingredients.
- (ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweetener listed in 21 CFR Part 168, except table syrup.

- (iii) Flavoring ingredients.
- (iv) Color additives.
- (v) Stabilizers.

59. MILK -

- (a) “Milk” is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, goats, sheep, water buffalo or other hooved mammal. Milk from cows that is in final package form for beverage use must contain not less than 8-1/4 percent milk solids not fat and not less than 3-1/4 percent milk fat. Milk may have been adjusted by separating part of the milk fat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.
- (b) Vitamin addition requirements (optional).
 - (i) If added, vitamin A must be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2000 International Units thereof within limits of good manufacturing practice.
 - (ii) If added, vitamin D must be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.
- (c) Optional Ingredients. The following safe and suitable ingredients may be used:
 - (i) Carriers for vitamin A and D.
 - (ii) Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:
 - (a) Fruit and fruit juice (including concentrated fruit and fruit juice).
 - (b) Natural and artificial food flavorings.

60. MILK DISTRIBUTOR - A “milk distributor” is any person who offers for sale or sells to another any milk or milk product in its final form.

61. MILK PLANT - “Milk plant” means any place, premises or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, aseptically processed, bottled or otherwise prepared for distribution and subsequent sale.

62. MILK PRODUCER - “Milk Producer” means any person who operates a dairy farm and provides, sells or offers milk for sale to a milk plant, receiving station or transfer station.
63. MILK PRODUCTS -
- (a) “Milk products” include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, milk, butter, evaporated milk, sweetened condensed milk, nonfat dry milk solids, half and half, sour half and half, acidified sour half and half, cultured sour half and half, concentrated milk and milk products, skim milk, reconstituted or recombined milk and milk products, low-fat milk, light milk, reduced fat milk, homogenized milk, frozen milk concentrate, eggnog, cultured milk, buttermilk, yogurt, cottage cheese, creamed cottage cheese, acidified milk, low-sodium milk, lactose-reduced milk, aseptically processed and packaged milk and milk products, milk with added safe and suitable microbial organisms, any other milk product, frozen dairy dessert or frozen dairy dessert mix, or cheese made by the addition or subtraction of milk fat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification. Any other product must be designated as a milk product by the Commissioner.
- (b) Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” dairy products, such as cottage cheese dressing mixes or starter cultures used to produce various Grade “A” cultured products, if they meet the requirements of this Rule. If used as an ingredient in Grade “A” products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” requirements. Grade “A” powder blend must be made from Grade “A” powdered dairy products, except that small amounts of functional ingredients, (total of all such ingredients must not exceed 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e. sodium caseinate. Dairy ingredients in small cans of freeze-dried starter culture need not be Grade “A” (FDA position).
64. MILK TANK TRUCK - A “milk tank truck” is the term used to describe both a bulk milk pickup tanker and a milk transport tank.
65. MILK TANK TRUCK CLEANING FACILITY - “Milk Tank Truck Cleaning Facility” means any place, premises, or establishment, separate from a milk plant, receiving or transfer station, where a milk tank truck is cleaned and sanitized.
66. MILK TANK TRUCK DRIVER - A “milk tank truck driver” is any person who transports raw or pasteurized milk and milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

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67. MILK TRANSPORT TANK - A “milk transport tank” is a vehicle, including the truck and tank, used by the bulk milk hauler/sampler or milk tank truck driver to transport bulk shipments of milk from a milk plant, receiving station or transfer station to another milk plant, receiving station or transfer station.
68. MILK TRANSPORTATION COMPANY - A “milk transportation company” is the company responsible for a milk tank truck(s).
69. MISBRANDED MILK AND MILK PRODUCTS - A food shall be deemed to be misbranded:
- (a) If its labeling is false or misleading and does not comply with Section XIV.
 - (b) If it is offered for sale under the name of another food.
 - (c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated.
 - (d) If its container is so made, formed, or filled as to be misleading.
 - (e) If in package form unless it bears a label containing:
 - (i) The name and place of business of the manufacturer, packer, or distributor; and
 - (ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: provided that, reasonable variations shall be permitted.
 - (f) If any word, statement, or other information required by or under authority of this rule to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
 - (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed, unless:
 - (i) Its label bears the name of the food specified in the definition and standard, and, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.
 - (h) If it purports to be or is presented as a food for which a standard of quality has been prescribed by regulations as provided by Section 401 of the FD&C Act (21 U.S.C. section 341(1993)), and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

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- (i) A food for which a standard or standards of fill of container have been prescribed and falls below the standard of fill of container applicable thereto, unless the label bears a statement that the contents fall below such standard.
 - (i) If it is not subject to the provisions of paragraph (g) of this Section, unless its label bears:
 - (i) The common or usual name of the food, if any, and
 - (ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each.
 - (j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Commissioner determines to be necessary in order fully to inform purchasers as to its value of such uses.
 - (k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.
 - (l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and function of such chemical: provided, however, that no such declaration shall be required, while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.
 - (m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive.
 - (n) If it contains saccharin, it is misbranded unless:
 - (i) Its label and labeling bear the following statement: 'USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS'. Such statement must be located in a conspicuous place on such label and labeling as proximate as possible to the name of such food and must appear in

conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling.

- (ii) It is offered for sale, but not for immediate consumption, at a retail establishment, unless such retail establishment displays prominently, where such food is held for sale, notice (provided by the manufacturer of such food pursuant to subparagraph (ii)) for consumers respecting the information required by paragraph (n) to be on food labels and labeling.
- (iii) The manufacturer of food which contains saccharin and which is offered for sale by retail establishments but not for immediate consumption took such action as may be necessary to provide such retail establishments with the notice required by subparagraph (i).

70. NCIMS - "NCIMS" means National Conference on Interstate Milk Shipments. The National Conference on Interstate Milk Shipments (NCIMS) has served as a model cooperative program between PHS/Food and Drug Administration (PHS/FDA), the States and the dairy industry and reflects the cooperative spirit of all those committed to ensuring a safe and wholesome supply of milk and milk products.

71. NONFAT YOGURT -

- (a) Nonfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this Section with a characterizing bacterial culture that contains the lactic acid- producing bacteria, *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. One or more of the other optional ingredients specified in paragraph (b) and (c) of this Section may also be added. When one or more of the ingredients specified in paragraph (c)(i) of this Section are used, they must be included in the culturing process. All ingredients used are safe and suitable. Nonfat yogurt, before the addition of bulky flavors, contains less than 0.5 percent milk fat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and may be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, nonfat yogurt may be heat-treated after culturing is completed, to destroy viable microorganisms.
- (b) Vitamin addition requirements (optional).
 - (i) If added, vitamin A must be present in such quantity that each 946 milliliters (1- quart) of the food contains not less than 2000 International Units thereof, within limits of current good manufacturing practice.

- (ii) If added, vitamin D must be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.
 - (c) Optional dairy ingredients. Cream, milk, partially skimmed milk, used alone or in combination. Other optional dairy ingredients include concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food; provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present must not be decreased as a result of adding such ingredients.
 - (d) Other optional ingredients:
 - (i) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweeteners listed in 21 CFR Part 168, except table syrup.
 - (ii) Flavoring ingredients.
 - (iii) Color additives.
 - (iv) Stabilizers.
72. NOT PASTEURIZED - "Not pasteurized" means any milk or milk product that has not been subjected to the temperature and time requirements of pasteurization using equipment designed for pasteurization or has not been aseptically processed and packaged. This does not apply to cheese that has been aged at a temperature above 35°F for at least 60 days prior to sale.
73. OFFICIALLY DESIGNATED LABORATORY - An "officially designated laboratory" is 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 drug residues and bacterial limits.
74. OFFICIAL LABORATORY - An "official laboratory" is a biological, chemical or physical laboratory which is under the direct supervision of the Department.

75. PASTEURIZATION - The terms "pasteurization", "pasteurized" and similar terms shall mean the process of heating every particle of milk or milk product in properly designed and operated equipment, to one of the temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

(a)

Temperature	Time
63°C (145°F) *	30 minutes
72°C (161°F) *	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
100°C (212°F)	0.01 seconds

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

(b) Provided, that Eggnog must be heated to at least the following temperature and time specifications:

Temperature	Time
69°C (155°F)	30 minutes
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

(c) Nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products which has been recognized by the FDA to be equally effective and which is approved by the Commissioner. Guidelines for properly designed and operated equipment may be found in the PMO.

76. PERSON - The word "person" includes any individual, plant operator, partnership, corporation, company, firm, trustee, association or institution.
77. PORTABLE/TEMPORARY MILKING PARLOR - A "portable/temporary milking parlor" is a mobile unit designed for occasional use.
78. RAW MILK - See Definition "Not Pasteurized".
79. RECEIVING STATION - A "receiving station" is any place, premise or establishment where raw milk is received, collected, handled, stored or cooled and prepared for further transporting.
80. RECONSTITUTED OR RECOMBINED MILK AND MILK PRODUCTS - "Reconstituted or recombined milk and/or milk products" means milk or milk products defined in this Section which result from reconstituting or recombining of milk constituents with potable water when appropriate.

81. REDUCED FAT MILK -
- (a) “Reduced fat milk” is milk that has less than or equal to 6 grams of fat per 8 ounce (240 mL) serving and contains not less than 8.25 percent milk solids not fat.
 - (b) Vitamin addition requirements.
 - (i) Vitamin A must be present in such quantity that each 964 milliliters (1 quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.
 - (ii) Addition of vitamin D is optional. If added, vitamin D must be present in such quantity that each 946 milliliters (1 quart) of the food contains 400 International Units thereof within limits of good manufacturing practice.
82. REGULATORY AGENCY - “Regulatory Agency” means a Governmental body designated with authority to regulate milk and milk products in a given jurisdiction.
83. SANITIZATION - “Sanitization” is the application of any effective method or substance to a properly cleaned surface for the destruction of pathogens and other microorganisms. Such treatment must not adversely affect the equipment, the milk or milk product or the health of consumers, and shall be acceptable to the Department.
84. SHEEP MILK - “Sheep milk” is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one or more healthy sheep. Sheep milk and sheep milk food products must be produced according to the sanitary standards of this rule.
85. SHERBET -
- (a) “Sherbet” is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (e) of this Section, and may contain one or more of the optional caseinates specified in paragraph (f) of this Section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used.
 - (b) Sherbet is sweetened with “SAFE AND SUITABLE SWEETENERS” and characterizing fruit ingredients specified in paragraph (g) of this Section or one or more of the non-fruit characterizing ingredients specified in paragraph (h) of this Section.
 - (c) Sherbet weighs not less than 6 pounds to the gallon. The milk fat content is not less than 1 percent nor more than 2

percent, the nonfat milk derived solids content not less than 1 percent, and the total milk or milk-derived solids content is not less than 2 percent nor more than 5 percent by weight of the finished food.

- (d) Sherbet that is characterized by a fruit ingredient must have a titratable acidity, calculated as lactic acid, of not less than .35 percent.
- (e) Optional dairy ingredients. The optional dairy ingredients referred to in paragraph (a) of this Section are:

Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that comply with 21 CFR Part 184. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk.

- (f) Optional caseinates. The optional caseinates referred to in paragraph (a) of this Section which may be added to sherbet mix are:

Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali; such caseinates are not considered to be milk solids.

- (g) Optional fruit-characterizing ingredients. The optional fruit characterizing ingredients referred to in paragraph (b) of this Section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other optional ingredients. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated. In the case of concentrated fruit or fruit juices, from which part of the water is removed, substances contributing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would be obtained if the whole fruit had been used. The quantity of fruit ingredients

used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 percent in the case of citrus sherbets, 6 percent in the case of berry sherbets, and 10 percent in the case of sherbets prepared with other fruits. For the purpose of this Section, tomatoes and rhubarb are considered as kinds of fruit.

