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CHAPTER 490.

REGULATIONS GOVERNING GRADE "A" MILK.

Part I – Definitions and standards of identity

2 VAC 5-490-10. Definitions and standards of identity.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"A hazard that is reasonable likely to occur" means a hazard for which a prudent milk plant, receiving station or transfer station operator would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of these controls, the hazard will occur in the particular type of milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product being processed.

"Abnormal milk" means milk that is visibly changed in color, odor or texture.

"Acidified lowfat milk" means "acidified lowfat milk" as defined in 21 CFR 131.136.

"Acidified milk" means "acidified milk" as defined in 21 CFR 131.111.

"Acidified milk product" means a product with an acidity of not less than 0.50% expressed as lactic acid, which product is obtained by the addition of food grade acids to pasteurized cream, half-and-half, heavy cream, light cream, lowfat milk, milk, skim milk, or sour cream.

"Acidified skim milk" means "acidified skim milk" as defined in 21 CFR 131.144.

"Acidified sour cream" means "acidified sour cream" as defined in 21 CFR 131.162.

"Acidified sour half-and-half" means "acidified sour half-and-half" as defined in 21 CFR 131.187.

"Adulterated milk" or "adulterated milk product" means any milk, milk product, condensed milk product, or dry milk product which meets one or more of the conditions specified in Section 402 of the Federal Food, Drug and Cosmetic Act, as amended (21 USC 342).

"Aseptically processed milk" means milk that is hermetically sealed in a container and so thermally processed before or after packaging in conformance with 21 CFR Part 113 and the provisions of this chapter so as to render the product free of microorganisms capable of reproducing in the product under nonrefrigeration conditions of storage and distribution and that is free of viable microorganisms (including spores) capable of causing disease in humans.

"Aseptically processed milk product" means any milk or milk product that is hermetically sealed in a container and so thermally processed before or after packaging in conformance with 21 CFR Part 113 and the provisions of this chapter so as to render the product free of microorganisms capable of reproducing in the product under normal nonrefrigeration conditions of storage and distribution and that is free of viable microorganisms (including spores) capable of causing disease in humans.

"Aseptic processing" 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 21 CFR 113 and the provisions of this chapter and to maintain the commercial sterility of the product under normal non-refrigerated conditions.

"Audit" means an evaluation of the entire milk plant, receiving station or transfer station facility and HACCP System to ensure compliance with the voluntary HACCP program requirements of this chapter.

"Automatic milking installation" means 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.

"Boiled custard" means "eggnog" as defined in 21 CFR 131.170.

"Bulk milk hauler" means any person who holds a permit issued by the Virginia

Department of Agriculture and Consumer Services to collect official milk samples and
transport: (i) raw milk from a dairy farm to a milk plant, receiving station or transfer
station; or (ii) raw milk products from one milk plant, receiving station or transfer station
to another milk plant, receiving station or transfer station.

"Butterfat" means the fat of milk.

"Buttermilk" means the fluid milk product that remains after the manufacture of butter from milk or cream and contains not less than 8.25% of milk solids not fat.

"Cancel" means to permanently nullify, void, or delete a grade A permit issued by the State Regulatory Authority.

"Centralized Deviation Log" means a centralized log or file identifying data detailing any deviation of critical limits and the corrective actions taken.

"CFR" means the Code of Federal Regulations.

"Clean" means the surfaces of equipment and facilities have had an effective and thorough removal of product, soils, and contaminants.

"Coffee cream" means "light cream."

"Commercially Sterile" means: (i) the food has been thermally processed by the application of heat to render the food free of viable microorganisms(including spores) of public health significance and microorganisms capable of reproducing in the food under normal non-refrigerated conditions of storage and distribution; or (2) the food has been processed with the application of heat and the water activity of the food has been controlled to render the food free of microorganisms capable of reproducing in the food under normal non-refrigerated conditions of storage and distribution.

"Concentrated milk" means "concentrated milk" as defined in 21 CFR 131.115.

"Concentrated milk product" means any of the following foods: homogenized concentrated milk, vitamin D concentrated milk, homogenized concentrated skim milk, fortified concentrated skim milk, concentrated lowfat milk, fortified concentrated lowfat

milk, concentrated flavored milk, concentrated flavored milk product, or concentrated products made from concentrated milk or concentrated skim milk concentrated milk, and concentrated skim milk which when combined with potable water according to the instructions printed on the food's container, conforms to the definition of the corresponding milk product in this chapter.

"Condensed buttermilk" means the product resulting from the removal of a considerable portion of water from buttermilk.

"Condensed and dry milk product" means grade A condensed milk, grade A condensed and dry whey, grade A dry milk product, or grade A dry milk and whey product.

"Condensed milk" means milk unsterilized and unsweetened, resulting from the removal of a portion of water concentrated milk as defined in 21 CFR 131.115. This definition does not include:

- 1. Any sterilized milk or milk product, when the sterilized milk or milk product is hermetically sealed in a container and processed, either before or after sealing, so as to prevent microbial spoilage; or
- 2. Any evaporated milk or sweetened condensed milk, except when the evaporated milk or sweetened condensed milk is combined with other substances in the commercial preparation of any pasteurized, ultra-pasteurized, or aseptically processed milk or milk product.

"Condensed whey" means the product resulting from the removal of a portion of the water contained in the whey "condensed whey" as defined in 21 CFR 184.1979(a)(2).

"Consumer" means any person who uses any grade A milk, grade A milk product, or milk product.

"Corrective action" means procedures followed when a deviation occurs.

"Cottage cheese" means "cottage cheese" as defined in 21 CFR 133.128.

"Cottage cheese dry curd" means "dry curd cottage cheese."

"Cream" means "cream" as defined in 21 CFR 131.3(a).

"Critical Control Point" means a step at which control can be applied and is essential to prevent or eliminate a milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product safety hazard or reduce it to an acceptable level."

"Critical limit" means a maximum value or a minimum value to which a biological, chemical, or physical parameter must be controlled at a Critical Control Point to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product safety hazard.

"Cultured half-and-half" means "sour half-and-half."

"Cultured lowfat milk" means "cultured lowfat milk" as defined in 21 CFR 131.138.

"Cultured milk" means "cultured milk" as defined in 21 CFR 131.112.

"Cultured skim milk" means "cultured skim milk" as defined in 21 CFR 131.146.

"Cultured sour cream" means "sour cream."

"Dairy farm" means any <u>place or premises</u> where any cow, goat, er sheep, water <u>buffalo, or other mammal (except humans)</u> is kept, from which cow, goat, er sheep, water <u>buffalo, or other mammal (except humans)</u> any milk or any milk product is provided, sold, or offered for sale <u>for human consumption or provided</u> to a milk plant, <u>cheese plant, frozen desserts plant, transfer station</u>, or receiving station.

"Deficiency" means an element that is inadequate or missing from the requirements of a HACCP System or with the voluntary HACCP program requirements of this Chapter.

"Deny" means the State Regulatory Authority will not issue a grade A permit to the applicant.

"Deviation" means a failure to meet a critical limit.

"Drug" means: (i) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; (ii) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (iii) articles other than food intended to affect the structure or any function of the body of man or other animals; and (iv) articles intended for use as a component of any articles specified in (i), (ii), or (iii) of this definition, but does not include devices or their components, parts, or accessories.

"Dry buttermilk" means "dry buttermilk" as defined in 7 CFR 58.251.

"Dry buttermilk product" means "dry buttermilk product" as defined in 7 CFR 58.251.

"Dry cream" means "dry cream" as defined in 21 CFR 131.149.

"Dry curd cottage cheese" means "dry curd cottage cheese" as defined in 21 CFR 133.129.

"Dry milk product" means a product resulting from the drying of any milk or milk product and any product resulting from the combination of a dry milk product with other safe and suitable dry ingredients.

"Dry whey" means the product resulting from the drying of whey, while leaving all other constituents in the same relative proportions as whey "dry whey" as defined in 21 CFR 184.1979.

"Dry whey product" means a product resulting from the drying of whey or whey products and any product resulting from the combination of dry whey products with other wholesome dry ingredients.

"Dry whole milk" means "dry whole milk" as defined in 21 CFR 131.147.

"Eggnog" means "eggnog" as defined in 21 CFR 131.170.

"Eggnog-flavored milk" means a milk product, to which an emulsifier and a maximum of 0.5% stabilizer may have been added consisting of a mixture of (i) at least 3.25% butterfat, (ii) at least 0.5% egg yolk solids, (iii) sweetener, and (iv) flavoring.

"Evaporated milk" means "evaporated milk" as defined in 21 CFR 131.130.

"Evaporated skimmed milk" means "evaporated skimmed milk" as defined in 21 CFR 131.132.

"Flavored milk" means milk to which a flavor or sweetener has been added.

"Flavored milk product" means any milk product to which a flavor or sweetener has been added.

"Fortified milk" means milk, other than vitamin D milk, the vitamin or mineral content of which milk has been increased.

"Fortified milk product" means any milk product, other than a vitamin D milk product, the vitamin or mineral content of which milk product has been increased.

"Frozen milk concentrate" means the frozen milk product which, when water is added in accordance with instructions on the package containing the frozen milk product, the reconstituted milk product contains the percentage of milkfat and the percentage of milk solids not fat of milk.

"Goat milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats which, when sold in retail packages, contains not less than 2.5% milkfat and not less than 7.5% nonfat milk solids not fat.

"Grade A condensed and dry whey" means condensed or dry whey which complies with the provisions of the "Grade A Condensed and Dry Milk Products and Condensed and Dry Whey," Supplement I to the Grade A Pasteurized Milk Ordinance-

1978 Recommendations" "Grade "A" Pasteurized Milk Ordinance, 2005 Revision" and this chapter.

"Grade A condensed milk" means condensed milk which complies with the provisions of the "Grade A Condensed and Dry Milk Products and Condensed and Dry Whey," Supplement I to the Grade A Pasteurized Milk Ordinance-- 1978

Recommendations" "Grade "A" Pasteurized Milk Ordinance, 2005 Revision" and this chapter.

"Grade A dry milk product" means any dry milk product which complies with the provisions of the "Grade A Condensed and Dry Milk Products and Condensed and Dry Whey," Supplement I to the Grade A Pasteurized Milk Ordinance-1978

Recommendations" "Grade "A" Pasteurized Milk Ordinance, 2005 Revision and this chapter.

"Grade A dry milk and whey product" means any dry milk or whey product which has been produced for use in any grade A pasteurized, ultra-pasteurized, or aseptically processed milk product; and which has been manufactured under the provisions of the "Grade A Condensed and Dry Milk Products and Condensed and Dry Whey,"

Supplement I to the Grade A Pasteurized Milk Ordinance-1978 1995

Recommendations"; "Grade "A" Pasteurized Milk Ordinance, 2005 Revision" and this chapter.

"Grade A permit" means the written document issued by the state regulatory authority to the person who operates a: (i) dairy farm to produce raw milk for

pasteurization, ultra-pasteurization, or aseptic processing; (ii) milk plant; (iii) receiving station; (iv) transfer station; (v) milk condensing plant; (vi) milk drying plant; (vii) whey condensing plant; or (viii) whey drying plant; after the State Regulatory Authority has inspected and approved the person's operation and determined the person's compliance with the provisions of this chapter for the operations specified in this definition.

"HACCP" means Hazard Analysis Critical Control Point

"HACCP Plan" means the written document, which is based upon the principles of HACCP and delineates the procedures to be followed.

"HACCP System" means the implemented HACCP Plan and prerequisite

programs, including other applicable requirements of the voluntary HACCP Program of

this Chapter.

"Hazard" means a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

"Hazard analysis" means the process of collecting and evaluating information on hazards associated with the milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product under consideration, to decide which are reasonably likely to occur and must be addressed in the HACCP Plan.

"Half-and-half" means "half-and-half" as defined in 21 CFR 131.180.

"Heavy cream" means "heavy cream" as defined in 21 CFR 131.150.

"Homogenized" means that milk or a milk product has been treated to ensure breakup of the fat globules in the milk or milk product to such an extent that, after 48 hours of undisturbed storage at 40°F, no visible cream separation occurs on the milk or milk product; and the fat percentage of the top 100 milliliters of the milk or milk product in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than 10% from the fat percentage of the remaining milk or milk product as determined after thorough mixing.

"Lactose-reduced lowfat milk" means the product resulting from the addition of safe and suitable enzymes to convert enough lactose to glucose or galactose so that less than 30% of the lactose remains in the lowfat milk from which the product is made.

"Lactose-reduced milk" means the product resulting from the addition of safe and suitable enzymes to convert enough lactose to glucose or galactose so that less than 30% of the lactose remains in the milk from which the product is made.

"Lactose-reduced skim milk" means the product resulting from the addition of safe and suitable enzymes to convert enough lactose to glucose or galactose so that less than 30% of the lactose remains in the skim milk from which the product is made.

"Light cream" means "light cream" as defined in 21 CFR 131.155.

"Light whipping cream" means "light whipping cream" as defined in 21 CFR 131.157.

"Lowfat cottage cheese" means "lowfat cottage cheese" as defined in 21 CFR 133.131.

"Lowfat dry milk" means "lowfat dry milk" as defined in 21 CFR 131.123.

"Lowfat milk" means "lowfat milk" as defined in 21 CFR 131.135.

"Lowfat yogurt" means "lowfat yogurt" as defined in 21 CFR 131.203.

"Low-sodium lowfat milk" means the milk product resulting from the treatment of lowfat milk by a process of passing the lowfat milk through an ion exchange resin process, or by any other process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

"Low-sodium milk" means the milk product resulting from the treatment of milk by a process of passing the milk through an ion exchange resin process, or by any other process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

"Low-sodium skim milk" means the milk product resulting from the treatment of skim milk by a process of passing the skim milk through an ion exchange resin process, or by any other process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

"Market milk" means milk.

"Market milk product" means milk product.