- (h) Optional non-fruit characterizing ingredients. The optional non-fruit characterizing ingredients referred to in paragraph (b) of this Section include but are not limited to the following:
 - (i) Ground spice or infusion of coffee or tea.
 - (ii) Chocolate or cocoa, including syrup.
 - (iii) Confectionery.
 - (iv) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the sherbet.
 - (v) Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).
- (i) Nomenclature.
 - (i) The name of each sherbet is as follows:
 - (a) The name of each fruit sherbet is “_____ sherbet”, the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names must be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.
 - (b) The name of each non-fruit sherbet is “_____ sherbet”, the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, “peppermint”, except that if the characterizing flavor used is vanilla, the name of the food is “sherbet”, the blank being filled in as specified by 21 CFR 135.110(e) (2) and (5) (i) (2019).
 - (ii) Artificial flavoring or artificial coloring - When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they must be named on the label as follows:
 - (a) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation must be "artificially flavored".

- (b) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation must be "artificial and natural flavoring added".
 - (c) The label must designate artificial coloring by the statement "artificially colored", "artificial coloring added", "with added artificial coloring", or "_____, and artificial color added", the blank being filled in with the name of the artificial coloring used.
- (j) Characterizing flavor(s). Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required in paragraph (i) (ii)(a) and (b) of this Section, as appropriate, must immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word "sherbet" may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10 point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12 point on packages containing 1 gallon or over.
- (k) Display of statements required in paragraph (i)(ii). Except as specified in paragraph (j) of this Section, the statements required by paragraph (i)(ii) of this Section must be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (l) Label declarations. Each of the optional ingredients used must be declared on the label, as required in Section XIV.

86. SKIM, FAT-FREE, NONFAT MILK -

- (a) "Skim, fat-free, nonfat milk" is milk that has less than 0.5 grams of fat per 8 ounce (240mL) serving and contains not less than 8.25 percent milk solids not fat.
- (b) Vitamin addition requirements.
 - (i) Vitamin A must be present in such quantity that each 946 milliliters (1 quart) of the food contains not less than 2,000 International Units thereof within limits of good manufacturing practice.
 - (ii) Addition of vitamin D is optional. If added, vitamin D must be present in such quantity that each 946 milliliters (1 quart) of the

food contains 400 International Units thereof within limits of good manufacturing practice.

87. SOUR CREAM OR CULTURED SOUR CREAM -

(a) “Sour cream” results from the souring, by lactic acid producing bacteria, of cream. Sour cream contains not less than 18 percent milk fat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milk fat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milk fat. Sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) Optional ingredients.

- (i) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.
- (ii) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.
- (iii) Rennet.
- (iv) Safe and suitable nutritive sweeteners.
- (v) Salt.
- (vi) Flavoring ingredients, with or without safe and suitable coloring, as follows:
 - (a) Fruit and fruit juice (including concentrated fruit and fruit juice).
 - (b) Safe and suitable natural and artificial food flavoring.

88. SOUR HALF-AND-HALF OR CULTURED SOUR HALF-AND-HALF -

(a) “Sour half-and-half” results from the souring, by lactic acid producing bacteria, of pasteurized half-and-half. Sour half-and-half contains not less than 10.5 percent but less than 18 percent milk fat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milk fat is not less than 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milk fat. Sour half-and-half has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

(b) Optional ingredients.

- (i) Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.
 - (ii) Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.
 - (iii) Rennet.
 - (iv) Safe and suitable nutritive sweeteners.
 - (v) Salt.
 - (vi) Flavoring ingredients, with or without safe and suitable coloring, as follows:
 - (a) Fruit and fruit juice (including concentrated fruit and fruit juice).
 - (b) Safe and suitable natural and artificial food flavoring.
 - (vii) Safe and suitable coloring.
89. STERILIZED - The term “sterilized” when applied to piping, equipment and containers used for milk and milk products means the condition achieved by the application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers free of viable microorganisms.
90. TIME/TEMPERATURE CONTROL FOR SAFETY OF MILK AND MILK PRODUCTS –
- Milk and milk products that require time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation includes:
- (a) Milk or milk products that are raw, heat-treated, pasteurized, or ultra-pasteurized; or
 - (b) Except as specified in c. below of this definition, a milk or milk product that because of the interaction of its a_w and pH values is designated as Product Assessment (PA) as required in either Table A or B as follows:

Table A. Interaction of pH and a_w for Control of Spores in Milk and Milk Products Pasteurized to Destroy Pathogenic Vegetative Cells and Subsequently Packaged*			
A_w values	pH values		
	4.6 or less	>4.6 - 5.6	>5.6
0.92 or less	Non-TCS**	Non-TCS	Non-TCS
> 0.92 - 0.95	Non-TCS	Non-TCS	PA***
> 0.95	Non-TCS	PA	PA

*Refer to Appendix R in the PMO for instruction on how to use Table A.

** TCS means TIME/TEMPERATURE CONTROL FOR SAFETY MILK AND MILK PRODUCTS.*** PA means either that the product needs time and temperature control or further PRODUCT ASSESSMENT is required to determine if the milk or milk product is Non-TCS.

A_w values	pH values			
	<4.2	4.2 - 4.6	>4.6 - 5.0	>5.0
<0.88	Non-TCS	Non-TCS	Non-TCS	Non-TCS
0.88 - 0.90	Non-TCS	Non-TCS	Non-TCS	PA
>0.90 - 0.92	Non-TCS	Non-TCS	PA	PA
> 0.92	Non-TCS	PA	PA	PA

* Refer to Appendix R in PMO for instruction on how to use Table B.

- (c) This definition does not include:
- (i) A milk or milk product that because of its pH or a_w value, or interaction of a_w and pH values, is designated as Non-TCS in Table A or B as specified in 2. above of this definition;
 - (ii) A milk or milk product, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;
 - (iii) A milk or milk product for which evidence (acceptable to FDA) demonstrates that time/temperature control for safety is not required as specified under this definition (such as, a product containing a preservative known to inhibit pathogenic microorganisms, or other barriers to the growth of pathogenic microorganisms, or a combination of barriers that inhibit the growth of pathogenic microorganisms); or
 - (iv) A milk or milk product that does not support the growth of pathogenic microorganisms as specified under this definition even though the milk or milk product may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.
91. TRANSFER STATION - A “transfer station” is any place, premises or establishment where milk or milk products are transferred directly from one milk tank truck to another.

92. ULTRA-PASTEURIZATION - The term “ultra-pasteurization”, when used to describe a dairy product, means that such product must have been thermally processed at or above 138°C (280°F) 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.
93. WATER BUFFALO MILK - “Water buffalo milk” is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy water buffalo. Water buffalo milk must be produced according to the sanitary standards of this Rule. The word “milk” shall be interpreted to include water buffalo milk.
94. WHIPPED CREAM - “Whipped cream” is heavy cream or light whipping cream into which air or inert gas has been incorporated.
95. WHIPPED LIGHT CREAM - “Whipped light cream” is light cream into which air or inert gas has been incorporated.
96. YOGURT -
- (a) “Yogurt” is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this Section with a characterizing bacterial culture that contains the lactic acid-producing bacteria *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. One or more of the other optional ingredients specified in paragraph (b) and (d) of this Section may also be added. When one or more of the ingredients specified in paragraph (d)(i) of this Section are used, they must be included in the culturing process. All ingredients used are safe and suitable. Yogurt, before the addition of bulky flavors, contains not less than 3.25 percent milk fat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and may be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf life of the food, yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.
 - (b) Vitamin Requirements (optional).
 - (i) If added, vitamin A must be present in such quantity that each 946 milliliters (1-quart) of the food contains not less than 2,000 International Units thereof within limits of current good manufacturing practice.
 - (ii) If added, vitamin D must be present in such quantity that each 946 milliliters (1-quart) of the food contains 400 International Units thereof, within limits of current good manufacturing practice.
 - (c) Optional dairy ingredients: Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

- (d) Other optional ingredients.
 - (i) Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food: provided that the ratio of protein to total nonfat solids of the food and the protein efficiency ratio of all protein present must not be decreased as a result of adding such ingredients.
 - (ii) Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or syrup form); brown sugar; refiner's syrup; molasses (other than blackstrap); high fructose corn syrup; fructose; fructose syrup; maltose; maltose syrup, dried maltose syrup; malt extract, dried malt extract; malt syrup, dried malt syrup; honey; maple sugar; or any other sweeteners listed in 21 CFR Part 168, except table syrup.
 - (iii) Flavoring ingredients.
 - (iv) Color additives.
 - (v) Stabilizers.

SECTION II - ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

No person may, within the State of Maine, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product which is adulterated or misbranded. Provided, that in an emergency, the sale of milk and milk products which do not fully meet the requirements of this Rule, may be authorized by the Commissioner.

Any adulterated or misbranded milk or milk products may be impounded by the Department and disposed of in accordance with applicable laws or rules.

SECTION III - LICENSING AND PERMITS

A. Licensing of Milk Distributors.

No milk distributor may sell milk or milk products without first obtaining a license from the Commissioner. The Commissioner shall prescribe the form of the license. The license must be renewed annually on or before the first day of January in each year, except for wholesale manufacturers of frozen dairy desserts who must apply on or before the first day of June. Each licensee must comply with all applicable State and Federal laws and rules. A satisfactory inspection is required before issuance of a license to milk distributors. A current Milk Distributor's license only authorizes sales and distribution of milk and/or milk products within the State of Maine. A SERVSAFE or similar food safety course is encouraged:

<https://www.servsafe.com/access/SS/Catalog/ProductDetail/SSECT6> .

B. Milk Distributor License Fee Schedule.

Annual sales or distribution over 25 million pounds - \$300.00
 Annual sales or distribution of 10-25 million pounds - \$200.00
 Annual sales or distribution of 1-10 million pounds - \$120.00
 Annual sales or distribution of 100,000 to 1 million pounds - \$70.00
 Annual sales or distribution of less than 100,000 pounds \$35.00

C. Permits

Every milk producer, bulk milk hauler and sampler, milk transportation company, receiving station, transfer station and portable/temporary milking parlor must hold a valid permit in accordance with the requirements of this rule and state law. A permit may be suspended for any failure to comply with these requirements. Permits are issued at no cost and are not transferable between person, businesses or farms. Any milk producer, bulk milk hauler and sampler, milk transportation company, receiving station, transfer station and portable/temporary milking parlor participating in the FDA Interstate Milk Shippers program must comply with applicable requirements and is subject to all regulatory standards and penalties as set forth in the PMO.

Permits are issued to:

1. Milk Producer: A permit authorizes the milk producer to ship, sell and/or receive milk
2. Bulk Milk Hauler/Sampler: A permit authorizes the bulk milk hauler/sampler to collect official samples and/or transport raw milk from a farm and/or raw milk products to or from a farm, milk plant, receiving station or transfer station.
3. Receiving stations: A permit authorizes the receiving station to receive, collect, handle, store or cool and prepare raw milk for further transporting.
4. Milk Tank Truck Cleaning Facilities: A permit authorizes the milk tank truck cleaning facility to clean and sanitize a milk tank truck.
5. Transfer Stations: A permit authorizes a transfer station to transfer milk or milk products directly from one milk tank truck to another.
6. Milk Transportation Company: A permit authorizes the milk transportation company to transport raw milk in a milk transport tank driven by a milk tank truck driver. Milk tank truck drivers are not required to obtain individual permits.
7. Portable/temporary milking parlor: A permit authorizes the operator of a portable/temporary milking parlor to ship, sell or receive milk.

SECTION IV – INSPECTION OF DAIRY FARMS AND MILK PLANTS

- A. Each single service container manufacturer, dairy farm, milk plant, receiving

station, milk tank truck cleaning facility and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck and its appurtenances must be inspected/audited by the Department. The Department shall:

1. Bulk Milk Pickup Tanker - Inspect each milk tank truck and its appurtenances, used by a milk hauler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twenty-four (24) months;
 - a. A copy of the current inspection report must accompany the bulk milk pickup tanker at all times.
 - b. When significant defects or violations are encountered by the Department or another State's regulatory authority, a copy of that report must be forwarded to the Department and also carried on the bulk milk pickup tanker until the violations are corrected.
 - c. Bulk milk pickup tanker inspection must be conducted in a suitable location, i.e., a dairy plant, receiving station or transfer station or milk tank truck cleaning facility. When significant cleaning, construction or repair defects are noted, the bulk milk pickup tanker must be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. An individual whose qualifications satisfy the Department may verify cleaning and repairs.
 - d. Inspection reports completed by regulatory authorities other than the Department must be forwarded to the Department for verification of annual inspection as required by this section and the Department may use these reports to satisfy permit requirements.
2. Dairy Plant, Industry Plant and Bulk Milk Hauler Samplers - Inspect at least once every 24 months the pickup and sampling procedure of each dairy plant sampler, each industry plant sampler, and each bulk milk hauler/sampler.
3. Dairy Plants -
 1. IMS Milk Plants: Each Milk plant, milk equipment and receiving station operating under the voluntary IMS program must be inspected at the intervals specified in the PMO;
 2. Non-IMS Milk Plants Each non-IMS milk plant, milk equipment and receiving station not operated under the IMS program must be inspected during regular production at least once every 12 months. New plants will be inspected initially and again in 6 months. Plants with violations which may adversely affect public health will be re-inspected at a frequency to be determined by the inspector until violations have been corrected. After two consecutive satisfactory inspections, the Department may then resume annual inspection frequency.

4. Milk Tank Truck Cleaning Facility and Transfer Stations -

Inspect each milk tank truck cleaning facility and transfer station at least once every six (6) months, except that, for those transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, regulatory audits shall replace the regulatory inspections described in this Section. The requirements and minimum frequencies for these regulatory audits are specified in Appendix K of the PMO.

5. Dairy Farms - Inspect each dairy farm at least once every six (6) months.

6. Portable / Temporary Milking Parlors - Inspect each portable/temporary milking parlor whenever it changes location.

7. Frozen Dairy Dessert Plants - Inspect seasonal frozen dairy dessert manufacturers at least once every 12 months.

8. Single Service Container Manufacturers - Inspect single service container manufacturers at least once every six (6) months.

- B. Requirements for follow up inspections: Should the violation of any requirement set forth in this Section, or in the case of a bulk milk hauler/sampler or industry plant sampler or milk tank truck also Section XIII and Appendix B of the PMO , be found to exist on an inspection/audit a second inspection is required after the time deemed necessary to remedy the violation, but not before 3 days. This second inspection/audit shall be used to determine compliance with requirements of Section IV or in the case of a milk hauler/sampler or industry plant sampler or milk tank truck also Section XIII and Appendix B of the PMO. Any violation of the same requirement of Section V, or in the case of a bulk milk hauler/sampler or milk tank truck also Section XIII and Appendix B of the PMO on such second inspection/audit, shall be grounds for an administrative permit suspension and/or court action or, a requirement that the collection of official regulatory samples cease until successfully re-trained and re-evaluated by the Department.

This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor shall be subject to suspension of permit and/or court action if two (2) successive inspections disclose a violation of the same requirement.

- C. Causes for immediately stopping the movement of milk and milk products -
The Department shall take immediate action to prevent further movement and/or processing of such milk or milk products until violations of critical processing elements or unsafe levels of adulterants or contaminants have been corrected. Should correction of such critical processing elements or contaminants not be accomplished immediately, the Department shall take prompt action to suspend the permit.
Critical process violations and contaminant violations include:

- (i) Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment; or

- (ii) A cross-connection exists, whereby direct contamination of pasteurized milk or milk product is occurring; or
 - (iii) Direct contamination of milk or milk products is occurring
- D. One (1) copy of the inspection/audit report shall be provided to the operator or other responsible person, or be posted in a conspicuous place on an inside wall of the establishment. Said inspection/audit report shall not be defaced and must be made available to the Department upon request. An identical copy of the inspection report must be filed with the records of the Department.
- E. Every permit and license holder must, upon request of the Department, permit access by officially designated persons to all parts of the establishment or facilities to determine compliance with the provisions of the rule and/or the PMO. A distributor or milk plant operator must furnish the Department, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, a list of all sources of such milk and milk products, records of inspections, tests, and pasteurization time and temperature records.

SECTION V - STANDARDS FOR MILK AND MILK PRODUCTS

A. PROCESSING STANDARDS:

ALL MILK PRODUCTS: All Grade A raw milk or milk products for pasteurization, ultra-pasteurization or aseptic processing and packaging and all Grade A pasteurized, ultra-pasteurized or aseptically processed and packaged milk and milk products must be produced, processed, manufactured and pasteurized, ultra-pasteurized or aseptically processed and packaged to conform with the following chemical, bacteriological and temperature standards, and the sanitation requirements of this section. Milk and milk products not pasteurized, must be produced and processed to conform with the following chemical, physical, bacteriological and temperature standards, and the sanitation requirements of this section (see Table 1).

No process or manipulation other than pasteurization, ultra-pasteurization, aseptic processing and packaging; processing methods integral therewith; along with appropriate refrigeration may be applied to milk and milk products for the purpose of removing or deactivating microorganisms. Filtration and/or bactofugation processes must be performed in the milk plant in which the milk or milk product is pasteurized, ultra-pasteurized or aseptically processed and packaged. Milk for aged cheese is exempt from this requirement.

CHEESE: All cheese products, except for aged cheese, must be made from milk that has been heat-treated or pasteurized. Heat-treated means processed by heating every particle of milk to a temperature of 145°F for at least thirty (30) minutes. All cheese products may list heat-treated milk as an ingredient on the label. All cheese products that are not pasteurized must be labeled as “not pasteurized” in accordance with Section XIV.

BULK SHIPPED PRODUCTS: When the raw milk is used to make cream, non-fat (skim) milk, reduced fat or low-fat milk, which will be bulk shipped for separation purposes, is heated one time, to temperatures greater than 52°C (125°F), but less than

72°C (161°F), the resulting bulk shipment(s) of cream, non-fat (skim) milk, reduced fat or low-fat milk must be labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

WHEY: Whey must be from cheese made from Grade "A" raw milk for pasteurization as provided in this Rule.

Whey must be from:

1. Cheese made from Grade "A" raw milk for pasteurization, which has been pasteurized prior to use, in accordance with Item 16p of the PMO, or
2. Cheese made from Grade "A" raw milk for pasteurization, which has been heat-treated to a temperature of at least 64°C (147°F) and held continuously at that temperature for at least twenty one (21) seconds or to at least 68°C (153°F) and held continuously at that temperature for at least fifteen (15) seconds, in equipment meeting the pasteurization requirements provided for in this Rule. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by the Department.

BUTTERMILK: Buttermilk must be from butter made from Grade "A" cream, which has been pasteurized prior to use in accordance with Item 16p of the PMO. Provided, that this requirement shall not be construed as barring any other heat treatment process which has been recognized by the FDA to be equally efficient in the destruction of staphylococcal organisms and which is approved by the Department.

B. CHEMICAL, PHYSICAL, BACTERIOLOGICAL, AND TEMPERATURE STANDARDS – TABLE 1

Table 1. Chemical, Physical, Bacteriological, and Temperature Standards		
GRADE "A" RAW MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC	Temperature....	Cooled to 10 °C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milk and subsequent milkings does not exceed 10°C (50°F). NOTE: Milk sample submitted for testing must be cooled and maintained at 0°C (32°F) to 4.5°C (40°F),

PROCESSING AND PACKAGING		where milk temperature of the sample source is $>4.5^{\circ}\text{C}$ (40°F), but $\leq 7^{\circ}\text{C}$ (45°F) and less than three (3) hours after collection has not increased in temperature.
	Bacterial Limits...	Individual producer milk not to exceed 100,000 colony forming units (cfu) per mL prior to commingling with other producer milk. Not to exceed 300,000 cfu per mL as commingled milk prior to pasteurization. NOTE: Tested in conjunction with the drug residue/inhibitory substance test.
	Drugs....	No positive results from drug residue detection methods as referenced in Section VI of the PMO, Methods of Analysis.
	Somatic Cell Count*	Individual producer milk not to exceed 750,000 or current PMO standard per mL.
GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS	Temperature....	Cooled to 7°C (45°F) or less and maintained thereat. NOTE: Milk sample submitted for testing cooled and maintained at 0°C (32°F) to 4.5°C (40°F), where milk temperature of the sample source is $>4.5^{\circ}\text{C}$ (40°F), but $\leq 7.0^{\circ}\text{C}$ (45°F) and less than three (3) hours after collection has not increased in temperature.

GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS	Bacterial Limits**....	Not to exceed 20,000 per mL, or gm.*** NOTE: Tested in conjunction with the drug residue/inhibitory substance test.
	Coliform *****....	Not to exceed 10 per mL. In the case of bulk milk transport tank shipments, must not exceed 100 per mL. NOTE: Tested in conjunction with the drug residue/inhibitory substance test.
	Phosphatase*****....	Less than 350 milliunits/L for fluid products and other milk products by FDA/NCIMS approved electronic phosphatase procedures.
	Drugs**....	No positive results on drug residue detection methods as referenced in Section VI of the PMO, Methods of Analysis which have been found to be acceptable for use with pasteurized milk and milk products.
ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS	Temperature....	None
	Bacterial Limits**....	No growth by test specified in Section VI of the PMO.
	Drugs**....	No positive results on drug residue detection methods as referenced in the PMO, Section VI

		Methods of Analysis which have been found to be acceptable for use with aseptically processed milk and milk products.
MILK AND MILK PRODUCTS (NOT PASTEURIZED) SOLD TO CONSUMERS	Temperature....	Cooled to 7°C (45°F) or less and maintained thereat.
	Bacterial Limits**	50,000 per Ml
	Coliform *****	Not to exceed 10 per mL
	Drugs**	No positive results on drug residue detection methods as referenced in Section VI Methods of Analysis which have been found to be acceptable for use with not pasteurized milk and milk products.
MILK AND MILK PRODUCTS (NOT PASTEURIZED) SOLD TO CONSUMERS		
AGED CHEESE	Temperature....	Aged cheese must be aged at a temperature above 35°F
GRADE "A" PASTEURIZED (UP) MILK AND MILK PRODUCTS	Temperature....	Cooled to 7°C (45°F) or less and maintained thereat.
	Bacterial Limits**	Not to exceed 20,000 per mL, or gm.***
	Coliform....	Not to exceed 10 per mL. Provided, that in the case of bulk milk transport

		tank shipments, must not exceed 100 per mL
	Phosphatase....	Phosphatase testing of UP milks is not required.
	Drugs**....	There are no validated and accepted drug residue tests for ultra-pasteurized milk and milk products
GRADE "A" PASTEURIZED CONCENTRATED (CONDENSED) MILK AND MILK PRODUCTS	Temperature....	Cooled to 7°C (45°F) or less and maintained thereat unless drying is commenced immediately after condensing.
	Coliform....	Not to exceed 10 per gram. Provided, that in the case of bulk milk transport tank shipments must not exceed 100 per gram.
GRADE "A" NONFAT DRY MILK AND DRY MILK AND DRY MILK PRODUCTS	Bacterial Estimate....	Not to exceed: 10,000 per gram
	Coliform....	Not to exceed: 10 per gram
GRADE "A" WHEY FOR CONDENSING AND/OR DRYING	Temperature....	Maintained at a temperature of 45°F (7°C) or less, or 57°C (135°F) or greater, except for acid-typewhey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below.
GRADE "A" PASTEURIZED CONDENSED WHEY AND WHEY PRODUCTS	Temperature....	Cooled to 10°C (50°F) or less within 72 hours of condensing during crystallization

	Coliform Limit....	Not to exceed 10 cfu per gram.
GRADE "A" DRY WHEY, GRADE "A" DRY WHEY PRODUCTS, GRADE "A" DRY BUTTERMILK, AND GRADE "A" DRY BUTTERMILK PRODUCTS	Coliform Limit....	Not to exceed 10 cfu per gram.
SINGLE SERVICE CONTAINER MANUFACTURERS	Bacterial Limits....	The residual bacteria count must not exceed 50 cfu per container, except that in containers less than 100 mL, the count must not exceed ten (10) cfu
	Coliform....	Zero (0) Coliform
MULTI-USE CONTAINERS	Bacterial Limits....	The residual bacteria count must not exceed 1 cfu per mL of capacity.
	Coliform....	Zero (0) Coliform
SOURCE WATER	Coliform	<1 by MMO-MUG (Minimal Medium ONPG – 4 methylumbelliferyl beta D-glucuronidase) Presence/Absence Method
RECIRCULATING WATER	Coliform	<1 by Most Probable Number Method or <1 by LTB (Lauryl Tryptose Broth) Presence/Absence Method (Single Tube)

* Goat Milk 1,500,000/mL, Sheep Milk 750,000/mL

** Not applicable to acidified or cultured products, eggnog and flavored (non-chocolate) milk and milk products.

*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm. (Refer to the current edition of the SMEDP.)