"Milk" means "milk" as defined in 21 CFR 131.110. Except as otherwise provided in this chapter, and except where the term "goat milk" is distinguished from "cow milk" in 2 VAC 5-490-30 L and 2 VAC 5-490-50 A 3 e of this chapter, wherever the term "milk" is used, it shall be deemed to include "sheep milk" and "goat milk." the whole, fresh, clean lacteal secretion obtained by the complete milking of one or more healthy cows, goats, sheep, water buffalo, or other mammal (except humans) intended for human consumption excluding that obtained before and after birthing, for such a period as may be necessary to render the milk practically colostrum free.

"Milk condensing plant" means any plant in which milk or any milk product is condensed or dried, or in which milk or any milk product is received, separated, or otherwise processed for drying and packaging.

"Milk drying plant" means any plant in which milk or any milk product is condensed or dried, or in which milk or any milk product is received, separated, or otherwise processed for drying and packaging.

"Milk distributor" means any person who offers for sale or sells to another person any milk or milk product.

"Milkfat" means the fat of milk.

"Milk hauler" means any person who transports any raw milk or raw milk product to or from a milk plant, a receiving station, or a transfer station.

"Milkhouse" means the building or room in which there is conducted on a grade A dairy farm (i) the cooling, handling, and storing of milk; and (ii) the washing, sanitizing, and storing of milk containers and utensils.

"Milk plant" means any place, premises, or establishment where any milk or milk product is collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, condensed, dried, bottled, or prepared for distribution.

"Milk producer" means any person who operates a dairy farm and who provides, sells, or offers milk for sale <u>for human consumption or</u> to a milk plant, receiving station or transfer station.

"Milk product" means: (i) acidified lowfat milk, acidified nonfat milk, acidified milk, acidified milk product, acidified reduced fat milk, acidified skim milk, acidified sour cream, acidified sour half-and-half, aseptically processed milk, aseptically processed milk product, buttermilk, coffee cream, concentrated milk, concentrated milk product, cottage cheese, cottage cheese dry curd, cream, cultured half-and-half, cultured milk, cultured lowfat milk, cultured nonfat milk, cultured reduced fat milk, cultured skim milk, cultured sour cream, cultured sour half-and-half, dry curd cottage cheese, eggnog, eggnog-flavored milk, flavored milk product, fortified milk, fortified milk product, frozen milk concentrate, goat milk, half-and-half, heavy cream, heavy whipping cream, lactose-reduced lowfat milk, lactose-reduced nonfat milk, lactose-reduced milk, lactose-reduced skim milk, light cream, light whipping cream, lowfat cottage cheese, lowfat milk, lowfat yogurt, low-sodium lowfat milk, low-

sodium nonfat milk, low-sodium milk, low-sodium reduced fat milk, low-sodium skim milk, milk, nonfat milk, nonfat yogurt, recombined milk, recombined milk product, reconstituted milk, reconstituted milk product, reduced fat milk, sheep milk, skim milk, sour cream, sour half-and-half, table cream, vitamin D milk, vitamin D milk product, whipped cream, whipped light cream, whipping cream, or yogurt; (ii) any of the following foods: milk, lowfat milk, or skim milk with added safe and suitable microbial organisms; or (iii) any food made with a food specified in (i) of this definition by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification. Nothing in this definition shall be deemed to include any evaporated milk, evaporated skim milk, condensed milk (sweetened or unsweetened), infant formula, ice cream or other dessert, dietary product, dry milk product (except as defined herein), canned eggnog in a rigid metal container, or butter or cheese, except when butter or cheese is combined with other substances to produce any pasteurized or aseptically processed food as specified in this definition.

"Misbranded milk" or "misbranded milk product" means any milk, milk product, or condensed and dry milk product that: (i) satisfies any of the conditions specified in § 403 of the Federal Food Drug, and Cosmetic Act, as amended (21 USC 343), (ii) does not conform to its definition; or (iii) is not labeled in accordance with 2 VAC 5-490-40 2 VAC 5-490-210.

"Non-conformity" means a failure to meet specified requirements of the HACCP System.

"Nonfat dry milk" means "nonfat dry milk" as defined in 21 CFR 131.125.

"Nonfat dry milk fortified with vitamins A and D" means "nonfat dry milk fortified with vitamins A and D" as defined in 21 CFR 131.127.

"Nonfat milk" means "skim milk" as defined in 21 CFR 131.143.

"Nonfat yogurt" means "nonfat yogurt" as defined in 21 CFR 131.206.

"Normal storage" means storage at a temperature of 45°F or cooler, but does not include freezing.

"Official laboratory" means a biological, chemical, or physical laboratory operated by the Commonwealth of Virginia.

"Officially designated laboratory" means: (i) <u>a</u> commercial laboratory authorized by the State Regulatory Authority to examine a milk, milk product, or condensed and dry milk product, producer samples of Grade "A" raw milk for pasteurization, or commingled milk tank truck samples of raw milk or milk products; or (ii) <u>a</u> milk-industry laboratory authorized by the State Regulatory Authority to examine milk producer samples of raw milk for pasteurization, and for drug residues and bacterial limits, samples of raw milk commingled in a tank truck.<sup>4</sup>

"Optional ingredient" means: (i) only an ingredient specified as an optional ingredient in the definition of a milk product; or (ii) in the case in which no optional ingredient is specified, grade A condensed milk, grade A dry milk product, grade A condensed whey, grade A dry whey, concentrated milk, concentrated milk product,

flavor, sweetener, stabilizer, emulsifier, acidifier, vitamin, mineral, or other safe and suitable ingredient.

"Pasteurization" or "pasteurized" means the process of heating every particle of milk, milk product, or whey in equipment designed and operated in conformance with this chapter, to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time for the equipment indicated:

Temperature	Time	<u>Equipment</u>
145 degree F*	30 minutes	Vat Pasteurization
161 degree F*	15 seconds	High Temperature Short Time
191 degree F	1.0 second	High Temperature Short Time
194 degree F	0.5 second	High Temperature Short Time
201 degree F	0.1 second	High Temperature Short Time
204 degree F	0.05 second	High Temperature Short Time
212 degree F	0.01 second	High Temperature Short Time

<sup>\*</sup>If: (i) the fat content of the milk or milk product is 10% or more;

<sup>(</sup>ii) the milk or milk product contains added sweeteners; (iii) the product is condensed milk; or (iv) the milk product is a condensed milk

product, then "pasteurization" means increasing the specified temperature by 5 degree F.

\*if the dairy product is cream for butter-making, then "pasteurization" means heating to at least 165°F and holding continuously in a vat pasteurizer for not less than 30 minutes or pasteurizing by the High Temperature Short Time method at a minimum temperature of not less than 185°F for not less than 15 seconds.

\*If the milk product is eggnog, then "pasteurization" means heating to at least the following temperatures for the corresponding time specifications and equipment:

\_\_\_\_\_\_

Temperature Time <u>Equipment</u>

155 degree F 30 minutes <u>Vat Pasteurization</u>

175 degree F 25 seconds <u>High Temperature Short Time</u>

180 degree F 15 seconds <u>High Temperature Short Time</u>

Nothing in this definition shall be construed as barring any other process which has been recognized by the Food and Drug Administration as being equally efficacious as pasteurization, so long as that other process has been approved by the State Regulatory Authority.

"Person" means any individual, plant operator, partnership, corporation, company, firm, trustee, or institution.

"Prerequisite Programs" means procedures, including Good Manufacturing

Practices which address operational conditions that provide the foundation for the

HACCP System.

"Public" means any person in the Commonwealth.

"Pull date" means the date affixed to a consumer package or container of grade

A pasteurized milk or grade A pasteurized milk product which is the date after the day of
manufacturing and processing of the package or container and the last day on which
the grade A pasteurized milk or grade A pasteurized milk product as determined by the
milk plant may be offered for sale to consumers under normal storage.

"Raw milk" means: (i) any milk or any milk product which has not been pasteurized, ultra-pasteurized, or aseptically processed; or (ii) or any milk or any milk product which has been pasteurized, ultra-pasteurized, or aseptically processed and which has been exposed to microbiological contamination before, during, or after packaging.

"Receiving station" means any place, premises, or establishment where raw milk is: (i) received, collected, handled, stored, or cooled; and (ii) prepared for further transporting.

"Recombined milk" means the food which, when combined with potable water according to the instructions printed on the food's container, conforms to the milk fat and nonfat milk solids requirements for milk, as specified in the definition of "milk."

"Recombined milk product" means the food which, when combined with potable water according to the instructions printed on the food's container, conforms to the milk fat and milk nonfat solids requirements for the milk product designated on the food's container.

"Reconstituted milk" means "recombined milk."

"Reconstituted milk product" means "recombined milk product."

"Reduced lactose whey" means "reduced lactose whey as defined in 21 CFR 184.1979a.

"Reduced minerals whey" means "reduced minerals whey as defined in 21 CFR 184.1979b.

"Revoke" means to permanently annul, repeal, rescind, countermand, or abrogate a Grade A permit issued by the State Regulatory Authority.

"Safe and suitable" means "safe and suitable" as defined in 21 CFR 130.3(d).

"Sanitization" means the application of any effective method or substance to a clean surface for the destruction of pathogens, and of other organisms as far as is practicable, <u>and</u> when used does not adversely affect: (i) the equipment which comes in contact with milk, milk product, or condensed and dry milk product; (ii) the milk, milk product, or condensed and dry milk product; or (iii) the health of consumers.

"Septage" means material accumulated in a pretreatment system or privy.

"Sewage" means water-carried and nonwater-carried human excrement; kitchen, laundry, shower, bath, or lavatory wastes separately or together with such underground,

surface, storm and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, industrial establishments or other places.

"Sheep milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy sheep.

"Skim milk" means "skim milk" as defined in 21 CFR 131.143.

"Sour cream" means "sour cream" as defined in 21 CFR 131.160.

"Sour half-and-half" means "sour half-and-half" as defined in 21 CFR 131.185.

"State Regulatory Authority" means the Commissioner of Agriculture and Consumer Services or his agent when carrying out any duty specified in § 3.1-530.3 of the Code of Virginia or the State Health Commissioner or his agent when carrying out any duty specified in § 3.1-530.4 of the Code of Virginia.

"Suspend" means to temporarily nullify, void, debar, or cease for a period of time a grade A permit issued by the State Regulatory Authority.

"Sweetened condensed milk" means "sweetened condensed milk" as defined in 21 CFR 131.120.

"Sweetened condensed skimmed milk" means "sweetened condensed skimmed milk" as defined in 21 CFR 131.122.

"Table cream" means "light cream" as defined in 21 CFR 131.155.

"Transfer station" means any place, premises, or establishment where milk or milk products are transferred directly from one milk transport tank truck to another.

"Trim" means to shorten the hair on the udder and tail of milking cows and goats by clipping, singeing, cutting, or other means.

"Ultra-pasteurized" means, when used to describe any milk or milk product, that the milk or milk product has been thermally processed at a temperature of 280°F (138°C) or hotter for at least two seconds, either before or after packaging, so as to produce a product that has an extended shelf life under normal storage.

"Validation" means the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP Plan, when properly implemented, will effectively control the hazards.

"Verification" means those activities, other than monitoring, that determine the validity of the HACCP Plan and that the HACCP System is operating according to the plan.

"Vitamin A milk" means milk, the vitamin A content of which has been increased to at least 2000 International Units per quart.

"Vitamin A milk product" means a milk product, the vitamin A content of which has been increased to at least 2000 International Units per quart.

"Vitamin D milk" means milk, the vitamin D content of which has been increased to at least 400 International Units per quart.

"Vitamin D milk product" means a milk product, the vitamin D content of which has been increased to at least 400 International Units per quart.

"Water buffalo milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy water buffalo.

"Whey" means the liquid substance obtained by separating the coagulum from milk, cream, or skim milk during the cheese making procedure and may have the acidity adjusted by the addition of safe and suitable pH-adjusting ingredients prior to pasteurization "whey" as defined in 21 CFR 184.1979.

"Whey condensing plant" means a plant in which whey is condensed or in which whey is received and processed for drying and packaging.

"Whey drying plant" means a plant in which whey is dried or in which whey is received and processed for drying and packaging.

"Whey product" means any fluid product removed from whey; or made by the removal of any constituent from whey, or by the addition of any wholesome substance to whey or parts thereof.

"Whipped cream" means "heavy cream" as defined in 21 CFR 131.150 or "light whipping cream" as defined in 21 CFR 131.157, into which air or gas has been incorporated.

"Whipped light cream" means "light whipped cream" as defined in 21 CFR 131.155, into which air or gas has been incorporated.

"Whipping cream" means "light whipping cream" as defined in 21 CFR 131.157.

"Yogurt" means "yogurt" as defined in 21 CFR 131.200.

FOOTNOTE 1 "IMS LIST - Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers"; the current edition of this publication contains the list of officially designated laboratories and may be obtained from the U.S. Food and Drug Administration, Milk Safety Branch, HFF-346, 200 'C' St., S.W., Washington, D.C. 20204.