**** Not applicable to UP products that have been thermally processed at or above 1380C (2800F) for at least two (2) seconds to produce a product which has an extended shelf life (ESL) under refrigerated conditions; and condensed products.

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

SECTION VI - SANITATION REQUIREMENTS FOR PRODUCTION AND PROCESSING

- A. SANITATION REQUIREMENTS FOR DAIRY FARMS – Guidelines for determining compliance with these requirements may be found in the PMO.
1. ABNORMAL MILK - Lactating animals which show evidence of the secretion of milk with abnormalities in one or more quarters, based upon bacteriological, chemical or physical examination, must be milked last or with separate equipment and the milk must be discarded. Lactating animals producing contaminated milk, that is lactating animals which have been treated with, or have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which, in the judgment of the Department, may be deleterious to human health, must be milked last or with separate equipment and the milk disposed of as the Department may direct. For applicability to Automatic Milking Installations (AMI) refer to the PMO.
 2. MILKING BARN, STABLE OR PARLOR--CONSTRUCTION - A milking barn, stable or parlor must be provided on all dairy farms in which the milking herd must be housed during times of milking operations. (For applicability to AMIs, refer to the PMO). The area used for milking purposes must:
 - (a) Have floors constructed of concrete or equally impervious materials;
 - (b) Have walls and ceilings which are constructed of smooth material, be in good repair, dust tight, and be painted or finished in an approved manner;
 - (c) Have separate stalls or pens for horses, calves, bulls, and any other livestock which are large enough to accommodate all animals without overcrowding;
 - (d) Be provided with natural and/or artificial light, well distributed, for day and/or night milking;
 - (e) Provide sufficient air space and air circulation to prevent condensation and excessive odors;
 - (f) Properly prepared plans for milking equipment installation in all milking facilities, milk plants, receiving stations and transfer stations regulated under this rule which are hereinafter constructed may be submitted to the Department. Equipment standards set forth in “3-A Accepted Practices

for the Design, Fabrication and Installation of Milk Handling Equipment” may be used as a guideline;

- (g) Use of emergency portable equipment will be reviewed by the Department on a case by case basis; and
- (h) Building construction must prevent contamination of feed area by wild birds.

3. MILKING BARN, STABLE OR PARLOR--CLEANLINESS - The interior must be kept clean. Floors, walls, ceilings, windows, pipelines and equipment must be free of filth and/or litter and must be clean. Swine and fowl must be kept out of the milking area. Area must be free of rodents.

Feed must be stored in such a manner that will not increase the dust content of the air or interfere with the cleaning of the floor.

Surcingles, milk stools and devices to prevent kicking and other equipment associated with dairy animal care must be kept clean and stored above the floor.

4. COWYARD - The cowyard must be graded to drain and must have no standing pools of water or accumulations of organic wastes. Animal droppings and soiled bedding must be removed, or clean bedding must be added to housing areas where animals frequently lie down and at sufficiently frequent intervals to prevent the soiling of the lactating animal’s udder and flanks. Cooling ponds may be allowed provided they are constructed and maintained in a manner that does not result in the visible soiling of flanks, udders, bellies and tails of lactating animals exiting the pond. Waste feed must not be allowed to accumulate. Packs that are used for animal bedding must be properly drained and must provide a reasonably firm footing. Swine must be kept out of the cowyard.

Nutrient Management Plans are required unless exempted by Maine law or Department Nutrient Management Rules, Chapter 565 for a person who owns or operates a farm if it meets one or more of the following criteria:

- (a) The farm confines and feeds 50 or more animal units at any one time;
- (b) The farm utilizes more than 100 tons of manure per year not generated on that farm;
- (c) The farm is the subject of a verified complaint of improper manure handling;
- (d) The farm stores or utilizes regulated residuals.

Nutrient Management Plans must be implemented in accordance with 7 M.R.S.A. Chapter 747, Nutrient Management Act.

5. MILKHOUSE--CONSTRUCTION AND FACILITIES - A milkhouse or room of sufficient size must be provided, in which the cooling, handling and storing of

milk and the washing, sanitizing and storing of milk containers and utensils must be conducted except as provided for in item 12 of this section.

- (a) The milkhouse must be provided with a smooth floor constructed of concrete or equally impervious material, graded to drain and maintained in good repair. Liquid waste must be disposed of in a sanitary manner. Floor drains must be accessible and must be trapped if connected to a sanitary sewer system.
- (b) The walls and ceilings must be constructed of smooth material, be in good repair, dust tight, and be painted or finished in an approved manner.
- (c) The milkhouse must have adequate natural and/or artificial light and be well ventilated.
- (d) The milkhouse must be used for no other purpose than milkhouse operations. There must be no direct opening into any barn, stable, parlor or into a room used for domestic purposes. Provided, that a direct opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided. Screened vents in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, are permitted, provided animals are not housed within the milking facility.
- (e) Water under pressure must be piped into the milkhouse.
- (f) The milkhouse must be equipped with a two-compartment wash vat and adequate hot water heating facilities.
- (g) A transportation tank may be used for the cooling and/or storage of milk on the dairy farm. Such tank must be provided with a suitable shelter for the receipt of milk. Such shelter must be adjacent to, but not a part of, the milkhouse and must comply with the requirements of the milkhouse with respect to construction items, light, drainage, insect and rodent control and general maintenance. In addition, the following minimum criteria must be met:
 - 1. An accurate, accessible temperature-recording device must be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with the applicable provisions of the PMO, with or without hard copy, may be used in place of temperature-recording records. An indicating thermometer must be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer must comply with all applicable requirements in the PMO. This thermometer must be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording record or into the electronic data collection, storage and reporting system.

2. Temperature-recording charts must be maintained on the premises for a period of a minimum of six (6) months and be available for review by the Department. Except that, the electronic storage of required temperature records, with or without hard copy, may be acceptable, provided the computer and computer generated temperature records are readily available for review by the Department.
 3. The milk must be sampled at the direction of the Department in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector.
 4. The milk tank truck must be effectively agitated in order to collect a representative sample.
- (h) When the Department determines conditions exist whereby the direct loading of a milk tank truck (through by-passing the use of a farm bulk milk tank(s) and/or silo(s)) can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:
1. The milk hose connection is accessible to, and made from within, the milkhous. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times. Provided, based on Department acceptance, the direct loading of milk from the milkhous to the milk tank truck may be conducted through a properly designed hose port that adequately protects the milkhous opening or by stubbing the milk transfer and associated CIP cleaned lines outside the milkhous wall in accordance with the ADMINISTRATIVE PROCEDURES in the PMO.
 2. To assure continued protection of the milk, the milk tank truck manhole must be sealed after the truck has been cleaned and sanitized.
 3. The milk tank truck must be washed and sanitized at the permitted milk plant, receiving station, or transfer station receiving the milk, or at a permitted milk tank truck cleaning facility.
 4. An accurate, accessible temperature-recording device must be installed in the milk line downstream from an effective cooling device, which cools the milk to 7°C (45°F) or less. Electronic records that comply with the applicable provisions of the PMO, with or without hard copy, may be used in place of temperature-recording records. An indicating thermometer must be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer must comply with all applicable requirements in the PMO. This

thermometer must be used to check the temperature-recording device during the regulatory inspection and the results recorded on the recording record or into the electronic data collection, storage and reporting system.

5. Temperature-recording records must be maintained on the premises for a period of a minimum of six (6) months and be available for review by the Department. Except that, the electronic storage of required temperature records, with or without hard copy, may be acceptable, provided the computer and computer generated temperature records are readily available for review by the Department.
 6. The milk must be sampled at the direction of the Department, in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector. The milk in the milk tank truck must be effectively agitated in order to collect a representative sample.
 7. The milk tank truck must be parked on a self-draining concrete or equally impervious surface during filling and storage.
 8. When direct loading of a milk tank truck using either a hose port, as addressed above, or stubbing the milk transfer and associated CIP cleaned lines outside the milkhous wall in accordance with, ADMINISTRATIVE PROCEDURES of the PMO, overhead protection of the milk hose connection to the milk tank truck must be provided.
 - (i) The milkroom must be provided with a hoseport conveniently located for use by milk haulers when applicable. The hoseport must be constructed and maintained as to prevent insect and rodent entry.
6. MILKHOUSE CLEANLINESS - The floors, walls, ceiling, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils and equipment and other milkhous equipment must be clean. Only articles directly related to milkhous activities may be permitted in the milkhous. The milkhous must be free of trash, animals and fowl.
 7. TOILET - Every dairy farm must be provided with one (1) or more toilets, conveniently located, properly constructed, operated and maintained in a sanitary manner. The waste must be inaccessible to flies and must not pollute the surface or contaminate any water supply. Tight fitting, self-closing, solid door must be provided to separate the toilet room from the milkhous.
 8. WATER SUPPLY - Water for milkhous and milking operations must be from a supply properly located, protected and operated and must be easily accessible, adequate and of a safe, sanitary quality.
 9. UTENSILS AND EQUIPMENT - CONSTRUCTION - All multi-use containers, equipment and utensils used in the handling, storage or transportation of milk

must be made of smooth, nonabsorbent, corrosion-resistant, nontoxic materials, and must be so constructed as to be easily cleaned. All containers, utensils and equipment must be in good repair. Multiple-use woven material must not be used for straining milk. All single-serve articles must have been manufactured, packaged, transported and handled in a sanitary manner and must comply with the applicable requirements of (C)(11) of the following section. Articles intended for single-service use must not be reused. Farm holding/cooling tanks, welded sanitary piping and transportation tanks must comply with the applicable requirements of (C)(10) and (C)(11) of the following section.

10. UTENSILS AND EQUIPMENT - CLEANING - The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk must be cleaned after each usage.
11. UTENSILS AND EQUIPMENT - SANITIZATION - The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk must be sanitized before each usage.
12. UTENSILS AND EQUIPMENT - STORAGE - All containers, utensils and equipment used in the handling, storage or transportation of milk, unless stored in sanitizing solutions, must be stored to assure complete drainage and must be protected from contamination prior to use. Pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for CIP cleaning and other equipment, as accepted by FDA which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times. Single service articles (filters) are to be stored free of contamination. In the case of a milking parlor that opens directly into an enclosed housing area, through a covered holding area, the holding area may be seasonally enclosed when:
 - a. There are no manure pit openings in the parlor, holding area or in the housing area close enough to affect the milking parlor.
 - b. The cattle holding and housing areas are maintained in good repair and reasonably clean.
 - c. With respect to dust, odors, rodents and insects, the entire area meets milking parlor standards and the parlor is free of evidence of birds.
13. MILKING-FLANKS, UDDERS AND TEATS - Milking must be done in the milking barn, stable or parlor except as provided by special permit. The flanks, udders, bellies and tails of all milking lactating animals must be free from visible dirt. All brushing must be completed prior to milking. The udders and teats of all lactating animals must be clean and dry before milking. Teats must be treated with a sanitizing solution just prior to the time of milking and must be dry before milking. Wet hand milking is prohibited.
14. PROTECTION FROM CONTAMINATION - Milking and milkhouse operations, equipment and facilities must be located and conducted to prevent any contamination of milk, equipment, containers and utensils. No milk shall be

strained, poured, transferred or stored unless it is properly protected from contamination.