#### Part II – Grade A milk and milk products

2 VAC 5-490-20. Grade A milk and milk products.

Grade A milk, milk products, condensed and dry milk products shall comply with the specific standard of identity established for each milk product, condensed milk product or dry milk product and the requirements of this chapter. Grade A milk and milk products, condensed and dry milk products include: (i) acidified lowfat milk, acidified nonfat milk, acidified milk, acidified milk product, acidified reduced fat milk, acidified skim milk, acidified sour cream, acidified sour half-and-half, aseptically processed milk, aseptically processed milk product, boiled custard, buttermilk, coffee cream, concentrated milk, concentrated milk product, condensed buttermilk, cottage cheese, cottage cheese dry curd, cream, cultured half-and-half, cultured milk, cultured lowfat milk, cultured nonfat milk, cultured reduced fat milk, cultured skim milk, cultured sour cream, cultured sour half-and-half, dry buttermilk, dry buttermilk product, dry cream, dry curd cottage cheese, dry whole milk, eggnog, eggnog-flavored milk, flavored milk, flavored milk, flavored milk, half-and-half, heavy cream, heavy whipping cream, lactose-reduced lowfat milk, milk, half-and-half, heavy cream, heavy whipping cream, lactose-reduced lowfat milk,

lactose-reduced nonfat milk, lactose-reduced milk, lactose-reduced reduced fat milk, lactose-reduced skim milk, light cream, light whipping cream, lowfat cottage cheese, lowfat dry milk, lowfat milk, lowfat yogurt, low-sodium lowfat milk, low-sodium nonfat milk, low-sodium milk, low-sodium reduced fat milk, low-sodium skim milk, milk, nonfat milk, nonfat dry milk, nonfat dry milk fortified with vitamins A and D, nonfat yogurt, recombined milk, recombined milk product, reconstituted milk, reconstituted milk product, reduced lactose whey, reduced fat milk, reduced minerals whey, sheep milk, skim milk, sour cream, sour half-and-half, table cream, vitamin A milk, vitamin A milk product, vitamin D milk, vitamin D milk product, whipped cream, whipped light cream, whipping cream, or yogurt; (ii) any of the following foods: milk, lowfat milk, or skim milk with added safe and suitable microbial organisms; or (iii) any food made with a food specified in (i) of this definition by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification; and (iv) grade A condensed milk, grade A condensed whey, grade A dry whey, grade A dry milk product, grade A dry milk and grade A dry whey product. Nothing in this section shall be deemed to include any evaporated milk, evaporated skim milk, condensed milk (sweetened or unsweetened), infant formula, ice cream or other dessert, dietary product, dry milk product (except as defined herein), canned eggnog in a rigid metal container, or butter or cheese, except when butter or cheese is combined with other substances to produce any pasteurized or aseptically processed food as specified in this definition.

### Part III – Adulterated or misbranded milk or milk products

- 2 VAC 5-490-20. 2 VAC 5-490-30. Adulterated or misbranded milk or milk products.
  - A. No person may produce, provide, sell, offer, expose for sale, or possess, any adulterated or misbranded: condensed milk product; and dry milk product; milk; or milk product.
  - B. Any Each person who produces, provides, sells, offers, exposes for sale, or possesses, any adulterated or misbranded: condensed milk product; and dry milk product; milk; or milk product shall be subject to having the person's adulterated or misbranded: condensed milk product; and dry milk product, milk, or milk product impounded by the State Regulatory Authority.
  - C. No person may provide, sell, offer, or expose for sale, any: condensed milk product; and dry milk product; milk; or milk product to any milk plant for use in any grade A milk or grade A milk product if the person does not possess a permit from the State Regulatory Authority, unless the Commissioner of Agriculture and Consumer Services makes a finding in writing (which the Commissioner of Agriculture and Consumer Services may renew for terms not to exceed 90 days per term, without limitation) that: (i) the supply of grade A raw milk for pasteurization, ultra-pasteurization, or aseptic processing is not adequate to meet the nutritional needs of any person who secures milk in the Commonwealth; or (ii) the supply of

pasteurized, ultra-pasteurized, or aseptically processed milk or milk product at retail is not available for purchase by any person who secures milk in the Commonwealth.

D. No person may produce, provide, sell, offer, expose for sale, or possess any: condensed milk product; and dry milk product; milk; or milk product; under the provision of subsection C of this section unless the condensed milk product, dry milk product, milk or milk product is labeled "ungraded."

- 2 VAC 5-490-40. Impounding of adulterated or misbranded condensed milk, condensed milk product, dry milk, dry milk product, milk, or milk product.
- A. The State Regulatory Authority shall comply with the following administrative procedures when impounding any adulterated or misbranded condensed milk, condensed milk product, dry milk, dry milk product, milk, or milk product:
- (1) The State Regulatory Authority shall serve the person with a written impoundment notice. The written impoundment notice shall specify the violations and inform the person of the opportunity to appear before the State Regulatory Authority in person, by counsel, or by other qualified representative at a fact-finding conference for the informal presentation of factual data, arguments, and proof to contest the written notice of violation;
- (2) The written impoundment notice shall include:
  - (a) The name of the adulterated or misbranded condensed milk, condensed milk product, dry milk, dry milk product, milk, or milk product;

- (b) The size and number of separate units in the lot being impounded;
- (c) The product code and sell by date for the lot of product, if each exists;
- (d) A statement directing the person to:
  - (1) Immediately remove from sale the entire lot of adulterated or misbranded condensed milk, condensed milk product, dry milk, dry milk product, milk, or milk product;
  - (2)Isolate and identify as not for sale the entire lot of adulterated or misbranded condensed milk, condensed milk product, dry milk, dry milk product, milk, or milk product in the person's storage area in a location separate from any storage accessible from a retail sales area;
  - (3) Comply with one of the following options:
    - (a) If the condensed milk, condensed milk product, dry milk, dry
      milk product, milk, or milk product is adulterated: (i) the entire lot
      shall be destroyed; or (ii) the entire lot shall be held and returned to
      the manufacturer, distributor, or producer; or
    - (b) If the condensed milk, condensed milk product, dry milk, dry milk product, milk, or milk product is misbranded: (i) the entire lot shall be destroyed; or (ii) the entire lot shall be held and returned to the manufacturer, distributor, or producer; or (iii) the entire lot shall be held and new labels affixed to each container in the lot which comply with all provisions for labeling of condensed milk,

condensed milk product, dry milk, dry milk product, milk, or milk product contained in this chapter prior to being offered for sale.

#### Part IV - Permits

2 VAC 5-490-50. Permits.

- A. No person may produce, provide, manufacture, sell, offer for sale, or store in the Commonwealth, or bring, send, or receive into the Commonwealth, any milk, milk product, market milk, market milk product or condensed and dry milk product for use in the commercial preparation of grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk product unless the person possesses a grade A permit from the State Regulatory Authority. Nothing in this chapter shall apply to any establishment where milk or milk product is served or sold at retail, so long as the milk or milk product is not processed at the establishment. Nothing in this chapter shall be deemed to require a person who is a broker, agent, or distributor's representative to have a grade A permit if the person buys condensed and dry milk product for, or sells condensed and dry milk product to, a milk plant that has a valid grade A permit from any state.
- B. Only a person who complies with the requirements of this chapter shall be entitled to receive and retain a grade A permit. Permits shall not be transferable with respect to persons or locations. Each person whose name appears on a grade

A permit shall be at least eighteen years of age. Each person requesting a grade A permit shall provide the State Regulatory Authority with the following information:

- 1. The name of the person or persons to whom the permit is to be issued;
- 2. If the person or persons are requesting a permit for a partnership, corporation, firm, trustee, or institution, the person or persons shall provide the articles of incorporation, partnership agreement, trust document, or other document identifying the names, titles, and mailing addresses of all responsible officials for the partnership, corporation, firm, trustee, or institution;
- 3. The address of the facility being permitted, including the street and number, city, state, and zip code. Addresses containing Post Office Box designations shall not be permitted;
- 4. The trade name the permit holder will use if the permit holder will not be trading in the name to which the grade A permit is issued;
- 5. The name, mailing address, and telephone number for one responsible person designated by the grade A permit holder to receive all sample reports and official correspondence from the State Regulatory Authority;
- 6. If the permit application is for a grade A dairy farm, the name of the milk marketing organization or milk marketing cooperative to which the permit holder belongs or the buyer of their milk;
- 7. The names and phones numbers of responsible persons to contact at the grade A dairy farm or plant;

- 8. <u>If the permit application is for a grade A dairy farm, the name, address, and</u> telephone number of the owner of the dairy farm;
- 9. The printed name, signature, title, and date signed for each person whose name appears on the permit;
- 10. The printed name, signature, title, and date signed by the most responsible official for the partnership, corporation, firm, trustee, or institution if the permit is to be issued in the name of a partnership, corporation, company, firm, trustee, or institution; and
- 11. If the permit application is for a grade A plant permit, the plant code
  embossed or printed on packages of milk, milk product, condensed milk, condensed
  milk product, dry milk, or dry milk product packaged by the plant to identify the plant
  in lieu of printing the plant's name and address on the packages of milk, milk
  product, condensed milk, condensed milk product, dry milk, or dry milk product, if
  one has been assigned.
- C. Each person who holds a grade A permit and who request a change in the name or names on an existing grade A permit shall provide the State Regulatory Authority with the following information:
  - 1. A written statement requesting that the existing grade A permit be cancelled that has been signed by each person whose name appears on the existing grade A permit; except that, when a person whose name on an existing grade A permit is deceased, the request for cancellation shall be made in writing by the executor or

administrator of the permit holder's estate. A copy of the qualification as executor or administrator shall accompany the request for cancellation along with a statement identifying the name of the deceased and the date of death. Each signature shall be made next to or above the person's printed name and shall be dated with the date on which the written statement was signed by the grade A permit holder;

- 2. If the existing grade A permit is held in the name of a partnership, corporation, company, firm, trustee, or institution the written statement requesting the existing grade A permit be cancelled shall be signed by a person who is authorized to sign on behalf of the partnership, corporation, company, firm, trustee, or institution. Each signature shall be made next to or above the persons printed name and official title for the partnership, corporation, company, firm, trustee, or institution and shall be dated with the date on which the written statement was signed by the person who is authorized to sign on behalf of the partnership, corporation, company, firm, trustee, or institution; and
- 3. All of the information required by §2 VAC 5-490-50(B) for the State Regulatory Agency to issue a grade A permit.
- D. No person may hold a grade A dairy farm permit if any part of his facilities,
  equipment, storage, or surroundings (except toilet rooms) requiring inspection is
  accessed through any room used for domestic purposes or part of any room used
  for domestic purposes. Toilet rooms used for domestic purposes may be approved
  as complying with the requirements of this chapter only if: (1) the toilet room is

located within 300 feet of the milkroom; and (2) all labor utilized in the milking parlor, milking barn, and milkroom is provided by members of the permit holder's immediate family.

- E. Each grade A permit holder operating a milk plant within the Commonwealth shall provide to the State Regulatory Authority laboratory determinations of the quantity of vitamin A and vitamin D present in the milk plant's milk, milk product, fortified milk, and fortified milk product to which vitamin A or vitamin D has been added. Each grade A permit holder who operates a milk plant shall provide these laboratory determinations at least annually from a utilizing "Determination of Vitamin D2 and Vitamin D3 in Foods, Feeds, and Pharmaceuticals, using High Performance Liquid Chromatography: Comparison of Three Different Columns." or "HPLC Assays for Vitamin A and E (HPLC Method 1)." as appropriate for vitamin A and vitamin D determination, or any other method approved for such testing by the Food and Drug Administration. Each grade A permit holder who operates a milk plant shall pay for the cost of the laboratory determinations. No person who holds a grade A permit shall use or allow anyone else to use his facilities and equipment for any purpose other than that for which the grade A permit was issued.
- F. Each person who holds a grade A dairy farm permit shall display his permit in the milkroom on his dairy farm.
- G. Each person who holds a grade A dairy plant permit shall display his grade A plant permit in his facilities where it is accessible for inspection.

- H. D. No grade A permit holder may transfer any grade A permit to another person or another location.
- I. No permit holder who has had their grade A dairy farm permit or dairy plant

  permit revoked by the State Regulatory Authority shall be eligible to hold a grade A

  dairy farm or dairy plant permit at any time after the permit holder's permit is

  revoked.
- J. No grade A dairy farm may hold more than one grade A dairy farm permit.

  Multiple milking facilities or milk tanks on a grade A dairy farm shall not be issued separate grade A dairy farm permits for any reason.

В.

- 2 VAC 5-490-60. Authority to cancel, suspend, revoke or deny a permit.
  - <u>A.</u> The State Regulatory Authority may cancel, suspend, or revoke the grade A permit of any person, or may deny to any person a grade A permit if:
  - 1. The grade A permit holder fails to engage daily in the business for which the grade A permit is issued;
  - 2. The grade A permit holder does not daily produce, provide, manufacture, sell, offer for sale, or store in the Commonwealth, or bring, send, or receive into the Commonwealth milk, milk product, or condensed milk product and or dry milk product;

- The grade A permit holder fails to provide at no cost to the State Regulatory
  - Authority samples of milk, milk product, or condensed milk product and dry milk product in the person's possession for testing by the State Regulatory Authority;
  - 4. The grade A permit holder fails to provide on a daily basis milk, milk product, or condensed milk product and or dry milk product in the person's possession for sampling and testing by the State Regulatory Authority;
  - 5. The grade A permit holder fails to comply with any requirement of this chapter, or of §§ 3.1-420 through 3.1-424, §§ 3.1-530.1 through 3.1-530.9 3.1-530.11 or §§ 3.1-531 3.1-531.1 through 3.1-545 3.1-545.1 of the Code of Virginia;
  - 6. A public health hazard exists that affects the grade A permit holder's milk, milk product, or condensed milk product and or dry milk product;
  - 7. The grade A permit holder or any agent of the grade A permit holder has obstructed or interfered with the State Regulatory Authority in the performance of it's duties;
  - 8. The person supplies false or misleading information to the State Regulatory Authority: (i) in the person's application for a grade A permit; (ii) concerning the identity of the person who will control the facility that is the subject of the grade A permit; (iii) concerning the amount of milk, milk product, er condensed milk product and or dry milk product which the person produces, provides, manufactures, sells, offers for sale, or stores, in the Commonwealth, or brings, sends, or receives into the Commonwealth and the distribution of the person's milk, milk product, er

condensed milk product and or dry milk product; (iv) concerning any investigation conducted by the State Regulatory Authority; or (v) concerning the location of any part of the person's operation that is subject to a grade A permit;

- 9. The grade A permit holder engages in fraudulent activity regarding: (i) the amount of milk, milk product, er condensed milk product and or dry milk product the person offers to sell or sells; or (ii) the collection of samples of the person's milk, milk product, er condensed milk product and or dry milk product used to determine compliance with any provision of this chapter or as a basis for payment for milk, milk product, er condensed milk product and or dry milk product;
- 10. Three of the most recent five bacteria counts, somatic cell counts, or cooling temperature determinations conducted on the grade A permit holder's raw milk exceed the standards specified in this chapter:
- 11. Three of the most recent five bacteria counts, coliform determinations, or cooling temperature determinations conducted on the grade A permit holder's milk, milk product, er condensed milk product and or dry milk product exceed the standards specified in this chapter:
- 12. Two of the most recent cryoscope tests on the grade A permit holder's milk violate the standard specified in this chapter and the most recent violative sample occurred within two years of the next most recent violative sample;
- 13. The most recent <u>aflatoxin or</u> drug residue test on the grade A permit holder's milk, milk product, condensed milk product or dry milk product violates the standards

specified in this chapter. In the event the State Regulatory Authority suspends the grade A permit the suspension shall be for a minimum of: (i) two days (except as specified in subdivision 13 b of this subsection); (ii) four days (except as specified in subdivision 13b of this subsection) on the second occurrence of violative drug residues in the grade A permit holder's milk within a 12-month period after the grade A permit holder's first positive test for violative drug residues; or (iii) four days (except as specified in subdivision 13 b of this subsection) on the third occurrence of violative drug residues in the grade A permit holder's milk within a 12 month period after the grade A permit holder's first positive test for violative drug residues and the grade A permit holder's permit shall be subject to revocation; and the grade A permit holder whose milk test positive for violative drug residues shall provide and complete for each separate violation, the Milk and Dairy Beef Residue Prevention Protocol<sup>2</sup>, and have a signed quality assurance certificate, displayed in the grade A permit holder's milkhouse, within 30 days after the date of suspension of the grade A permit holder's permit;

a. The number of days represented by the grade A permit holder's milk shipment which tests positive for violative drug residues shall be determined by the State Regulatory Authority using: (i) the number of milkings included in the grade A permit holder's milk shipment which tests positive for violative drug residues; and (ii) the number of times each day the grade A permit holder milks; and

- b. The number of days determined by the State Regulatory Authority shall satisfy the same portion of the grade A permit holder's required suspension period as the grade A permit holder's milk shipment represents;
- 14. The most recent phosphatase test on the grade A permit holder's milk, milk product, or condensed milk product and or dry milk product violates the standard specified in this chapter;
- 15. The most recent chemical residue test or pesticide residue test on the grade A permit holder's milk, milk product, er condensed milk product and or dry milk product exceeds the actionable level, tolerance level, or safe level for any chemical residue or pesticide residue specified in: 40 CFR Parts Part 180, 185, or 186; and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 564, 570, 573, 589. In the event that no actionable level, tolerance level, or safe level for a chemical residue or pesticides residue has been established in: 40 CFR Parts Part 180, 185, or 186; and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 564, 570, 573, 589, the tolerance level shall be deemed to be zero;
- 16. The grade A permit holder fails to correct any: (i) violation of this chapter documented as a result of an inspection; or (ii) deficiency or non-conformity documented as a result of a HACCP audit that the State Regulatory Authority has cited in a written notice of intent to suspend the person's grade A permit, as a violation of this chapter;

- 17. The grade A permit holder's raw milk for pasteurization is warmer than 50°F two hours after the completion of the first milking or the grade A permit holder's raw milk for pasteurization is warmer than 50°F during or after any subsequent milking;
- 18. The grade A permit holder's equipment is covered or partially covered by an accumulation of milk solids, milk fat, or other residue so that the milk, milk product, or condensed milk product and or dry milk product is adulterated;
- 19. The grade A permit holder sells or offers for sale milk, milk products, er condensed milk product and or dry milk product which violate any requirement of this chapter;
- 20. The grade A permit holder fails to complete the "Milk and Dairy Beef Residue Prevention Protocol," 2 and have a signed quality assurance certificate, for display in the grade A permit holder's milkhouse, within 30 days after the date of the suspension of the grade A permit holder's permit because of the grade A permit holder's violation of subsection B 13 or The grade A permit holder's permit is suspended three times within a twelve month period;
- 21. The authority in another state responsible for issuing grade A permits has denied, suspended, or revoked the permit of the person in that state for any act or omission that would violate this chapter or the statutes under which this chapter was adopted, had the act or omission occurred in the Commonwealth-: or
- 22. The Virginia Department of Agriculture and Consumer Services has previously revoked the person's grade A permit.

C. B. The State Regulatory Authority may summarily suspend a grade A permit for violation of any of the following subdivisions of subsection B 2 VAC 5-490-60(A) of this section: 6, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, or 19, or 20.

C. The State Regulatory Authority may suspend from sale any condensed milk, condensed milk product, dry milk, dry milk product, milk or milk product in violation of the requirements of this chapter processed by any grade A dairy plant permit holder in lieu of suspending the grade A dairy plant permit holder's permit.

D. If the State Regulatory Authority suspends a permit holder's permit more than three times within any twelve month period, the permit holder's permit shall not be reinstated for a period of three days on the fourth suspension within any twelve month period and six days on the fifth suspension within any twelve month period with three days being added to the required suspension period for each additional suspension thereafter within any twelve month period.

E. If the State Regulatory Authority issues two written notices of intent to suspend a person's permit for failure to correct the same deficiency within any twelve month period, the State Regulatory Authority may issue and enforce a written notice of intent to summarily suspend the person's permit at anytime within six months after the date the

written notice of intent to summarily suspend is issued, to summarily suspend the person's permit if the same violation exist on any inspection during the six month period specified in the written notice of intent to summarily suspend.

2 VAC 5-490-70 Authority to impound milk and milk products.

The State Regulatory Authority may impound any condensed milk, condensed milk product, dry milk, dry milk product, milk product if the condensed milk, condensed milk product, dry milk, dry milk product, milk or milk product is in violation of any requirement of this chapter.

2 VAC 5-490-80 Written warning and suspension notices for violations of quality standards; required procedures.

A. Whenever two of the last four consecutive cooling temperature checks, bacteria counts or somatic cell counts taken on separate days for a grade A dairy farm permit holder exceed the standard established for grade A raw milk; the State Regulatory Agency shall send a written warning notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence.

The warning notice shall inform the permit holder or his representative: (1) concerning which quality standards the permit holder has violated; (2) that another sample will be collected within 21 days to determine compliance with the requirements; and (3) that his grade A dairy farm permit will be suspended whenever three out of the last five

consecutive cooling temperature checks, bacteria counts or somatic cell counts exceed the standards. The warning notice shall be in effect so long as two out of the last four consecutive samples exceed the standard for grade A raw milk. An additional sample shall be collected to determine compliance with the standards for grade A raw milk within 21 days after sending the warning notice, but not before the lapse of three days.

B. Whenever the last cryoscope test result for a grade A dairy farm permit holder exceeds the standard established for grade A raw milk for the first time in the past two years; the State Regulatory Agency shall send a written warning notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence. The warning notice shall inform the permit holder or his representative: (1) concerning which quality standards the permit holder has violated: (2) that another sample will be collected in the near future to determine compliance with the requirements; and (3) that his grade A dairy farm permit will be suspended whenever two cryoscope test results on separate samples exceed the standard within the past two years. The warning notice shall be in effect so long as any sample exceeds the cryoscope standard for grade A raw milk within the past two years. Additional samples shall be collected in the future to determine compliance with the standards for grade A raw milk, but not before the lapse of three days.

- C. Whenever two of the last four consecutive cooling temperature checks or bacteria counts taken on separate days from a grade A permit holder's dairy plant exceed the standard established for commingled grade A raw milk for pasteurization, ultrapasteurization or aseptically processed milk or milk product; the State Regulatory Agency shall send a written warning notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence. The warning notice shall inform the permit holder or his representative: (1) concerning which quality standards the permit holder has violated; (2) that another sample will be collected within 21 days to determine compliance with the requirements of this chapter; and (3) that the permit holder's grade A permit will be suspended whenever three out of the last five consecutive cooling temperature checks or bacteria counts exceed the quality standards. The warning notice shall be in effect so long as two out of the last four consecutive samples exceed the standard for grade A commingled raw milk for pasteurization, ultrapasteurization or aseptically processed milk or milk product. An additional sample shall be collected to determine compliance with the standards for grade A raw milk within 21 days after sending the warning notice, but not before the lapse of three days.
- D. Whenever two of the last four consecutive cooling temperature checks, bacteria
  counts or coliform counts taken on separate days from a grade A permit holder's dairy
  plant exceed the standard established for grade A pasteurized or ultra-pasteurized milk

or milk products in retail containers; the State Regulatory Agency shall send a written warning notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence. The warning notice shall inform the permit holder or his representative: (1) concerning which quality standards the permit holder has violated for each grade A pasteurized or ultra-pasteurized milk or milk product in retail containers; (2) that another sample will be collected within 21 days to determine compliance with the requirements of this chapter; and (3) that the permit holder's grade A pasteurized or ultra-pasteurized milk or milk product in retail containers will be suspended from sale whenever three out of the last five consecutive cooling temperature checks, bacteria counts or coliform counts exceed the quality standards. The warning notice shall be in effect so long as two out of the last four consecutive samples exceed the standard for grade A pasteurized or ultra-pasteurized milk or milk products in retail containers. An additional sample shall be collected to determine compliance with the standards for grade A raw milk within 21 days after sending the warning notice, but not before the lapse of three days.

E. Whenever two of the last four consecutive cooling temperature checks or bacteria counts taken on separate days from a grade A permit holder's dairy plant exceed the standard established for grade A bulk shipped heat-treated milk products; the State Regulatory Agency shall send a written warning notice to the permit holder or to the person identified by the permit holder to receive sample reports and official

correspondence. The warning notice shall inform the permit holder or his representative: (1) concerning which quality standards the permit holder has violated for each grade A bulk shipped heat-treated milk product; (2) that another sample will be collected within 21 days to determine compliance with the requirements of this chapter; and (3) that the permit holder's grade A permit will be suspended whenever three out of the last five consecutive cooling temperature checks or bacteria counts exceed the quality standards. The warning notice shall be in effect so long as two out of the last four consecutive samples exceed the standard for grade A bulk shipped heat-treated milk products. An additional sample shall be collected to determine compliance with the standards for grade A raw milk within 21 days after sending the warning notice, but not before the lapse of three days.

F. Whenever three out of the last five consecutive cooling temperature checks, bacteria counts or somatic cell counts taken on separate days for a grade A dairy farm permit holder exceed the standard established for grade A raw milk; the State Regulatory Agency shall send a written suspension notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence.

The suspension notice shall inform the grade A dairy farm permit holder: (1) why his grade A permit is being suspended; (2) that he will be contacted by the State Regulatory Authority to establish a date on which the suspension of his permit will be effective; and

- (3) that his grade A permit will not be reinstated until laboratory analysis determine that his raw milk is in compliance with the quality standards.
- G. Whenever two cryoscope test results taken on separate days for a grade A dairy farm permit holder exceed the standard established for grade A raw milk within the past two years; the State Regulatory Agency shall send a written suspension notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence. The suspension notice shall inform the grade A dairy farm permit holder: (1) why his grade A permit is being suspended; (2) that he will be contacted by the State Regulatory Authority to establish a date on which the suspension of his permit will be effective; and (3) that his grade A permit will not be reinstated until laboratory analysis determine that his raw milk is in compliance with the quality standards.
- H. Whenever three out of the last five consecutive cooling temperature checks or bacteria counts taken on separate days from a grade A permit holder's dairy plant exceed the standard established for commingled grade A raw milk for pasteurization, ultra-pasteurization or aseptically processed milk or milk products; the State Regulatory Authority shall send a written suspension notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence.

  The suspension notice shall inform the grade A dairy plant permit holder: (1) that the

dairy plant permit holder desire to have his grade A dairy plant permit reinstated; he must make his request in writing to the State Regulatory Authority detailing the actions he has taken and will take to avoid violating the standard he exceeded for commingled grade A raw milk in the future, establishing a date and time by which these actions will be fully implemented and stating the reasons why his request should be granted.

I. Whenever three out of the last five consecutive cooling temperature checks, bacteria counts or coliform counts taken on separate days from a grade A permit holder's dairy plant exceed the standard established for grade A pasteurized or ultra-pasteurized milk or milk products in retail containers; the State Regulatory Authority shall send a written suspension notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence. The suspension notice shall inform the grade A dairy plant permit holder: (1) that the pasteurized or ultra-pasteurized milk and dairy products in violation of the quality standard are suspended from sale; (2) why the pasteurized or ultra-pasteurized milk and dairy products are suspended from sale; (3) that the permit holder must contact the State Regulatory Authority when corrections have been made to bring their pasteurized or ultra-pasteurized milk and milk products into compliance before any action will be taken to reinstate sales of his suspended pasteurized or ultra-pasteurized milk and milk products; and (4) that his pasteurized or ultra-pasteurized milk and milk products will not be reinstated for sale until laboratory

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analysis determine that the pasteurized or ultra-pasteurized milk and milk products are in compliance with the quality standards.