After sanitization, all containers, utensils and equipment must be handled in such a manner as to prevent contamination of any product-contact surface.

Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station must be constructed and operated to protect their contents from the sun, freezing and contamination. Such vehicles must be kept clean, inside and out, and no substance capable of contaminating the milk shall be transported.

15. DRUG AND CHEMICAL CONTROL - Cleaners and sanitizers must be stored in properly identified, dedicated end-use containers. Animal drugs and drug administration equipment must be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination. Animal drugs must be properly labeled and segregated, lactating from non-lactating. Unapproved drugs must not be used. Effective measures must be taken to prevent the contamination of milk, containers, equipment, and utensils by cleaners and sanitizers, drugs and drug administering equipment.
- a. Lactating animals treated with medicinal agents must be handled using one of the following:
 - b.
 1. Identified, i.e. leg bands, chalk marks, etc.;
 2. Segregated;
 3. Otherwise handled in a manner such as to preclude the adulteration of milk offered for sale.
 - c. Treatment Records (which may consist of paper and file folders, card files, appointment book type calendars, monthly calendars, chalk boards (temporary records), electronic computer records, etc.) must include the following information:
 1. Identity of the animal (s) treated;
 2. Date(s) of treatment;
 3. Drug(s) or other chemicals administered;
 4. Dosage administered;
 5. Milk discard time; and
 6. Withdrawal time prior to slaughter, even if zero.

- d. Maintenance of Records: Producers should maintain all treatment records for a minimum of two (2) years in the event of a need to trace back or follow up on a confirmed milk or meat residue.
 - e. Treated animal must be quarantined or segregated, or otherwise handled in a manner to preclude the sale of milk or the offering of treated animals for sale for slaughter prior to the end of the prescribed withdrawal time.
 - f. Farm personnel involved in the treatment of animals must receive instruction and understand proper drug use and methods to avoid the marketing of adulterated milk or meat for human food.
16. PERSONNEL-HAND-WASHING FACILITIES - Adequate hand-washing facilities must be provided, including a lavatory fixture with hot and cold or warm running water, soap or detergent and individual sanitary towels, convenient to the milkhouse, milking barn, stable, parlor and flush toilet.
 17. PERSONNEL-CLEANLINESS - Hands must be washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function and immediately after the interruption of any of these activities. Milkers and milk haulers/samplers must wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.
 18. RAW MILK COOLING - Raw milk for pasteurization must be cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).
 19. INSECT AND RODENT CONTROL - Effective measures must be taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents and by chemicals used to control vermin. Milkhouses must be free of insects and rodents. Surroundings must be kept neat, clean and free of conditions which might harbor or be conducive to the breeding of insects and rodents. Feed must be stored in such a manner that it will not attract birds, rodents or insects.
 20. Requirements for Automatic Milking Installations (AMI) can be found in the PMO.
- B. SANITATION REQUIREMENTS FOR PASTEURIZED, ULTRA- PASTEURIZED, ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS - Any person, firm or corporation engaged in pasteurizing, ultra-pasteurizing or aseptically processing milk or milk products must comply with all applicable requirements for these activities as found in the PMO.
- C. SANITATION REQUIREMENTS FOR NOT-PASTEURIZED MILK AND MILK PRODUCTS -
1. FLOORS--CONSTRUCTION - The floors of all rooms in which milk or milk products are processed, handled or stored, or in which milk containers,

equipment and utensils are washed, must be constructed of concrete or other equally impervious and easily cleanable material; and must be smooth, properly sloped, provided with trapped drains and kept in good repair. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for storing dry ingredients and/or packaging materials need not be provided with drains and the floors may be constructed of tightly joined wood.

2. WALLS AND CEILINGS--CONSTRUCTION - Walls and ceilings of rooms in which milk or milk products are handled, processed, packaged or stored or in which milk containers, utensils and/or equipment are washed, must have a smooth, washable, light-colored surface and be in good repair.
3. DOORS AND WINDOWS - Effective means must be provided to prevent the access of insects and rodents. All openings to the outside must have solid doors or glass windows which must be closed during dusty weather.
4. LIGHTING AND VENTILATION - All rooms in which milk or milk products are handled, processed or stored or in which milk containers, equipment and/or utensils are washed must be well lighted and well ventilated.
5. TOILET-SEWAGE DISPOSAL FACILITIES - Every milk plant must be provided with toilet facilities conforming to the regulations of the State of Maine Plumbing Code. Toilet rooms must not open directly into any room in which milk and/or milk products are processed. Toilet rooms must be completely enclosed and must have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures must be kept in a clean condition, in good repair and must be well ventilated and well lighted. Sewage and other liquid wastes must be disposed of in a sanitary manner.
6. WATER SUPPLY - Water for milk plant purposes must be from a supply properly located, protected and operated and must be easily accessible, adequate and of a safe, sanitary quality.
7. HAND-WASHING FACILITIES - Convenient hand-washing facilities must be provided, including hot and cold running water; soap and individual sanitary towels or other approved hand-drying devices. Hand-washing facilities must be kept accessible, in a clean condition, in good repair and must not be utilized for any other use except hand washing.
8. SEPARATE ROOMS -
 - (a) There must be separate rooms or areas for:
 - (i) The processing, packaging and cooling of not pasteurized milk and milk products.
 - (ii) The cleaning of milk cans, bottles and cases.
 - (b) Rooms or areas in which not pasteurized milk or milk products are handled, processed or stored, or in which milk containers, utensils and

equipment are washed or stored, must not open directly into any stable or any place where animals are kept, and must have a self-closing door. All rooms must be of sufficient size for their intended purpose.

9. MILK PLANT CLEANLINESS - All rooms in which milk and milk products are handled, processed or stored and/or in which containers, utensils or equipment are washed or stored, must be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to the processing operations or to handling of containers, utensils and equipment is permitted in the processing, cooling, packaging and bulk milk storage rooms.
10. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT - The product-contact surfaces of all multi-use containers used in the transportation, processing and storage of not pasteurized milk and milk products must be effectively cleaned and must be sanitized before each use.
11. PROTECTION FROM CONTAMINATION - Milk plant operations, equipment and facilities must be located and operated in a manner to prevent any contamination of milk or milk products, ingredients, equipment, containers and utensils. All milk or milk products or ingredients which have been spilled, overflowed or leaked must be discarded. The processing or handling of products other than milk or milk products in the plant must be performed to preclude the contamination of such milk and milk products. The storage, handling and use of poisonous or toxic materials must be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products or the product-contact surfaces of all equipment, containers or utensils.
12. COOLING OF NOT PASTEURIZED MILK - All not pasteurized milk and milk products must be maintained at 7°C (45°F) or less until processed or sold.
13. BOTTLING AND PACKAGING - Bottling and packaging of not pasteurized milk and milk products must be done at the place of processing in a manner approved by the Department.
14. VEHICLES - All vehicles used in the transportation of not pasteurized milk and milk products must be constructed and operated so that the milk and milk products are maintained at 7°C (45°F) or less, and are protected from sun, from freezing and from contamination.
15. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT - All multi-use containers and equipment that milk or milk products come into contact with must be of smooth, impervious, corrosion-resistant, nontoxic material; must be constructed for ease of cleaning; and must be kept in good repair. All single-service containers, closures, gaskets and other articles that milk or milk products come in contact must be nontoxic and must have been manufactured packaged, transported and handled in a sanitary manner. Articles intended for single-service use must not be reused.
16. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT - After cleaning, all multi-use milk or milk products containers, utensils and equipment

must be transported and stored to assure complete drainage and must be protected from contamination before use.

17. STORAGE OF SINGLE-SERVICE CONTAINERS, UTENSILS AND MATERIALS - Single-service caps, cap stock, parchment paper, containers, gaskets, liners, bags and other single-service articles for use in contact with milk and milk products must be purchased and stored in sanitary tubes, wrappings or cartons; must be kept therein in a clean, dry place until used; and must be handled in a sanitary manner.
 18. PERSONNEL--CLEANLINESS - Hands must be thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination. Employee must thoroughly wash their hands before resuming work after visiting the toilet room. All persons, while engaged in the processing, pasteurization, handling, storage, packaging or transportation of milk, milk products, containers, equipment or utensils must wear clean outer garments. All persons, while engaged in the processing of milk or milk products, must wear adequate hair coverings and must not use tobacco.
 19. SURROUNDINGS - Milk plant surroundings must be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance.
- D. SANITATION REQUIREMENT FOR BULK MILK HAULER/SAMPLERS AND MILK TANK TRUCKS – Requirements and guidelines for determining compliance may be found in the PMO.
- E. SANITATION REQUIREMENTS FOR SINGLE SERVICE CONTAINER MANUFACTURERS – Requirements and guidelines for determining compliance may be found in the PMO.

SECTION VII - ANIMAL HEALTH

- A. Tuberculosis Testing Requirements
1. All milk must be from herds under a tuberculosis eradication program, which meets one (1) of the following conditions:
 - (a) Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA;
 - (b) An area which fails to maintain such status, but the herd meets one of the following:
 - (1) Any herd must have been accredited by USDA; or
 - (2) Must have passed an annual tuberculosis test; or
 - (c) The area must have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the

dairy industry within the area and that is approved by FDA, USDA and the Department.

2. Milk from cow, goat, sheep, water buffalo or other hooved mammal herds used for not pasteurized milk and milk products must be from lactating animals which have been tested using USDA approved methods every 3 years for tuberculosis with an allowable maximum grace period not exceeding 2 months.

B. Brucellosis Testing Requirements

1. All cattle and bison milk must be from herds under a brucellosis eradication program that meets one (1) of the following conditions:
 - (a) Participates in a milk ring testing program at least two (2) times per year at approximately one hundred eighty (180) day intervals and all herds with positive milk ring tests results must have the entire herd blood tested within thirty (30) days from the date of the laboratory ring tests;
 - (b) Has an annual individual blood agglutination test on all cattle or bison six (6) months of age or older, except steers and spayed heifers. An allowable maximum testing grace period will not exceed two (2) months.
2. Under the Federal USDA Brucellosis Eradication Program, only cattle and bison are covered under the USDA State brucellosis status determination. Other hooved mammals (goats, sheep, water buffalo, etc.) are not covered within the Program and must comply with one of the options cited below.
 - (a) Goat, sheep, water buffalo, or any other hooved mammal except cows for pasteurization and/or not pasteurized milk and milk product production must be from a herd or flock where all lactating females and breeding males are tested and are found to be negative for brucellosis every three (3) years.
 - (b) For herd or flock size, refer to the following table for required sampling size.

Herd/Flock Size	Sampling Size	Herd/Flock Size	Sampling Size
20	20	500	82
50	41	600	83
100	59	700	84
150	67	800	85
200	72	1000	86
250	75	1400	87
300	77	1800	88
350	79	4000	89
400	80	10000	89
450	81	100000	90

C. Other Testing Requirements

For diseases other than brucellosis and tuberculosis, the Department shall require such physical, chemical or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency. Any diseased animal disclosed by such test(s) must be disposed of as the Department directs.

D. Records supporting the tests required in this Section must be available to the Department and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official Agency.