- J. Whenever three out of the last five consecutive cooling temperature checks or bacteria counts taken on separate days from a grade A permit holder's dairy plant exceed the standard established for grade A bulk shipped heat-treated milk products; the State Regulatory Authority shall send a written suspension notice to the permit holder or to the person identified by the permit holder to receive sample reports and official correspondence. The suspension notice shall inform the grade A dairy plant permit holder: (1) that the permit holder's grade A dairy plant permit is suspended; and (2) that should the grade A dairy plant permit holder desire to have his grade A dairy plant permit reinstated; he must make his request in writing to the State Regulatory Authority detailing the actions he has taken and will take to avoid violating the standard he exceeded for grade A bulk shipped heat-treated milk products in the future, establishing a date and time by which these actions will be fully implemented and stating the reasons why his request should be granted.
- F. 2 VAC 5-490-90. Inspection of dairy farms, milk plants, condensing plants and drying plants; HACCP audits of dairy plants.
  - A. 1. No person who operates a dairy farm, milk plant, receiving station, transfer station, condensing plant, or drying plant within the Commonwealth may hold a

grade A permit until the <u>his</u> dairy farm, milk plant, receiving station, transfer station, condensing plant, or drying plant has been inspected and approved by the State Regulatory Authority;

- B. 2. The State Regulatory Authority shall inspect at least once every three months each dairy farm that holds a grade A permit; After permitting, each person's dairy farm, milk plant, receiving station, transfer station, condensing plant, or drying plant within the Commonwealth shall be inspected as often as the State Regulatory Authority deems is necessary.
- C. After permitting, each person's milk plant, receiving station, transfer station, condensing plant, or drying plant within the Commonwealth participating in the voluntary HACCP program shall be HACCP audited as often as the State Regulatory Authority deems is necessary.
  - 3. The State Regulatory Authority shall inspect at least every month each milk plant, transfer station, and receiving station that holds a grade A permit;
  - 4. The State Regulatory Authority shall inspect at least once every three months each condensing plant or drying plant that holds a grade A permit;
- G. 2 VAC 5-490-100. The examination of milk and milk products.
  - A. 1. The State Regulatory Authority shall collect during any consecutive six months at least four samples of raw milk, collected in <u>at least four</u> separate months, except when three months show a month containing two sampling dates separated

by at least twenty days for pasteurization, ultra-pasteurization, or aseptic processing from each dairy farm that holds a grade A permit.

- B. 2. After receipt of the milk by the milk plant and prior to pasteurization, ultrapasteurization or aseptic processing the State Regulatory Authority shall collect
  during any consecutive six months at least four samples of raw milk, collected in at
  least four separate months, except when three months show a month containing
  two sampling dates separated by at least twenty days for pasteurization, ultrapasteurization, or aseptic processing from each milk plant located within the
  Commonwealth that holds a grade A permit.
- C. 3. The State Regulatory Authority shall collect <u>during any consecutive six-month</u> <u>period at least</u> four samples of each <u>heat-treated</u>, pasteurized, ultra-pasteurized, er <u>and</u> aseptically processed milk product, <u>each sample to be</u> collected in <u>at least four</u> separate months, <u>except when three months show a month containing two sampling</u> <u>dates separated by at least twenty days during any consecutive six-month period</u>, from each milk plant <u>located in the Commonwealth and</u> holding a grade A permit.
- D. 4. The State Regulatory Authority shall, except when the production is not on a yearly basis, during each month collect from each milk condensing plant, milk drying plant, whey condensing plant or whey drying plant holding a grade A permit at least one sample of raw milk for pasteurization, after receipt of the milk by the plant and before pasteurization, and at least one sample of each grade A condensed milk product, grade A dry milk product, grade A condensed whey, and grade A dry whey

manufactured. If the production of grade A dry milk products or grade A dry whey is not on a yearly basis, the State Regulatory Authority the shall collect at least five samples within a continuous production period.

- E. 5. The State Regulatory <u>Authority</u> shall <u>may</u> collect at least once every three months samples of milk and milk product products as it deems necessary from retail establishments selling milk or milk product products to determine compliance with 2 VAC 5-490-20 2 VAC 5-490-30, 2 VAC 5-490-40 2 VAC 5-490-210, 2 VAC 5-490-502 VAC 5-490-220 and 2 VAC 5-490-80 2 VAC 5-490-270 of this chapter. The Each person who operates the retail establishment shall furnish the State Regulatory Authority, upon the request of the State Regulatory Authority, with the names of all distributors from whom the person has obtained milk or milk product products.
- F. 6. The State Regulatory Authority shall provide the remaining portion of the original raw milk sample from each grade A dairy farm which has been screened positive for animal drug residues by a milk plant, receiving station, or transfer station to the grade A dairy farms' milk marketing organization upon request.
- G. Each grade A permit holder operating a milk plant within the Commonwealth shall provide to the State Regulatory Authority laboratory determinations of the quantity of vitamin A and vitamin D present in each of the milk plant's milk and milk products to which vitamin A or vitamin D has been added. Each grade A permit holder who operates a milk plant shall provide these laboratory determinations at

least annually from a laboratory certified to determine the amount of vitamin A and vitamin D in milk and milk products under the requirements established in "Evaluation of Milk Laboratories," 2005 revision, available from the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of HACCP, Laboratory Quality Assurance Branch, HFH-450, 6502 South Archer Road, Summit-Argo, Illinois, 60501, USA. Each grade A permit holder who operates a milk plant shall pay for the cost of the laboratory determinations.

- H. 2 VAC 5-490-110. Drug residue monitoring, and farm surveillance and follow up.
  - A. 1. Any Each grade A permit holder operating a milk plant, receiving station, or transfer station shall:
- a. 1. Prior to processing any raw milk from bulk tanks on farms, test for residues of beta lactam drugs all raw milk that the milk plant, receiving station, or transfer station receives for pasteurization, ultra-pasteurization, or aseptic processing;
- b. 2. Test each shipment of bulk tank raw milk received for pasteurization, ultrapasteurization, or aseptic processing by screening tests methods which have been
  evaluated by Virginia Polytechnic Institute and State University in the study "Evaluation
  of Animal Drug Residue Detection Methods" and which have been demonstrated by
  "Evaluation of Animal Drug Residue Detection Methods" to provide positive results for
  residues of beta lactam drugs, unless Association of Official Analytical Chemists-

(AOAC)-reviewed and Food and Drug Administration- (FDA)-accepted methods are available. In lieu of any test specified in subdivision 1 b 2 VAC 5-490-110 (A)(2) of this subsection a grade A permit holder may use AOAC first-action and AOAC final-action tests methods. Nothing in subdivision 1 b of this subsection 2 VAC 5-490-110 (A)(2) shall be deemed to include require the testing of individual raw milk samples prior to processing collected from each grade A dairy farm included in any shipment of bulk tank raw milk for pasteurization, ultra-pasteurization, or aseptic processing; e. 3. Implement a random-sampling program when the Commissioner of the Food and Drug Administration determines that a potential problem exists with animal drug residues or other contaminants in the milk supply. Any Each grade A permit holder operating a milk plant, receiving station, or transfer station shall analyze the samples for the contaminant by a method determined by FDA to be effective in determining compliance with actionable levels or established tolerances. Any Each grade A permit holder operating a milk plant, receiving station, or transfer station shall continue the random-sampling program until such time that the Commissioner of the Food and Drug Administration is reasonably assured that the problem has been corrected. The sampling program shall represent and include during any consecutive six months, at least four samples collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least twenty days. d.4. Retain any each sample found to be positive for drug residues for a period of 120 hours after the sample test result is positive for drug residues for the use of the State

Regulatory Authority <u>unless directed otherwise by a representative of the State</u>
Regulatory Authority;

- e. 5. Abstain from selling or offering for sale any pasteurized, ultra-pasteurized, or aseptically processed milk, milk product, or condensed and dry milk product processed from raw milk for pasteurization, ultra-pasteurization, or aseptic processing before results of drug screening tests are available and which raw milk later tests positive for drug residues. All of the grade A permit holder's milk commingled with any raw milk which tests positive for drug residues shall be deemed adulterated. Any grade A permit holder operating a milk plant, receiving station, or transfer station shall report to the State Regulatory Authority instances of adulteration immediately;
- f. 6. Record the results of tests on samples of raw milk and retain such records for a period of six months; report records of all results of tests on samples of raw milk to the State Regulatory Authority by the fifteenth day of each month for the preceding month; and maintain and make available to the State Regulatory Authority for inspection and review at the permitted facility records of results of tests on samples of raw milk. Any Each record of results of tests on samples of raw milk required by this subdivision shall include:
- (1 a) The analyst's signature, date, and time, of and place where the test was performed;
- (2 b) The registration identification of each pickup tanker of bulk raw milk or raw milk sampled;

- (3 c) The test method used; and
- (4 d) The Interstate Milk Shipper Bulk Tank Unit identification number of each Grade A milk supply included on each pickup tanker of bulk raw milk tested; and
- (e) A statement as to whether the test results were positive or negative. If the results were positive, the grade A permit holder shall also record:
- (a 1) The identity of each producer contributing to the load from which the positive sample of raw milk was taken;
- (b 2) The name of the person notified at the State Regulatory Authority of the positive test results;
- (e <u>3</u>) The date and time of day the person at the State Regulatory Authority was notified of the positive test results; and
  - (d 4) The method of notification of the State Regulatory Authority;
- g. 7. Immediately notify the State Regulatory Authority and the milk marketing cooperative or broker of any shipment of bulk tank raw milk for pasteurization, ultra-pasteurization, or aseptic processing when the shipment of bulk tank raw milk is found to be positive for drug residues. Nothing in this subdivision shall be deemed to include individual raw milk samples collected from each grade A dairy farm included in any shipment of bulk tank raw milk for pasteurization, ultra-pasteurization, or aseptic processing;
- h. 8. Test each producer sample of raw milk to determine the farm of origin represented by any sample of raw milk which tests positive for drug residues and immediately report

to the State Regulatory Authority the result of each producer sample representing the raw milk for pasteurization, ultra-pasteurization, or aseptic processing found to be positive for drug residues; and

- 9. Provide by facsimile machine or other electronic means to the Virginia Department of Agriculture and Consumer Services copies of load manifests, producer weight tickets, laboratory worksheets where the results of laboratory tests are originally recorded, and records from electronic readers documenting the results for samples tested for all positive loads; and
- i. 10. Immediately discontinue receiving shipments of raw milk from the grade A permit holder whose milk tests positive for drug residues, until subsequent tests by the State Regulatory Authority are no longer positive for drug residues and the producer has satisfied the requirements of subdivision B 13 of this section;
- B. Each grade A dairy farm permit holder's milk marketing cooperative or milk marketing agent shall be responsible for the collection and testing of follow-up milk samples for animal drug-residues required for permit reinstatement and resumption of milk shipment from the dairy farm each time the grade A dairy farm permit holder's milk test positive for animal drug-residues.
- C. Each grade A dairy farm permit holder's milk marketing cooperative or milk

  marketing agent shall comply with the following when following-up on a producer's dairy

  farm after a positive animal drug-residue:

1. Only person's who hold valid permits to weigh, sample and collect milk issued
by the Virginia Department of Agriculture and Consumer Services shall collect and
deliver follow-up milk samples to laboratories for official testing for the purpose of permit
reinstatement and the resumption of milk shipments from the dairy farm;
2. Reports of laboratory testing shall be provided from officially designated
laboratories for each milk sample tested for animal drug-residues and shall include the
following information:
a. The name of the grade A dairy farm permit holder;
b. The patron number of the grade A dairy farm permit holder;
c. The date, time and temperature of the milk sample when collected;
d. The name of the person who collected the milk sample;
e. The name of the test method used to test the milk sample; and
f. The test result for the milk sample; and
3. Only confirmation test methods approved under the current revision of M-I-96-
10 and titled "Drug Residue Test Methods for Confirmation of Presumptive Positive
Results and Initial Producer Traceback" may be used for follow-up milk sample testing.

# 2 VAC 5-490-120. Laboratory Certification.

A. Each grade A permit holder operating a dairy plant that receives any milk that could require load confirmation or producer trace-back as a result of a positive animal drug residue on a load of milk delivered at the plant shall provide to the Virginia Department

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of Agriculture and Consumer Services results of animal drug-residue tests from an officially designated laboratory. Each officially designated laboratory shall maintain a listing in the IMS List – Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers as an approved milk laboratory certified to test load and producer samples. All laboratory results from officially designated laboratories shall be reported to the Virginia Department of Agriculture and Consumer Services within six hours of the initial presumptive positive result at the plant. Existing dairy plants holding permits on the effective date of this regulation shall have until December 31, 2007 to comply with this section.

B. Each officially designated laboratory shall comply with the requirements contained in the "Evaluation of Milk Laboratories, 2005 revision" for certification and listing in the "IMS List – Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers".

## 2. 2 VAC 5-490-130. Disposal of adulterated milk.

Any Each grade A permit holder whose milk tests positive for drug residues shall dispose of such milk in a manner that removes it from the human food chain or in any manner approved by the Food and Drug Administration;

L. 2 VAC 5-490-140. Records of milk purchased or sold; list of sources.

Any Each grade A permit holder who operates a milk plant, receiving station, or transfer station, and any person who distributes milk or milk products shall furnish the State Regulatory Authority upon request:

- 1. A true statement of the quantities of milk and milk products of each grade purchased or sold by the milk plant, receiving station, transfer station, or distributor of milk or milk product; and
- 2. A list of all sources from which the milk plant, receiving station, transfer station, or distributor of milk or milk product, received milk or milk.
- J. 2 VAC 5-490-150. Receiving Raw or untreated sewage on a dairy farm prohibited.

  No person holding a grade A permit may operate a dairy farm that receives on the dairy farm raw or untreated sewage or septage from any septic tank, from any private or public sewage system, from any septic tank pump operator, from any hauler of septic tank waste or sewage, or from any other source;

#### K. 2 VAC 5-490-160. Milk that may be held in a milk storage tank.

No person who holds a grade A permit may place or hold in his milk storage tank: any milk except that milk which was obtained from cows, sheep, or goats, water buffalo, or other mammal milked at the grade A permit holder's dairy farm; any milk which did not enter the milk storage tank through the milking and milk-handling equipment on the grade A permit holder's dairy farm during the milking of the grade A permit holder's

cows, sheep, or goats, water buffalo, or other mammal; any milk which has been held without refrigeration; or which has been exposed to chemical or physical contamination; and.

L. 2 VAC 5-490-170. Commingling of milk from different species prohibited.

No person may produce, provide, manufacture in, sell, offer for sale, or store in the Commonwealth, or, bring, send, or receive into the Commonwealth, any milk, milk product, or condensed and dry milk product for use in the commercial preparation of grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products, any part of which is a combination of goat milk and cow milk, sheep milk and cow milk, or goat milk and sheep milk the milk from any two or more species of mammal.

2 VAC 5-490-180. Feeding poultry litter and unprocessed body discharges prohibited.

No person holding a grade A permit to produce milk for pasteurization, ultra
pasteurization or aseptic processing shall feed their lactating cows, goats, sheep, water

buffalo, or other milking mammals any unprocessed poultry litter or other unprocessed

body discharges from any animal.

2 VAC 5-490-190. Limit for aflatoxin residue in feed of lactating mammals.
No person holding a grade A permit to produce milk for pasteurization, ultra-pasteurization or aseptic processing shall feed their lactating cows, goats, sheep, water

buffalo, or other milking mammals any feed separately or in combination that contains an aflatoxin residue greater than 20 parts per billion.

2 VAC 5-490-200 Limit for aflatoxin residue in milk and milk products.

No person may sell or offer for sale any milk or milk product if it contains an aflatoxin residue equal to or greater than 0.50 parts per billion.

FOOTNOTE 2 "Milk and Dairy Beef Residue Prevention Protocol," available from Milk & Dairy Beef Quality Assurance Center, 801 Shakespeare, Box 497, Stratford, lowa 50294.

Pharmaceuticals, Using High Performance Liquid Chromatography: Comparison of Three Different Columns," Melina C. Villalobos, Norman R. Gregory & Martin P. Bueno, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Nutrition, HFF-266, Washington, D.C. 20204.

FOOTNOTE 4 "HPLC Assays for Vitamin A and E (HPLC Method 1)," available from Laboratory Assurance Branch, HFH-450, Division of Microbiology, Food and Drug Administration Center for food Safety, 6502 S. Archer Rd., Summit Argo, IL 60501-1399.

Bishop, Susan E. Duncan, Gerald M. Jones, and William D. Whittier, available from Food Science and Technology, Virginia Polytechnic Institute and State University, Blacksburg, VA 24061.

# Part V - Labeling

2 VAC 5-490-40 2 VAC 5-490-210. Labeling.

A. No person may produce, provide, manufacture, sell, offer for sale, or store in the Commonwealth or, bring, send into, or receive into the Commonwealth any milk, milk product, or condensed and dry milk product for use in the commercial preparation of grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products which are not labeled in compliance with the following:

- 1. Except for nutrition labeling, the Each grade A permit holder's bottles, containers, and packages enclosing any milk or milk products shall be labeled in accordance with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, the Fair Packaging and Labeling Act Nutrition Labeling and Education Act (NLEA) of 1990, and regulations developed there under;
- 2. The grade A permit holder shall label or mark all bottles, containers, and packages enclosing any milk or milk products with:

- a. The name of a defined milk product, if there is a definition, and if there is no definition, a name that is not false or misleading;
- b. The word "reconstituted" or "recombined" if the milk product is made by reconstitution or recombination;
- c. The term "grade A" located on the exterior of the package on the principal display panel, the secondary or informational panel, or the cap or cover;
- d. The identity of the plant where the grade A permit holder's milk or milk product is pasteurized, ultra-pasteurized, or aseptically processed by specifying:
- (1) The street address, city, state, and zip code of the plant; or
- (2) The code assigned the plant under the National Uniform Coding System for Packaging Identification of Milk and Milk Product Processing Plants.<sup>6</sup>
- e. In the case of concentrated milk, concentrated or concentrated milk products the volume or proportion of water to be added for recombining;
- f. The name of the milk product that the concentrated milk product will produce, which name shall be preceded by the term "concentrated." In the case of flavored milk or flavored reconstituted milk, the grade A permit holder shall substitute the name of the principal flavor for the word "flavored";
- g. In the case of aseptically processed milk and milk products the words "keep refrigerated after opening;"
- h. In the case of aseptically processed and packaged milk or milk products, the term "UHT" ultra-high-temperature;

- i. The term "ultra-pasteurized" if the milk or milk product has been ultra-pasteurized;
- j. The term "goat" preceding the name of the milk or milk product when the milk or milk product is goat milk or is made from goat milk;
- k. The term "sheep" preceding the name of the milk or milk product when the milk or milk product is sheep milk or is made from sheep milk;
- I. The term "water buffalo" preceding the name of the milk or milk product when the milk or milk product is water buffalo milk or is made from water buffalo milk;
- m. As in the case of cow's milk, goat's milk, sheep's milk, and water buffalo milk, the common or usual name of the mammal from which the milk was obtained shall precede the name of the milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product;
- Ln. The information appearing on the label of any bottle, container, or package of milk or milk product shall contain no marks, pictures, graphics, or words which are misleading; m-o. The "pull date" which shall not interfere with the legibility of other labeling required for the milk or milk product and shall be expressed by: the first three letters in the name of the month, followed by or preceded by the numeral or numerals constituting the calendar date after which the product shall not be sold or expressed numerically by the number of the month followed by the number of the day. For example, June 1 shall be expressed "JUN 1," "1 JUN," "06 01," or "06-01." Nothing in this chapter pertaining to pull dates shall apply to grade A pasteurized milk and grade A pasteurized milk products bottled in glass containers for home delivery;

n-p. The grade A permit holder who operates a milk plant and offers for sale milk or milk product within the Commonwealth shall file and certify with the State Regulatory Authority the maximum number of days after manufacturing or processing the grade A permit holder's milk or milk products which will be used to determine the "pull date". The grade A permit holder shall establish a "pull date" that under normal storage the milk or milk product meets for a minimum of 96 hours after the "pull date," standards set by this chapter;

- q. No person may sell or offer for sale any packaged grade A pasteurized milk, grade A pasteurized milk product, or milk product after the date of the "pull date" on the package;
- e g. No person may sell or offer for sale any grade A pasteurized milk, grade A pasteurized milk product, or milk product in a package that does not bear the "pull date;" and
- p r. Nothing in this chapter shall apply to containers of grade A pasteurized milk, grade

  A milk products, or milk products which are not to be sold in the Commonwealth.

  FOOTNOTE 6 "IMS LIST Sanitation Compliance and Enforcement Ratings of
  Interstate Milk Shippers," specifies the requirements for the "National Uniform Coding

  System for Packaging Identification of Milk and Milk Product Processing Plants" and list
  the code for each milk or milk product processing plant. This document is available

from the U.S. Food and Drug Administration, Milk Safety Branch, HFF-346,200 "C" St.,

S.W., Washington, D.C. 20204.

## Part VI – Standards for milk and milk products

2 VAC 5-490-50 2 VAC 5-490-220. Quality Standards standards for milk and milk products.

A. No person may produce, provide, manufacture, sell, offer for sale, or store in the Commonwealth, or, bring, send, or receive into the Commonwealth, any milk, milk product, or condensed milk product and or dry milk product for use in the commercial preparation of grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products which do not comply with the following:

- 1. Grade A raw milk for pasteurization or ultra-pasteurization or aseptic processing and all grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products shall be produced, processed, and pasteurized or ultra-pasteurized, or aseptically processed to conform with the following chemical, bacteriological, somatic cell, cryoscope, and temperature standards, and with the requirements of this chapter;
- 2. No process or manipulation other than (i) pasteurization; (ii) ultra-pasteurization; (iii) aseptic processing; or (iv) processing methods integral with pasteurization, ultra-pasteurization, or aseptic processing; and refrigeration may be applied to milk or milk products for the purpose of removing or deactivating microorganisms. Nothing in this chapter is deemed to prohibit any grade A permit holder who operates a milk plant from preparing bulk shipments of cream, skim milk, or lowfat milk labeled as "heat treated"; if the raw milk, raw cream, skim milk, or lowfat milk is heated, one time, to a temperature warmer than 125°F but cooler than 161°F for separation purposes;

- 3. Grade A raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall comply with the following standards:
- a. The temperature of the raw milk shall be cooled to 40°F or cooler, but not frozen, within two hours after milking and the temperature after the first or any subsequent milking shall not be warmer than 50°F;
- b. The bacteria count of the raw milk shall not exceed 100,000 bacteria per milliliter prior to commingling with any other milk; and the bacteria count of the raw milk that is commingled shall not exceed 300,000 bacteria per milliliter prior to pasteurization;
- c. Raw milk shall freeze at or below -0.530° Hortvet;
- d. Raw milk shall produce no zone greater than or equal to 16 millimeters when tested by the Bacillus sterothermophilus disc assay method or other equivalent method and shall have no positive results of tests for drug residues by detection methods reported to the State Regulatory Authority by official laboratories, officially designated laboratories, milk plants, receiving stations, or transfer stations;
- e. The somatic cell count of raw cow's milk, water buffalo's milk or raw sheep's milk shall not exceed 1,000,000 somatic cells per milliliter through June 30, 1993. Effective July 1, 1993, raw cow's milk or raw sheep's milk shall not exceed 750,000 somatic cells per milliliter. The somatic cell count of raw goat's milk shall not exceed 1,000,000 somatic cells per milliliter; and
- f. Raw milk shall not exceed the actionable level, tolerance level, or safe level for any chemical residue or pesticide residue specified in: 40 CFR Parts Part 180, 185, or 186;

and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, <del>564, 570, 573, 589.</del> In the event that no actionable level, tolerance level, or safe level for a chemical residue or pesticides residue has been established in 40 CFR Parts Part 180, 185, or 186; and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, <del>564, 570, 573, 589, the tolerance level shall be deemed to be zero, <u>;and</u></del>

- g. Raw milk shall not contain aflatoxin residues equal to or greater than 0.50 parts per billion as determined by the Charm II aflatoxin test or other equivalent method.
- 4. Grade A pasteurized or ultra-pasteurized, milk and milk products shall comply with the following standards:
- a. The temperature of milk products shall be cooled to 45°F or cooler (but not frozen) and maintained at that temperature;
- b. The bacteria count<sup>2</sup> for any milk or milk products (except cultured products) shall not exceed 20,000 bacteria per milliliter;
- c. Except for commingled milk shipped in a transport tank the coliform count for any milk or milk products shall not exceed 10 coliform organisms per milliliter. Commingled milk shipped in a transport tank shall not exceed 100 coliform organisms per milliliter;
- d. The phosphatase<sup>8</sup> test result of any milk or milk product shall be less than 1
  microgram per milliliter when tested by the Scharer Rapid Method or other equivalent
  method. The phenol value of test samples of pasteurized finished product shall be no
  greater than the maximum specified for the particular product as determined and

specified by: (1) any phosphatase test method prescribed in the eighteenth edition of Official Methods of Analysis published by the Association of Official Analytical Chemists; or (2) the Fluorometer test method; or (3) the Charm ALP test method; or (4) other equivalent method as determined by the Virginia Department of Agriculture and Consumer Services. A phenol value greater than the maximum specified for the particular product shall mean that the product was not properly pasteurized. A phenol value less than the maximum specified for the particular product shall not be deemed to mean that the product was properly pasteurized, unless there is evidence of proper pasteurization equipment in conformance with this chapter and records to determine an adequate pasteurization process has been completed for each separate batch or lot of milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product;

- e. Milk or milk products shall produce no zone greater than or equal to 16 millimeters when tested by the Bacillus sterothermophilus disc assay method or other equivalent method shall have no positive results of tests for drug residues by detection methods reported to the State Regulatory Authority by official laboratories, officially designated laboratories, milk plants, receiving stations, or transfer stations;
- f. Milk or milk products shall not exceed the actionable level, tolerance level, or safe level for any chemical residue or pesticide residue specified in: 40 CFR Parts Part 180, 185, or 186; and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 564, 570, 573, 589. In the event that no actionable

level, tolerance level, or safe level for a chemical residue or pesticides residue has been established in 40 CFR Parts Part 180, 185, or 186; and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 564, 570, 573, 589, the tolerance level shall be deemed to be zero-; and g. Milk or milk products shall not contain aflatoxin residues equal to or greater than 0.50 parts per billion as determined by the Charm II aflatoxin test or other equivalent method.

- 5. Grade A aseptically processed milk and milk products shall comply with the following standards:
- a. The bacteria count of any aseptically Aseptically processed milk and milk products shall demonstrate no growth be commercially sterile;
- b. Aseptically processed milk and milk products shall produce no zone greater than or equal to 16 millimeters when tested by the Bacillus sterothermophilus disc assay method or other equivalent method shall have no positive results of tests for drug residues by detection methods reported to the State Regulatory Authority by official laboratories, officially designated laboratories, milk plants, receiving stations, or transfer stations; and
- c. Aseptically processed milk and milk products shall not exceed the actionable level, tolerance level, or safe level for any chemical residue or pesticide residue specified in 40 CFR Parts Part 180, 185, or 186; and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 564, 570, 573, 589. In the event

that no actionable level, tolerance level, or safe level for a chemical residue or pesticides residue has been established in 40 CFR Parts Part 180, 185, or 186; and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 564, 570, 573, 589, the tolerance level shall be deemed to be zero-; and d. Aseptically processed milk and milk products milk shall not contain aflatoxin residues equal to or greater than 0.05 parts per billion.