E. Federal Animal ID program information link:
<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/NVAP-Reference-Guide/Control-and-Eradication/Tuberculosis>

SECTION VIII - TRANSFERRING; DELIVERY CONTAINERS; COOLING

Except as permitted in this section, no milk producer, milk hauler or distributor shall transfer milk or milk products from one container or milk tank truck to another on the street, in any vehicle, store or in any place except a milk plant, receiving station, transfer station or milkhouse especially used for that purpose. The dipping or lading of milk or fluid milk products is prohibited.

It shall be unlawful to sell or serve any milk or fluid milk product except in the individual, original container received from the distributor, or from an approved bulk dispenser. This requirement shall not apply to milk for mixed drinks requiring less than 236 milliliters ($\frac{1}{2}$ pint) of milk, or to cream, whipped cream or half-and-half which is consumed on the premises and which may be served from the original container of not more than 1.9 liter ($\frac{1}{2}$ gallon) capacity or from a bulk dispenser approved for such service by the Department.

It shall be unlawful to sell or serve any milk or milk product which has not been maintained at the temperature set forth in Section V of this rule. If containers of pasteurized or not pasteurized milk or milk products are stored in ice, the storage container must be properly drained.

SECTION IX - MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

Milk and milk products from points beyond the limits of routine inspection of the Department, may be sold in Maine, provided they are produced and pasteurized, ultra-pasteurized or aseptically processed and packaged, retort processed after packaging, concentrated (condensed) or dried under regulations which are substantially equivalent to this rule and have been awarded acceptable milk sanitation compliance and enforcement ratings; or have been awarded an acceptable HACCP listing under the NCIMS HACCP Program as specified in Appendix K of the PMO; or are from a country that PHS/FDA has determined, after conferring with the NCIMS, to have in place a public health regulatory program and government oversight of that program that have an equivalent effect on the safety of the regulated milk and/or milk products.

SECTION X – REQUIRED APPROVAL OF PLANS FOR CONSTRUCTION AND RECONSTRUCTION

Properly prepared plans for all milkhouses, milking barns, stables and parlors, milk tank truck cleaning facilities, milk plants, receiving stations and transfer stations regulated under this Rule and participating in the NCIMS program, which are hereafter constructed, reconstructed or extensively altered must be submitted to the Department for written approval before work is begun.

SECTION XI - PERSONNEL HEALTH REQUIREMENTS

No persons affected with any disease capable of being transmitted to others through the contamination of food may work at a milk plant in any capacity which brings them into direct contact with not-pasteurized milk and milk products for retail sale, pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk products or which brings them into direct contact with associated not-pasteurized milk and milk products for retail sale, pasteurized, ultra-pasteurized or aseptically processed and packaged milk or milk product-contact surfaces. In the case of milk plants, receiving stations, or transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, the HACCP System must address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section.

*See Administrative Procedures in the PMO for requirements, guidance and any applicable regulatory action.

SECTION XII - PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized, ultra-pasteurized, aseptically processed and packaged milk or milk products or not pasteurized milk or milk products or has been in an area with milk and milk product contact surfaces where these milk and milk products are processed, produced or handled meets one or more of the conditions specified in Section XI, the Department is authorized to require any or all of the following measures:

- A. Milk plant operators who have received reports, under this section, from employees who have handled pasteurized milk, pasteurized milk products or associated product contact surfaces must immediately report these facts to the Department.
- B. Dairy plant employees (or applicants to become employees) must be instructed by the dairy plant that the employee or applicant is responsible to report to the dairy plant management, in a manner that allows the dairy plant to prevent the likelihood of disease transmission of diseases that are transmissible through food, if the employee or applicant:
 1. Is diagnosed with an illness due to Hepatitis A virus, Salmonella Typhi, Shigella Species, Norwalk and Norwalk-like Viruses, Staphylococcus aureus, Streptococcus Pyogenes, Escheriachia coli 0157:H7, enterohemorrhagic Escherichia coli, enterotoxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotovirus, Taenia Solium, Yersinia enterocolitica, Vibrio cholerae 01 or other infectious disease that has been declared by the Secretary of Health and Human Services to be transmissible to others through the handling of food, or has been clearly shown to be so based upon verifiable epidemiological data; or

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2. Is exposed to, or suspected of causing, a confirmed foodborne disease outbreak of one of the diseases specified in #1 above, including an outbreak at an event such as a family meal, church supper or ethnic festival because the applicant or employee:
 - (a) Prepared food implicated in the outbreak, or
 - (b) Consumed food implicated in the outbreak, or
 - (c) Consumed food at the event prepared by a person who is infected or ill.
 3. Lives in the same household as a person who attends or works in a day care center or school, similar institution experiencing a confirmed outbreak of one of the diseases specified in #1 above.
- C. Dairy plant employees must be instructed by the dairy plant management to report to the dairy plant management if the employee (or applicant):
1. Has a symptom associated with acute gastrointestinal illness such as: abdominal cramps or discomfort, diarrhea, fever, loss of appetite for three or more days, vomiting, jaundice, or
 2. Has a pustular lesion such as a boil or infection wound that is:
 - (a) On the hands, wrists or exposed portions of the arms, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier, or
 - (b) On other parts of the body if the lesion is open or draining, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier.
- D. The immediate restricting of that person from duties which require handling finished product, such as pasteurized or not pasteurized milk or milk products or the handling of related product contact surfaces. This restriction may be lifted after an appropriate medical clearance or cessation of symptoms or both, according to the following criteria:

Table 5. Removal of Restrictions when Infection or High Risk of Infection is Discovered	
Health Status	Authorization to Remove Restrictions
a. Person is diagnosed with an illness due to Hepatitis A virus, Salmonella typhi, Shigella species, Norwalk and Norwalk-like Viruses, Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli 0157:H7, enterohemorrhagic Escherichia coli, enterotoxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotavirus, Taenia solium, Yersinia enterocolitica, Vibrio cholerae O1 or other infectious or communicable disease that has been declared by the Secretary of Health and Human Services to be transmissible to others through the handling of food or has been clearly shown to be so based upon verifiable epidemiological data.	Restrictions lifted by medical clearance.
b. Person meets a high-risk scenario as specified in Section 13 (2 or 3) of the PMO and/or experiencing symptoms in Section 13 (4 or 5) of the PMO.	Restrictions lifted when symptoms cease or medical documentation is provided that infection does not exist.
c. Person is asymptomatic, but stools positive for Salmonella typhi, Shigella or Escherichia coli 0157:H7.	Restrictions lifted by medical clearance.
d. Person has had past illness from Salmonella typhi, Shigella, Escherichia coli 0157:H7 or other human pathogens for which humans have been determined to be carriers.	Restrictions lifted by medical clearance.
e. In the case of diagnosed or suspected Hepatitis A, person has experienced onset of jaundice within the last seven (7) days.	Restrictions lifted by medical clearance.
f. In the case of diagnosed or suspected Hepatitis A, person has experienced onset of jaundice occurred more than seven (7) days ago.	Restrictions lifted by medical clearance or jaundice ceases.

- E. The immediate exclusion of the affected dairy products from distribution and use when medically appropriate (i.e., a medical evaluation of the sequence of events indicates that contamination of product may have occurred).
- F. The immediate requesting of medical and bacteriological examination of the person at risk. (Note: Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle finished products, such as pasteurized or

aseptically processed or not pasteurized milk or milk products, and associated product contact surfaces).

- G. In the case of milk plants, receiving stations or transfer stations that have HACCP Systems, which are regulated under the NCIMS HACCP Program, the HACCP System must address the public health concerns described in this Section in a manner that provides protection equivalent to the requirements in this Section.

SECTION XIII – EXAMINATION OF MILK AND MILK PRODUCTS

A. SAMPLE COLLECTION

1. It shall be the responsibility of the milk hauler to collect a representative sample of milk from each farm bulk tank, silo, or from a properly installed and operated in-line sampler or aseptic sampler that is approved for use by the Department and FDA to collect samples, prior to transferring or as transferring milk utilizing an aseptic sampler from a farm bulk tank, silo, truck or other container. All samples must be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the Department.
2. It shall be the responsibility of the industry plant sampler to collect a representative sample of milk from each milk tank truck or from a properly installed and operated aseptic sampler, which is approved for use by the Department and FDA to collect representative samples, prior to transferring milk from a milk tank truck. Industry plant samplers collect official samples for regulatory purposes at a milk plant, receiving station or transfer station.
3. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization, or aseptic processing and packaging must be collected, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples must be obtained under the direction of the Department or must be taken from each producer under the direction of the Department and delivered in accordance with this Section.
4. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing and packaging must be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty(20) days. These samples must be obtained by the Department, from each milk plant after receipt of the milk by the plant and prior to pasteurization, ultra-pasteurization or aseptic processing and packaging.
5. During any consecutive six (6) months, at least four (4) samples of heat-treated milk products, from plants offering such products for sale, must be collected in at least four (4) separate months, except when three (3) months show a month containing two sampling dates separated by at least 20 days and delivered to the Department in accordance with this section.

6. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, ultra-pasteurized milk, flavored milk, flavored reduced fat or low-fat milk, flavored nonfat (skim) milk, each fat level of reduced fat or low-fat milk and each milk product defined in this Rule, must be obtained by the Department in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant. All required sampling and testing of pasteurized and ultra-pasteurized milk and milk products to be done only when there are test methods available that are validated by FDA and accepted by the NCIMS. Products with no validated and accepted methods are not required to be tested. Aseptically processed and packaged milk and milk products shall be exempt from the sampling and testing requirements of this item. Samples must include a representative sample of every specific type of milk and milk product offered for sale.
7. During any consecutive six (6) months, at least four (4) samples of each variety, flavor or type of “not pasteurized” milk and milk products must be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, from every milk distributor, by the department.
8. During any consecutive six (6) months at least four (4) sample sets of single service containers from each manufacturing line, must be collected by the Department in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every manufacturer. A sample set is at least four (4) containers.
9. Once every twelve (12) months at least four (4) samples of multi-use containers, must be collected by the Department from each milk distributor.
10. Samples of milk and milk products must be taken while the milk and milk products are in the possession of the producer, milk plant or distributor at any time prior to delivery to the store or consumer. All retail samples shall be collected from the labeled containers in which they are sold. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and milk products are sold may be examined periodically as determined by the Department and the results of such examination shall be used to determine compliance with Sections II and VIII. Managers of such establishments must furnish the Department, upon request, with the names of all distributors from whom milk or milk products are obtained.
11. Milk and milk products not produced continuously throughout the year are exempt from being sampled four (4) times in any six (6) consecutive months. Frozen dairy desserts and eggnog must be sampled one (1) time, each month during the production season.
12. Water samples, from the water supply for the milk house and milking operations, must be taken at least once every three (3) years or more frequently at the Department’s discretion. The Department may also, at its discretion, inspect the water supply system including any disinfection components as applicable. Water supplies with buried well casing seals, must be sampled at intervals no greater

than six (6) months apart. Water samples, from the water supply for milk plant purposes, must be collected every six (6) months for IMS plants and every twelve (12) months for all other plants. Recirculating water must be sampled every six (6) months for all dairy plants. Dairy farms and dairy plants that use municipal water supplies shall be exempt from these water testing requirements.

- (a) Failure of an official water sample will result in a letter being sent to the farm, plant, dairy or any other milking operation requiring a clean water supply giving notice of the failure. Water will be resampled at a future date to be determined by the Department;
 - (b) After a second sample failure a warning letter or notice of intended enforcement will be sent to the farm, plant, dairy or any other milking operation requiring a clean water supply giving notice that a third sample will be taken.
 - (c) If the third sample fails the permit or license to operate will be suspended, until such time as a clean (satisfactory) water sample is obtained, but not more than a period of 30-days pending an administrative hearing to indefinitely suspend the permit or license.
13. Failure to provide the required samples of milk or milk products as specified in this section may result in enforcement action up to and including suspension of permit or license.

B. METHODOLOGY FOR EXAMINATION OF SAMPLES

Samples from sources participating in FDA's voluntary IMS program must be examined and tested as prescribed by the PMO using test methodology validated and accepted by FDA.

1. Required bacterial counts, somatic cell counts and cooling temperature checks must be performed on raw milk from the farm bulk tank. In addition, drug tests of each producer's milk must be conducted at least four (4) times during any consecutive six (6) months.
2. Required bacterial counts, somatic cell counts and cooling temperature checks must be performed on raw milk for pasteurization, ultra-pasteurization or aseptic processing and packaging.
3. Required bacterial counts, coliform determinations, drug tests, somatic cell counts and cooling temperature checks must be performed on heat treated milk and milk products.
4. Required bacterial counts, drug tests, coliform determinations, and cooling temperature checks must be performed on not pasteurized milk and milk products.
5. Required bacterial counts must be performed on single service and multi-use containers.

6. When multiple samples of the same milk or milk products, except for aseptically processed milk and milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Department and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.

C. VIOLATIONS

1. Whenever two (2) of the last four (4) bacterial counts, somatic cell counts, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products as defined in this Rule or the PMO, the Department shall send a written notice to the person concerned. This notice shall be in effect so long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample must be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) days. Immediate administrative suspension of the permit, and/or court action, shall be instituted whenever the standard is violated by three (3) of the last five (5) bacterial counts, somatic cell counts, coliform determinations or cooling temperatures.
2. When a milk plant's product is in violation of the standard for three (3) of the last five (5) tests, the plant's senior management will be notified (by telephone and certified letter) to suspend distribution of product. The Department will also be notified (by telephone and/or other methods of communication) and they will conduct a plant inspection as soon as possible. This inspection must note the probable cause of the violation(s) and any corrective action(s) necessary. After inspection, the plant will be allowed to resume distribution of product. Product will be sampled on an accelerated schedule (not more than two (2) samples per week for three (3) weeks). Once the plant has been inspected and allowed to resume distribution, previous test history will not be used to calculate two (2) out of four (4) or three (3) out of five (5) violations. Calculation will be based on test results from the accelerated sampling schedule.
3. When a producer's bulk tank milk is in violation of standard for three (3) of the last five (5) samples, the permit must be suspended by the department and the following steps shall be taken: (a) For violation of bacterial standard, the Department must conduct a farm inspection. This inspection must note the probable cause of the violation(s) and any corrective action(s) necessary. A permit must be issued upon inspection. (b) For violation of somatic cell standard, permit will be issued when an official bulk tank sample is tested within the standard established by this Rule at an official laboratory.

For bacterial or somatic cell violations, the producer's bulk tank milk will be sampled on an accelerated schedule (not more than two (2) samples per week for three (3) weeks). Once the accelerated sampling has begun, the previous test history will not be used to calculate two (2) out of four (4) or three (3) out of five (5) violations. Calculations will be based on test results from the accelerated sampling schedule.

4. Whenever a phosphatase test is positive, the cause will be determined. Where the cause is improper pasteurization, it must be corrected and any milk or milk product involved must not be offered for sale.
5. Whenever a pesticide residue test is positive, an investigation will be made to determine the cause and the cause must be corrected. An additional sample will be taken and tested for pesticide residues and no milk or milk products will 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.
6. Whenever a drug residue test is confirmed positive, an investigation must be made to determine the cause, and the cause must be corrected in accordance with the provisions of Section XIII.
7. Whenever a container or containers of aseptically processed milk or milk product is found to be unsterile, due to under-processing, the Department will consider this to be an imminent hazard to public health and suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. Aseptically processed milk and milk product must not be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All product from the lot that was found to contain one or more unsterile units must be recalled and disposed of as directed by the Department.
8. When single service or multi-use containers exceed the standard in three (3) out of four (4) samples taken at random on a given day, the Department must conduct an inspection to determine the probable cause(s) and note corrective action(s).
9. When a water sample is unable to meet bacteriological standards for three (3) consecutive tests, the Department may require a written corrective action plan specifying steps to be taken providing a continuous source of bacteriologically safe water. This plan may include a continuous disinfection utilizing UV light, or continuous chemical treatment. See Appendix D of the PMO.

D. INDEPENDENT TESTING OF NOT PASTEURIZED MILK PRODUCTS

When the official milk laboratory operated by the Department has tested not pasteurized milk products and determined that those milk products do not meet the standards for not pasteurized milk products established by this rule, the person operating the milk plant that processed the milk products may request further testing by an independent FDA certified laboratory. The not pasteurized milk products must not be sold pending the completion of the independent testing. Within three (3) business days of receipt by the Department of a request for independent testing, the Department shall obtain duplicate samples of the not pasteurized milk products from the processor. These samples will be delivered by the Commissioner or his/her agent to the state milk laboratory and shipped by the Department to an independent FDA certified laboratory for testing. The processor is responsible for the cost of shipping and testing performed by the independent FDA certified laboratory. The test results will be sent by the Department to the processor within 24-hours of receiving the results.

The not pasteurized products in dispute may be offered for sale only after testing at the official milk laboratory and the independent official laboratory has been completed and the Department has received results from either laboratory which are within the established standards set forth in this rule. If the results from both the independent official laboratory and the official milk laboratory do not meet the standards for not pasteurized products, the products must not be sold until they meet the established standards.

E. METHODS OF ANALYSIS

1. Samples must be analyzed at an appropriate official or officially designated laboratory. All sampling procedures, including the use of approved in-line samplers and approved aseptic samplers for milk tank trucks or for farm bulk tanks and/or silos, and required laboratory examination must be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (SMEDP) of the American Public Health Association and the PMO. Such procedures, including the certification of sample collectors, and examinations must be evaluated in accordance with the “Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program on the National Conference on Interstate Milk Shipments.” Aseptically processed milk and milk products packaged in hermetically sealed containers must be tested in accordance with the FDA’s Bacteriological Analytical Manual. Examination and tests to detect adulterants, including pesticides, must be conducted as the Department requires. When the Commissioner of the FDA determines that a potential problem exists with animal drug residues or other contaminants in the milk supply, samples must be analyzed for the contaminant by a method(s) determined by the FDA to be effective in determining compliance with actionable levels or established tolerances. This testing will continue until such time that the Commissioner of the FDA is reasonably assured that the problem has been corrected. The determination of a problem is to be based upon:

1. Sample survey results;
2. USDA tissue residue data from cull and other slaughtered dairy animals;
3. Animal drug disappearance and sales data;
4. State feedback; and
5. Other relevant information.

Assays of milk and milk products as defined in this Rule, including aseptically processed and packaged milk and milk products, to which vitamin(s) A and/or D have been added for fortification purposes, must be made at least annually in a laboratory which has been accredited by the FDA and which is acceptable to the Department, using the test methods acceptable to FDA and other official methodologies which give statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and meet the quality control requirements of the program established by

FDA. Laboratory accreditation and analyst certification parameters are specified in the Evaluation of Milk Laboratories 2019 Revision (EML) manual.

In addition, all facilities fortifying products with vitamin(s) must keep volume control records. These volume control records must cross reference the form and amount of vitamin D, vitamin A and/or vitamin A & D used with the amount of products produced and indicate a percent of expected use, plus or minus.

2. The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists", 16th Ed. (1997), which is incorporated by reference.
 - (a) Milk fat content--As determined by the method, "Roese-Gottlieb Method (Reference Method) (11)--Official Final Action", under the heading "Fat".
 - (b) Milk solids not fat content--Calculated by subtracting the milk fat content from the total solids content as determined by the method, "Method I--Official Final Action", under the heading "Total Solids".
 - (c) Titratable acidity--As determined by the method, "Acidity (2)--Official Final Action", or by an equivalent potentiometric method.
 - (d) Vitamin D content – “Vitamin D – Official Final Action”.

NOTE: Milk from animals not currently in the *Grade "A" PMO* may be labeled as Grade "A" and IMS listed upon FDA's acceptance of validated *Grade "A" PMO*, Section 6. of this *Ordinance* and Appendix N. test methods for the animal to be added. (Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted test methods.)

SECTION XIV – DRUG RESIDUE TESTING AND FARM SURVEILLANCE

This Section is established to reference safe levels and/or establish tolerances and to assure that milk supplies are in compliance with these safe levels or established tolerances for drug residues in milk. Additional requirements and guidelines for determining compliance with these requirements may be found in the PMO.

A. INDUSTRY RESPONSIBILITIES

1. MONITORING AND SURVEILLANCE - Industry must screen all bulk milk pickup tankers, regardless of final use, for beta lactam drug residues. Specific requirements for establishing a drug residue testing program can be found in Appendix N of the PMO. Additionally, other drug residues must be screened for by employing a random sampling program on bulk milk pickup tankers when the Commissioner of the Maine Department of Agriculture, Conservation and Forestry or the Commissioner of the FDA determines that a potential problem exists as cited in Section 6 of the PMO. The random bulk milk pickup tanker sampling program must represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two sampling dates

separated by at least twenty (20) days. Samples collected under this random sampling program must be analyzed as specified by FDA. (Refer to section 6 of the PMO.)

The bulk milk pickup tanker must be sampled after the last producer has been picked up and before any additional commingling. These bulk milk pickup tanker samples may be collected from an approved aseptic sampler. The sample must be representative. Bulk milk pickup tanker testing must be completed prior to processing the milk. Industry samplers must be evaluated according to the requirements specified in Section XIII, THE EXAMINATION OF MILK AND MILK PRODUCTS of this Rule and at the frequency addressed in Section IV, INSPECTION OF DAIRY FARMS AND MILK PLANTS of this Rule. Bulk milk pickup tanker samples found to be confirmed positive for drug residues must be retained as determined necessary by the Department. All presumptive positive test results for drug residues from analysis done on commingled raw milk tanks, bulk milk pickup tankers, farm raw milk tanks (only milk offered for sale) or finished milk or milk product samples must be reported to the Department.

2. **REPORTING AND FARM TRACEBACK:** – When a bulk milk pickup tanker is found to be positive for drug residues, the Department must be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker, found to be positive for drug residues, must be individually tested to determine the farm of origin. The samples must be tested as directed by the Department.

The producer must be notified by telephone and in writing by the milk plant.

Further pickups of the violative individual producer must be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

3. **RECORD REQUIREMENTS**

Records of all sample results must be maintained for a minimum of six (6) months by the milk plant at the location where the tests were run, and/or another location as directed by the Department. Such records shall be made available to the Department for inspection and copying, upon request and at all reasonable times.

Results of all testing may be recorded in any format acceptable to the Department and must include at least the following information:

1. Identity of the person doing the test;
2. Identity of the bulk milk pickup tanker being tested*;
3. Date/time the test was performed (Time, Day, Month and Year);
4. Identity of the test performed/lot #/any and all controls (+/-);

5. Results of the test;
6. Follow-up testing if initial test was positive/any and all controls (+/-);
7. Site where test was performed and
8. Prior test documentation must be provided for a presumptive positive load.

*Include the BTU number(s) of the farms present on the bulk milk pickup tanker with the above information.

B. DEPARTMENT RESPONSIBILITIES

1. Upon receipt of notification from industry of a bulk milk pickup tanker, which contains milk from another State(s), that is found to be presumptive positive for drug residues, it is the responsibility of the Department to notify the Regulatory Agency(ies) of all States of origin.
2. **MONITORING AND SURVEILLANCE** – The Department will monitor industry surveillance activities during either routine or unannounced, on-site quarterly inspections to collect samples from bulk milk pickup tankers and to review industry records of the random sampling program. Samples should be collected and analyzed from at least ten percent (10%) of the bulk milk pickup tankers scheduled to arrive on the day of the inspection. The method used must be appropriate for the drug being analyzed and must be capable of detecting the same drugs at the same concentrations as the method being used by industry.
3. The Department or Laboratory Evaluation Officer (LEO) may take known samples with him/her on the audit visit and observe the industry analyst test the samples. Receiving locations that choose to certify all receiving analysts, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section.