- B. Sanitation requirements for grade A raw milk.
- 1. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall comply with:
- a. The following administrative procedures contained in the "Grade A Pasteurized Milk Ordinance-1989 Recommendations 2005 Revision": Section 4. Labeling, Items 1r, 2r, 3r, 4r, 5r, 6r, 7r, 8r, 9r, 10r, 11r, 12r, 13r, 13r(1), 13r(2), 13r(4), 13r(5), 14r, 15r, 16r.1 through 16r.10, 16r, 17r, 18r(2), 9r.2, 20r, and 21r, 19r, Section 8. Animal Health; Section 10. Transferring; Delivery Containers; Cooling; and Section 13. Personnel Health;
- b. The following appendices contained in the "Grade A Pasteurized Milk Ordinance-1989 Recommendations 2005 Revision": Appendixes A, B.I, B.IV, B.V, B.VI, B, C, D, F, and G, N, Q and R; and
- c. Item 1r. Abnormal milk. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

- (1) Milk last or with separate equipment cows, sheep, or goats, water buffalo, or other mammals which show evidence of the secretion of abnormal milk in one or more quarters (based upon bacteriological, chemical, or physical examination) and discard the milk obtained from cows, sheep, or goats, water buffalo, or other mammals which show evidence of the secretion of abnormal milk in one or more quarters based upon bacteriological, chemical, or physical examination and;
- (2) Milk last or with separate equipment cows, sheep, er goats, water buffalo, or other mammals treated with, or which have consumed, chemical, medicinal, or radioactive agents which are capable of being secreted in the milk and which may be deleterious to human health; and dispose of in a manner which will not pollute the environment or any human food the milk obtained from cows, sheep, er goats, water buffalo, or other mammals treated with, or which have consumed, chemical, medicinal, or radioactive agents which are capable of being secreted in the milk and which may be deleterious to human health;
- d. Item 2r. Milking barn, stable, or parlor-construction. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Provide on the persons dairy farm a milking barn, stable, or parlor in which the milking herd shall be housed during milking time; and
- (2) Provide on the grade A permit holder's dairy farm a milking barn, stable, or parlor which, milking barn, stable, or parlor shall:

- (a) Have floors constructed of concrete or equally impervious material;
- (b) Have walls and ceiling which are smooth, painted, or finished in an approved manner, and in good repair and have a ceiling which is dust tight;
  - (c) Have separate stalls or pens for horses, calves, and bulls;
  - (d) Have natural or artificial light, well distributed for day or night milking;
- (e) Have sufficient air space and air circulation to prevent condensation and excessive odors;
- (f) Have dust-tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed; and
  - (g) Not be overcrowded;
- (3) Provide and use only an "automatic milking installation" that complies with the requirements of Appendix Q of the "Grade A Pasteurized Milk Ordinance" if the person milks any cows, goats, sheep, water buffalo, or other mammals (except humans) using robots or other automated means in the absence of any human;
- e. Item 3r. Milking barn, stable, or parlor-cleanliness. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Keep the interior of the milking barn, stable, or parlor clean;
- (2) Keep the floors, walls, windows, pipelines, and equipment in the milking barn, stable, or parlor free of filth or litter and clean; and
  - (3) Keep swine and fowl out of the milking barn, stable, and parlor-; and

- (4) Keep surcingles, belly straps, milk stools and antikickers clean and stored above the floor;
- f. Item 4r. Cow yard, sheep yard, or goat yard, water buffalo yard or other milking mammal yard. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Provide and maintain the cow yard, sheep yard, or goat yard, water buffalo yard or other milking mammal yard, to be graded and drained, and to have no standing pools of water or accumulations of organic wastes;
- (2) In the cow loafing, goat loafing, sheep loafing, water buffalo loafing, or other milking mammal loafing, cattle-housing, sheep-housing, or goat-housing, water buffalo-housing, or other milking mammal-housing areas remove cow droppings, sheep droppings, and goat droppings, water buffalo droppings, and other milking mammal droppings and remove soiled bedding or add clean bedding at sufficiently frequent intervals to prevent the soiling of the cow's, sheep's, or goat's, water buffalo's, or other milking mammal's udders udder and flanks;
- (3) Assure that waste feed does not accumulate in the goat yard, cow yard, sheep yard, water buffalo yard, other milking mammal yard, cow loafing, sheep loafing, goat loafing, water buffalo loafing, other milking mammal yard, cattle-housing, sheep-housing, or other milking mammal-housing area;

- (4) Maintain any manure packs so as to be properly drained and so as to provide a reasonably firm footing; and
- (5) Keep swine and fowl out of the cow yard, sheep yard, goat yard, water buffalo yard, other milking mammal yard, cow loafing, sheep loafing, goat loafing, water buffalo loafing, other milking mammal loafing, cattle-housing, sheep-housing, or goat-housing, water buffalo-housing, or other milking mammal-housing area.
- g. Item 5r. Milkhouse or room-construction and facilities. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Provide a milkhouse or milkroom of sufficient size in which the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted except as provided for under 2 VAC 5-490-220(B)(1)(n);
- (2) Provide a milkhouse with a smooth floor, constructed of concrete or equally impervious material graded to drain, and maintained in good repair;
  - (3) Dispose of in a sanitary manner all liquid waste generated in the milkhouse;
- (4) Provide one or more floor drains in the milkhouse, which floor drains shall be accessible, and if connected to a sanitary sewer system trapped;
- (5) Provide in the milkhouse walls and ceilings constructed of a smooth material, in good repair, well painted, or finished in an equally suitable manner;
  - (6) Provide adequate natural or artificial light and ventilation in the milkhouse;
  - (7) Use the milkhouse for no other purpose than milkhouse operations;

- (8) Provide no direct opening from the milkhouse into any barn, stable, or into any room used for domestic purposes, other than a direct opening between the milkhouse and milking barn, stable, or parlor provided with a tight-fitting, self-closing, solid door, which door has been hinged to be single or double acting;
- (9) Provide in the milkhouse water under pressure which has been piped into the milkhouse;
- (10) Provide in the milkhouse a two-compartment wash vat and adequate hot water heating facilities and;
- (11) Except as provided for under 2 VAC 5-490-220(B)(1)(g)(12) Provide provide a suitable shelter for the receipt of milk when the grade A permit holder uses a transportation tank for the cooling and or storage of milk on the grade A permit holder's dairy farm, which shelter adjacent to, but not a part of, the milkroom; and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control, and general maintenance. In addition to providing a suitable shelter as required by this subsection, the grade A permit holder shall:
- a. Install an accurate, accessible temperature-recording device in the milk line used to fill the transportation tank downstream from an effective cooling device capable of cooling the milk to 40°F or less before the milk enters the transportation tank;
- b. Install an indicating thermometer as close as possible to the temperaturerecording device in the milk line used to fill the transportation tank to be used for verification of recording temperatures, which indicating thermometer shall:

- 1. Have a temperature span of not less than fifty degrees Fahrenheit including normal storage temperatures plus or minus five degrees Fahrenheit, with an extension of the scale on either side permitted and graduated in not more that two degree Fahrenheit divisions;
- 2. Have temperature scale divisions spaced not less that 0.0625 inches apart between 35 degrees Fahrenheit and 55 degrees Fahrenheit
- 3. Have an accuracy within plus or minus 2 degrees Fahrenheit throughout the scale range; and
- 4. Have the stem fitting installed in a pressure-tight seat or other sanitary fitting with no threads exposed;
- c. Provide an effective means to agitate the transport tank or an approved in-line sampling device in order to collect a representative milk sample;
- (12) If the State Regulatory Authority determines conditions exist whereby the milk transport tank may be adequately protected and sampled without contamination, a shelter need not be provided if the grade A permit holder:
- a. Provides a means to make all milk hose connections to the transport tank accessible from within the milkhouse;
- b. Provides a means to completely protect the milk hose connection to the transport tank from the outside environment;
- c. Ensures he utilizes only milk transport tanks the manholes of which have been sealed after cleaning and sanitizing

- d. Ensures he utilizes only milk transport tanks that have been washed and sanitized at permitted dairy plants or a permitted milk tank truck cleaning facilities acceptable to the State Regulatory Agency;
- e. Installs an accurate, accessible temperature-recording device in the milk line used to fill the transportation tank downstream from an effective cooling device capable of cooling the milk to 40°F or less before the milk enters the transportation tank;
- f. Installs an indicating thermometer as close as possible to the temperature-recording device in the milk line used to fill the transportation tank to be used for verification of recording temperatures, which indicating thermometer shall:
  - 1. Have a temperature span of not less than fifty degrees Fahrenheit including normal storage temperatures plus or minus five degrees Fahrenheit, with an extension of the scale on either side permitted and graduated in not more that two degree Fahrenheit divisions;
  - 2. Have temperature scale divisions spaced not less that 0.0625 inches apart between 35 degrees Fahrenheit and 55 degrees Fahrenheit
  - 3. Have an accuracy within plus or minus 2 degrees Fahrenheit throughout the scale range; and
  - 4. Have the stem fitting installed in a pressure-tight seat or other sanitary fitting with no threads exposed;
- g. Provides an effective means to agitate the transport tank or an approved inline sampling device in order to collect a representative milk sample; and

h. Provides a self-draining concrete or equally impervious surface on which the transport tank can be parked during filling and storage;

h. Item 6r. Milkhouse or milkroom-cleanliness. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

- (1) Keep clean the floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils, equipment, and other milkroom equipment in the milkroom;
  - (2) Place in the milkroom only those articles directly related to milkroom activities; and
  - (3) Keep the milkroom free of trash, animals, and fowl-;
- i. Item 7r. Toilets. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Provide on the person's grade A dairy farm one or more toilets, which shall be conveniently located and properly constructed, and operated, and maintained in a sanitary manner;
  - (2) Prevent the access of flies to the waste contained in or from the toilet;
- (3) Prevent the waste contained in or from the toilet from polluting the soil surface or contaminating any water supply; and
  - (4) Assure that there is no direct opening from the toilet into any milkroom-;
- j. Item 8r. Water supply. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

- (1) Provide water for milkhouse and milking operations from a water supply properly located, protected, and operated. The water supply shall be easily accessible, adequate, and of a safe, sanitary quality;
- (2) Assure that any well casing which is part of a water supply that provides water for any milkhouse or milking operation is not located closer to any source of contamination which may contaminate the water supply than is specified as follows:
- (a) No grade A permit holder may locate a well casing closer than 10 feet to a pit;
- (b) No grade A permit holder may locate a well casing closer than 10 feet to any sewer pipe, floor drain, or other pipe which may back up;
- (c) No grade A permit holder may locate a well casing closer than 50 feet to any aboveground gas, oil, petroleum, or chemical storage tank;
- (d) No grade A permit holder may locate a well casing closer than 50 feet to any accumulated animal manure;
- (e) No grade A permit holder may locate a well casing closer than 50 feet to any area to which livestock has access; or animal-holding area, feedlot, or loafing area on dirt;
- (f) No grade A permit holder may locate a well casing closer than 50 feet to any pit not drained to the surface of the ground. Nothing in this requirement shall apply to a residential basement;
- (g) From and after September 1, 1993, no No grade A permit holder may locate a well casing closer than 100 feet to any pit privy. Existing well casings located on grade A dairy farms holding valid permits issued by the State Regulatory Authority on

September 1, 1993, shall be exempt from the 100 foot distance requirement of this subdivision until the existing permit is canceled or revoked;

- (h) No grade A permit holder may locate a well casing closer than 100 feet to any animal-manure disposal area;
- (i) No grade A permit holder may locate a well casing closer than 100 feet to any cess pool;
- (j) No grade A permit holder may locate a well casing closer than 100 feet to any dry well;
- (k) No grade A permit holder may locate a well casing closer than 100 feet to any structure which stores animal manure;
- (I) No grade A permit holder may locate a well casing closer than 100 feet to any septic tank or drain field; and
- (m) No grade A permit holder may locate a well casing closer than 100 feet to any underground or partially-buried gas, oil, petroleum, or chemical storage tank;
- (3) Construct the water supply so that the well casing terminates at least two feet above the highest-known flood plane for the location in which the water supply is located; and
- (4) Construct the water supply so that no potable water supply pipe attached to the water supply is located closer than 10 feet measured horizontally to any sewer pipe, soil pipe, or drain.

k. Item 9r. Utensils and equipment-construction. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

- (1) Provide multiuse containers, equipment, and utensils for use in the handling, storage, or transportation of any milk, which multiuse containers, equipment, and utensils, shall be made of smooth, nonabsorbent, corrosion-resistant, and nontoxic materials; constructed as to be easily cleaned; and in good repair;
- (2) Provide milk pails which are constructed to be seamless and of the hooded type if the grade A permit holder does hand milking and stripping;
  - (3) Abstain from using multiple-use woven material for straining any milk;
- (4) Use only single-service articles which have been manufactured, packaged, transported, stored, and handled in a sanitary manner and that comply with the requirements of subdivision C 1 2 VAC5-490-220(C)(1)(m) of this section;
  - (5) Abstain from reusing any article intended for single-service use; and
- (6) Provide farm holding or cooling tanks, welded sanitary piping, and transportation tanks which comply with the requirements of subdivisions C 1 I, and C 1 m of this section 2 VAC 5-490-220(C)(1)(m) and 2 VAC 5-490-220(C)(1)(l) on any grade A dairy farm;
- I. Item 10r. Utensils and equipment; cleaning. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

- (1) Clean after each use the product-contact surfaces of all multiuse containers, multiuse equipment, and multiuse utensils used in the handling, storage, or transportation of any milk; and
- (2) Offer for sale or sell no milk which has passed through any equipment, if the milk-contact surfaces of the equipment are no longer visible, or are covered or partially covered by an accumulation of milk solids, milk fat, cleaning compounds or other soils. Any milk which passes through equipment, the milk-contact surfaces of which are no longer visible, or are covered or partially covered by an accumulation of milk solids, milk fat, cleaning compounds, or other soils shall be deemed adulterated;

  m. Item 11r. Utensils and equipment; sanitization. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall sanitize before each use the product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of any milk;
- n. Item 12r. Utensils and equipment; storage. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall store containers, utensils, and equipment used in the handling, storage, or transportation of any milk in a sanitizing solution or store the containers, utensils, and equipment used in the handling, storage, or transportation of any milk to assure complete drainage, and protected from contamination prior to use. Nothing in this requirement shall be deemed to prohibit a grade A permit holder from storing in a

milking barn or milking parlor a milk pipeline, or the following pipeline milking equipment: milker claw, inflation, weigh jar, meter, milk hose, milk receiver, tubular cooler, plate cooler, or milk pump; if the milk pipeline or pipeline milking equipment specified in this subdivision is designed for mechanical cleaning; and designed, installed, and operated to protect the milk product and solution-contact surfaces from contamination at all times;

- o. Item 13r. Utensils and equipment; handling. Any person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall handle all containers, utensils, and equipment in such a manner so as to prevent the contamination of any milk-contact surface of any containers, utensils, or equipment after the containers, utensils, or equipment have been sanitized Milking; flanks, udders, and teats. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Milk all cows, sheep, goats, water buffalo, and other mammals in a milking barn, stable, or parlor;
- (2) Trim the hair from the udder and tail of all milking cows, sheep, goats, water buffalo, and other mammals to facilitate cleaning of the udder and tail;
- (3) Keep the flanks, udders, bellies, and tails of all milking cows, sheep, goats, water buffalo, and other mammals free of visible dirt;
- (4) Keep the hair on the udders of all milking cows, sheep, goats, water buffalo and other mammals to a length that the hair on the udder of any cow, sheep, goat, water

buffalo, or other mammal can not be incorporated with the teat in the inflation during milking;

- (5) Abstain from milking any cow, sheep, goat, water buffalo, or other mammal whose udder or teats is not clean and dry;
- (6) Treat with a sanitizing solution, just prior to milking, the teats of each milking cow, sheep, goat, water buffalo, and other mammal and dry the teats of each milking cow, sheep, goat, water buffalo, and other mammal before milking; and
- -(1) Milk all cows, sheep, and goats in a milking barn, stable, or parlor;
- (2) Trim the hair from the udder and tail of all milking cows, sheep, and goats to facilitate cleaning of the udder and tail;
- -(3) Keep the flanks, udders, bellies, and tails of all milking cows, sheep, and goats free of visible dirt;
- (4) Keep the hair on the udders of all milking cows, sheep, and goats to a length that the hair on the udder of any cow, sheep, or goat can not be incorporated with the teat in the inflation during milking;
- (5) Abstain from milking any cow, sheep, or goat whose udder or teats is not clean and dry;

- (6) Treat with a sanitizing solution, just prior to milking, the teats of each milking cow, sheep, and goat, and dry the teats of each milking cow, sheep, and goat before milking; and
- (7) Milk all cows, sheep, and goats with dry hands Protection from contamination.