Receiving locations where all approved receiving Industry Analysts and Industry Supervisors successfully participate in a biennial on-site evaluation and annual split sample comparisons by LEOs are also exempt from the sample collection requirements of this Section. A review must include, but not be limited to, the following:

- (a) Is the program an appropriate routine monitoring program, utilizing appropriate test methods for the detection of drug residues?
- (b) Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in A.1. above for drug residues?
- (c) Is the program assuring timely notification to the Department of positive results, the ultimate disposition of the bulk milk pickup tanker milk and of the trace back to the farm of origin?

- (d) Is farm pickup suspended until subsequent testing establishes the milk is no longer positive for drug residues?

To satisfy these requirements:

1. There should be an agreement between the Department and industry that would specify how this notification is to take place. This notification must be “timely” for example by telephone or electronic device, and supported in writing.
 2. The ultimate disposition should either be prearranged in an agreement between the Department and the industry, or physically supervised by the Department. If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide (CPG 675.200 “Division of Adulterated Food to Acceptable Animal Feed Use” current revision).
 3. All screening test positive (confirmed) loads must be broken down (producer traceback) using the same or an equivalent test method (FDA, NCIMS Milk Safety Program, M-I-96-10, Drug Residue Test Methods for Confirmation, latest version). Confirmation tests (load and producer trace back/permit action) must be performed by an Official or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers must be handled in accordance with Section XIII of this rule.
 4. The suspension and discontinuance of farm bulk milk tank pick up is the responsibility of the industry, under the direction and supervision of the Department. At the discretion of the Department, records must be maintained by industry and/or the Department that:
 - a. Establish the identity of the producer and the identity of the load that tested positive; and
 - b. Establish that no milk is picked up from the positive testing producer until the Department has fulfilled their obligations under Section XIII. B.2. of this Rule and cleared the milk.
4. Sufficient records shall be reviewed to assure that all farm bulk milk pickup tankers are sampled before commingling and the results were made available to the appropriate BTU(s).
 5. The Department shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in the PMO

6. DRUG RESIDUE ENFORCEMENT - If testing reveals milk positive for drug residues, the milk must be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA Compliance Policy Guide. The Department shall determine the producer(s) responsible for the violation.
- a. **Suspension:** Any time milk is found to test positive for a drug residue, the Department will immediately suspend the producer's Grade "A" permit or equally effective measures will be taken to prevent the sale of milk containing drug residues.
 - b. **Penalties:** Future pick-ups are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty will be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The Department may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.
 - c. **Reinstatement:** The Grade "A" producer permit may be reinstated, or other action taken, to allow sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.
 - d. **Follow Up:** Whenever a drug residue test is positive an investigation must be made to determine the cause.

The investigation will include a farm inspection completed by the Department to determine the cause of the residue and actions taken to prevent future violations including:

- (a) On farm changes in procedures necessary to prevent future occurrences as recommended by the Department.
- (b) Discussion and education on the Drug Residue Avoidance Control measures outlined in the PMO and Milk and Dairy Beef Residue Prevention Protocol.

Permit Revocation: After a third violation in a twelve (12) month period, the Department may initiate proceedings to revoke the producer's Grade A permit.

7. DEPARTMENT RECORDS - In the event a processor reports a positive tanker result, the Department's records should indicate the following:
- a. What were the Department's directions?
 - b. When was the Department notified? By whom?
 - c. What was the identity of the load?
 - d. What screening and/or confirmatory test(s) were used and who were the analyst(s)?

- e. What was the disposition of the adulterated milk?
- f. Which producer(s) was responsible?
- g. Record of negative test results prior to subsequent milk pickup from the violative producers(s).

C. APPEALS PROCESS

If a producer wishes to dispute producer traceback test results, milk from the original sample will be sent by the milk plant to the DQCI laboratory in Minnesota for high pressure liquid chromatograph (HPLC) analysis. Costs of testing will be paid by the producer if the sample is determined to be positive or false violative. Testing costs plus costs of the discarded milk will be paid by the processor if the HPLC results indicate a false positive on original screening test.

SECTION XV - LABELING

All bottles, containers and packages enclosing milk or milk products defined in Section 1 of this Rule must be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act of 1990, and in addition, must comply with applicable requirements of this section as follows:

- A. All bottles, containers and packages enclosing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, must be conspicuously marked with:
 - 1. The words "Grade "A", as applicable on the exterior surface. Acceptable locations include the principal display panel, the secondary or informational panel, or the cap/cover.
 - 2. The identity of the milk plant where packaged, pasteurized, ultra-pasteurized, condensed and/or dried or aseptically processed.
 - 3. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.
 - 4. The volume or proportion of water to be added for reconstituting or recombining in the case of concentrated milk or milk products.
 - 5. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.
 - 6. In the case of aseptically processed and packaged milk or milk products, the term "UHT".
 - 7. The words "ultra-pasteurized" if the milk or milk product has been ultra-pasteurized.

8. The common name of the hooved mammal producing the milk must precede the name of the milk or milk product when the product is or is made from other than cattle's milk. As an example, "Goat", "Sheep", or "Water Buffalo milk or milk products respectively.
9. A list of ingredients in descending order of predominance.
10. The words "not pasteurized" if the milk or milk product has not been pasteurized. This does not apply to cheese that has been aged at a temperature above 35°F for at least 60 days prior to sale.
11. The full name of the food must appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food must be accompanied by a declaration indicating the presence of any characterizing flavoring, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients when used.
12. The following terms must accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:
 - (a) The phrase "vitamin A" or "vitamin A added" or "vitamin D" or "vitamin vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit".
 - (b) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.
13. The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.
14. The term "pasteurized" may appear on the label if the dairy ingredients used are pasteurized.
15. The net weight or volume.
16. The word "aged" when the product has been aged for more than 60 days.
17. The lot number. The lot number must correspond with accurate records which show time, temperature and date of production. Records will be kept for at least twelve months from the date produced.
18. Condensed or dry milk product labels must contain:
 - (a) The identity of the Regulatory Agency issuing such permit; and if distributed by another party, the name and address of the distributor must be shown by a statement, such as "Distributed by".
 - (b) A code or lot number identifying the contents with a specific date, run, or batch of the product, and the quantity of the contents of the container.

- B. All vehicles and milk tank trucks containing milk or milk products must be legibly marked with the name and address of the milk plant or hauler in possession of the contents. Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station are required to be marked with the name and address of the milk plant or hauler and must be sealed. Each milk tank truck containing milk must be accompanied by documentation, weigh ticket or manifest, which must include the IMS BTU Identification Number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant. For each such shipment, a shipping statement must be prepared containing at least the following information:
1. Shipper's name, address and permit number. Each milk tank truck load of milk must include the IMS Bulk Tank Unit (BTU) identification number(s) or the IMS Listed Milk Plant Number, for farm groups listed with a milk plant, on the farm weight ticket or manifest;
 2. Permit identification of the hauler, if not an employee of the shipper;
 3. Point of origin of shipment;
 4. Milk tank truck identification number
 5. Name of product;
 6. Weight of product;
 7. Temperature of product when loaded;
 8. Date of shipment;
 9. Name of supervising Regulatory Agency at the point of origin of shipment;
 10. Whether the contents are raw, pasteurized, or in the case of cream, low-fat or skim milk, whether it has been heat-treated;
 11. Seal number on inlet, outlet, wash connections and vents; and
 12. Grade of product.
- C. All cans of raw milk from individual dairy farms must be identified by the name or number of the individual milk producer.
- D. LABELING - EMERGENCY SUPPLIES

When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section II, the label must bear the designation "ungraded." When such labeling is not available, the Department will take immediate steps to inform the public that the particular supply is ungraded and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

E. IDENTITY LABELING –

"Identity", as used in this Section, is defined as the name and address of the milk distributor at which the packaging, condensing and/or drying pasteurization, ultra-pasteurization or aseptic processing takes place. It is recommended that the voluntary national uniform coding system for the identification of milk plants, at which milk and milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.

In cases where several plants are operated by one firm, the common firm name may be utilized on milk bottles or containers. Provided, that the location of the milk plant at which the contents were pasteurized, ultra-pasteurized or aseptically processed and packaged, condensed and/or dyed is also shown, either directly or by a code.

The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label, milk and milk products processed and packaged at another plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging plant is identified by a proper code.

- F. MISLEADING LABELS --The Department will not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label when, in their opinion, they are not misleading and are not so used as to obscure the labeling required by the rule. For dry milk products, the outer bag must be preprinted "Grade "A" before filling. The use of super grade designations is not permitted. However, this should not be construed as prohibiting the use of official grade designations awarded to dry milk products by the United States Department of Agriculture(USDA). Grade designations such as "Grade AA Pasteurized", "Selected Grade A Pasteurized", "Special Grade A Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade "A". Such an implication is false, because the rule requirements for Grade "A" pasteurized, ultra-pasteurized or aseptically processed and packaged milk and milk products when properly enforced, will ensure that this grade of milk and milk products will be as safe as they can practicably be made. Descriptive labeling terms must not be used in conjunction with the Grade "A" designation or name of the milk or milk product and must not be false or misleading.

SECTION XVI. ENFORCEMENT

This Rule will be enforced by the Department in accordance with the *PMO*, with ADMINISTRATIVE PROCEDURES, current edition. A certified copy¹⁶ of which shall be on file at the appropriate Department's office. Where the mandatory compliance with provisions of the Appendices is specified, such provisions will be deemed a requirement of this Rule.

SECTION XVII. REPEAL AND DATE OF EFFECT

All ordinances and parts of ordinances in conflict with this Rule will be repealed after the adoption of this Rule, at which time this Rule will be in full force and effect, as provided by law.

SECTION XVIII- REFERENCES

1. Grade "A" Pasteurized Milk Ordinance and Appendices, 2019 Edition. Web Address: <https://ncims.org/wp-content/uploads/2020/07/2019-PMO.pdf>

2. Bacteriological Analytical Manual, 8th Edition, 1995, AOAC International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD, 20877. Web site: <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm>
3. Code of Federal Regulations, Title 21, April 1999, U.S. Government printing office, Washington, D.C. Web Address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=168>
4. Federal Food, Drug and Cosmetic Act, as Amended, 1993, U.S. Government Printing Office, Washington, D.C.
5. Nutrition Labeling and Education Act, 1990, U.S. Government Printing Office, Washington, D.C. Web Address: <https://www.congress.gov/bill/101st-congress/house-bill/3562>
6. Standard Methods for the Examination of Dairy Products, most recent edition, American Public Health Association, 1015 Fifteenth Street, Washington, D.C.
7. Official Methods of Analysis, 19th Edition, 2012, AOAC International, 2275 Research Blvd, Ste 300, Rockville, MD 20850-3250.
8. Standard Methods for the Examination of Water and Wastewater, 22nd Edition, 2012, American Public Health Association, 1015 Fifteenth Street, Washington, D.C., 2005.
9. 3-A Accepted Practices for the Design, Fabrication and Installation of Milk Handling Equipment, Number 606-03, March 20, 1990, International Association of Milk, Food and Environmental Sanitarians, United States Public Health Service, The Dairy Industry Committee.
10. Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2019 Revision. Web Address: <https://ncims.org/wp-content/uploads/2020/07/2019-PROCEDURES-FINAL.pdf>
11. Evaluation of Milk Laboratories, 2019 Edition, Food and Drug Administration, CFSAN, Office of Food Safety, Division of Food Processing Science and Technology, Laboratory Proficiency and Evaluation Team, HFH-450, 6502 South Archer Road, Benford Park, IL 60501. Web Address: <https://ncims.org/wp-content/uploads/2020/05/2019-EML-Final.pdf>
12. FDA-2400 series evaluation forms, United States Public Health Service, Food and Drug Administration, Bedford Park, IL 60501. Web Address: <https://www.fda.gov/about-fda/reports-manuals-forms/forms>

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7 MRS §2910

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