  Each person who holds a grade A permit to produce raw milk for pasteurization, ultrapasteurization, or aseptic processing shall:
- (1) Locate and operate the milking and milk house operations, equipment, and facilities to prevent any contamination of the milk, equipment, containers, or utensils;
- (2) Transfer immediately from the milking barn, stable, or parlor to the milkhouse each pail or container of milk;
- (3) Strain, pour, transfer, or store any milk unless it is protected from contamination;
- (4) Handle all containers, utensils and equipment that have been sanitized in such a manner as to prevent contamination of any product-contact surfaces;
- (5) Transport from the grade A permit holder's dairy farm to a milk plant or receiving station all milk in cans, using vehicles which are constructed and operated to protect the milk from sun, freezing, and contamination;
- (6) Keep clean the inside and outside of each vehicle used to transport from the grade

  A permit holder's dairy farm to a milk plant or receiving station any milk in cans; and

  (7) Transport no substance capable of contaminating the milk when transporting milk;

  q. Item 15r. Milking; surcingles, milk stools, and antikickers. Any person who holds a

  grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic

the floor Drug and chemical control. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Store all drugs and medicinals in such a manner that neither the drugs nor the medicinals can contaminate any milk or the milk product-contact surface of any equipment, containers or utensils;

- (2) Abstain from using unapproved or improperly labeled medicinals or drugs to treat any dairy animals or store unapproved or improperly labeled medicinals or drugs in the milkhouse, milking barn, stable or parlor. Except for topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage form vitamins and mineral products a drug or medicinal is properly labeled only if the drug or medicinal is labeled with the following:
- (a) For over-the-counter medicinals or drugs, the name and address of the manufacturer or distributor, or for prescription and extra-label use medicinals or drugs, the name of the veterinary practitioner dispensing the product;
  - (b) Directions for use of the drug or medicinal and the prescribed holding time;
  - (c) Any cautionary statement for the drug or medicinal, if needed; and
  - (d) The active ingredient or ingredients in the drug or medicinal;
- (3) Except for topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage form vitamins and mineral

products, segregate all medicinals and drugs used for lactating dairy animals from any medicinals and drugs used for nonlactating dairy animals;

- (4) Except for topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage form vitamins and mineral products, provide separate shelves in a cabinet, refrigerator, or other storage facility for the storage of all medicinals and drugs for treatment of nonlactating dairy animals separate from those medicinals or drugs used for lactating dairy animals; and
- (5) Store topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage-form vitamins and mineral products in a manner that does not contaminate any milk or the milk-product surfaces of any containers or utensils;
- r. Item 16r. Protection from contamination. Any person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Locate and operate the milking and milk house operations, equipment, and facilities to prevent any contamination of the milk, equipment, containers, or utensils;
- (2) Transfer immediately from the milking barn, stable, or parlor to the milkhouse each pail or container of milk;
- (3) Strain, pour, transfer, or store any milk unless it is protected from contamination;
- -(4) Store all drugs and medicinals in such a manner that neither the drugs nor the medicinals can contaminate any milk or the milk product-contact surface of any equipment, containers or utensils;

- (5) Abstain from using unapproved or improperly labeled medicinals or drugs to treat any dairy animals or store unapproved or improperly labeled medicinals or drugs in the milkhouse, milking barn, stable or parlor. Except for topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage form vitamins and mineral products a drug or medicinal is properly labeled only if the drug or medicinal is labeled with the following:

  (a) For over-the-counter medicinals or drugs, the name and address of the
- (a) For over-the-counter medicinals or drugs, the name and address of the manufacturer or distributor, or for prescription and extra-label use medicinals or drugs, the name of the veterinary practitioner dispensing the product;
- (b) Directions for use of the drug or medicinal and the prescribed holding time;
- (c) Any cautionary statement for the drug or medicinal, if needed; and
- (d) The active ingredient or ingredients in the drug or medicinal;
- (6) Except for topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage form vitamins and mineral products, segregate all medicinals and drugs used for lactating dairy animals from any medicinals and drugs used for nonlactating dairy animals;
- (7) Except for topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage form vitamins and mineral products, provide separate shelves in a cabinet, refrigerator, or other storage facility for the storage of all medicinals and drugs for treatment of nonlactating dairy animals separate from those medicinals or drugs used for lactating dairy animals; and

- (8) Store topical antiseptics, wound dressings, (unless intended for direct injection into the teat) vaccines and other biologics, and dosage-form vitamins and mineral products in a manner that does not contaminate any milk or the milk-product surfaces of any containers or utensils;
- s. Item 17r r. Item 16r. Personnel; hand-washing facilities. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall provide hand-washing facilities that are convenient to the milkhouse, milking barn, stable, or parlor, and flush toilet and that include separate hot and cold running water; soap or detergent; and individual sanitary towels;
- t. Item 18r s. Item 17r. Personnel; cleanliness. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Wash clean and dry with an individual sanitary towel the person's hands immediately before milking, before performing any milkhouse function, and immediately after the interruption of milking or performing any milkhouse function; and
- (2) Wear clean outer garments while milking or handling any milk, milk containers, utensils, or equipment. Milk Bulk milk haulers shall wear clean outer garments while handling any milk, milk containers, utensils, or equipment;
- u. Item 19r t. Item 18r. Cooling. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

- (1) Cool to 40°F or cooler (but not freeze), all raw milk for pasteurization, ultrapasteurization, or aseptic processing, within two hours after the grade A permit holder
  completes milking; and assure that the temperature of the grade A permit holder's raw
  milk is not warmer than 50°F after the first milking or any subsequent milking. Raw milk
  for pasteurization which is warmer than a temperature of 50°F after the first milking or
  any subsequent milking shall be deemed a public health hazard and shall not be offered
  for sale or sold; and
- (2) Agitate all raw milk for pasteurization for not less than five minutes at least once every hour; assure that the milk in the farm's bulk milk cooling or holding tank covers the agitator paddle sufficiently to facilitate proper cooling and sampling after the completion of the first milking; and abstain from selling or offering for sale milk which does not cover the agitator paddle sufficiently to facilitate facilitate proper cooling and sampling after the completion of the first milking;
- (v) Item 20r. Vehicles. Any person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:
- (1) Transport from the grade A permit holder's dairy farm to a milk plant or receiving station all milk in cans, using vehicles which are constructed and operated to protect the milk from sun, freezing, and contamination;
- (2) Keep clean the inside and outside of each vehicle used to transport from the grade
   A permit holder's dairy farm to a milk plant or receiving station any milk in cans; and
   (3) Transport no substance capable of contaminating the milk when transporting milk;

w. Item 21r u. Item 19r. Insect and rodent control. Any Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

- (1) Take effective measures to prevent the contamination of any milk, containers, equipment, and utensils by insects, rodents, and other animals, and by chemicals used to control insects, rodents, and other animals;
  - (2) Maintain the milkroom free of insects, rodents and other animals; and
- (3) Keep the areas surrounding the: milkhouse; milking barn; milking stable; milking parlor; cattle, sheep, water buffalo, other mammal, or goat housing; cattle, sheep, water buffalo, other mammal, or goat loafing; water supply; or other facilities on the grade A permit holder's dairy farm neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents; and

  (4) Store all feed in such a manner that the feed will not attract birds, rodents or
- C. Sanitation requirements for grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products.

insects.

- 1. Any Each person who holds a grade A permit to produce grade A pasteurized, ultrapasteurized, or aseptically processed milk or milk products shall comply with:
- a. The following administrative procedures contained in the "Grade A Pasteurized Milk Ordinance-1989 Recommendations 2005 Revision": Items 1p, 2p, 3p, 4p, 5p, 6p, 7p,

8p, 9p, 10p, 11p<del>.1 through 11p.9</del>, 12p<del>.1 through 12p.5, 12p.7</del>, 13p, 14p, 15p, 16p, 17p, 18p, 19p, 20p, 21p, and 22p<del>.</del>;

- b. The following appendices contained in the "Grade A Pasteurized Milk Ordinance-
  1989 Recommendations 2005 Revision": Appendices C, D, F, G, H, I, and J, K, L, N, O

  and R;
- c. Item 1p. Floors; construction. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Except as specified in subdivision C 1 c 2) C(1)(c)(2) of this section, provide floors, for all rooms in which milk or milk products are processed, handled, or stored, or in which milk containers, equipment, or utensils are washed constructed of concrete or other equally impervious and easily cleaned material and which are smooth, properly sloped, provided with trapped drains, and kept in good repair;
- (2) The floor in any cold-storage room used for storing milk and milk products need not be provided with floor drains if the floors are sloped to drain to one or more exits from the cold-storage room. The floor in any storage room used for storing dry ingredients or packaging materials need not be provided with drains and the floor in any storage room used for storing dry ingredients or packaging materials may be constructed of tightly joined wood;
- d. Item 2p. Walls and ceilings; construction. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk,

or milk products shall provide walls and ceilings of rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, or equipment are washed, that have a smooth, washable, light-colored surface, and that are in good repair;

- e. Item 3p. Doors and windows. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall provide:
- (1) Effective means to prevent the access of flies and rodents to any part of a milk plant, receiving station, or transfer station; and
- (2) Solid doors or glazed windows for all openings to the outside of any milk plant, receiving station, or transfer station and keep the doors and windows closed during dusty weather;
- f. Item 4p. Lighting and ventilation. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall provide rooms in which any milk or milk products are handled, processed, or stored or in which any milk containers, equipment, or utensils are washed, that are well lighted and well ventilated;
- g. Item 5p. Separate rooms. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

- (1) Provide separate rooms for: (i) pasteurizing, processing, cooling, and packaging milk er and milk products; (ii) cleaning milk cans, bottles, and cases; (iii) the fabrication of containers and closures for milk and milk products; (iv) cleaning and sanitizing facilities for bulk milk transport tanks if the grade A permit holder receives any milk or milk product in bulk milk transport tanks; and (iv v) receiving cans of milk and milk products separate from subdivisions (i), (ii), and (ii) (iii) of this subsection, unless all of the grade A permit holder's milk or milk products are received in bulk milk transport tanks;
- (2) Not use any room with a direct opening into any stable or room used for domestic purposes to handle, process, or store any milk or milk products or; wash or store any milk containers, utensils, or equipment; and
- (3) Use rooms of sufficient size so as not to be crowded to handle, process, or store any milk or milk products or wash or store any milk containers, utensils, or equipment; and
- (4) Provide designated areas or rooms for the receiving, handling and storage of returned packaged milk and milk products if the permit holder receives any returned packaged milk or milk products;
- h. Item 6p. Toilet-sewage disposal facilities. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall provide each milk plant with toilet facilities conforming with the regulations of the Commonwealth and the following requirements: no toilet room may

open directly into any room in which milk or milk products are processed; the toilet room shall be completely enclosed and shall have tight-fitting, self closing doors; the dressing room, toilet room, and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted; and sewage and other liquid wastes from the toilet room shall be disposed of in a sanitary manner;

- i. Item 7p. Water supply. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Provide water for each milk plant from a supply which is properly located, protected, and operated; and
- (2) Provide water from a supply which is easily accessible for inspection by the State Regulatory Authority, adequate, and of a safe, sanitary quality;

  j. Item 8p. Hand-washing facilities. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Provide hand-washing facilities, including separate hot and cold running water, mix valve, soap, and individual sanitary towels or other approved hand-drying devices, convenient in any area where milk or milk products are handled, processed, or stored, and any area where containers, utensils, or equipment, are washed or stored; and
  - (2) Keep the hand-washing facilities clean and in good repair;

k. Item 9p. Milk plant cleanliness. Any <u>Each</u> person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

- (1) Keep clean, neat, and free of any evidence of animals, insects or rodents, all rooms in which milk or milk products are handled, processed, or stored or in which containers, utensils, or equipment are washed or stored;
- (2) Use pesticides safely; and
- (3)(2) Permit only equipment directly related to processing operations or to the handling of containers, utensils, and equipment, in pasteurizing, processing, cooling, packaging, or bulk milk storage rooms;
- I. Item 10p. Sanitary piping. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Use only sanitary piping, fittings, and connections consisting of smooth, impervious corrosion-resistant, nontoxic, easily cleanable materials that are exposed to any milk or milk products, or from which liquids may drip, drain, or be drawn into any milk or milk products;
- (2) Keep all piping in good repair;
- (3) Except as specified in subdivision C 11 2 VAC 5-490-220(C)(1)(I)(4) of this section, use only sanitary piping to transfer any pasteurized or ultra-pasteurized milk or milk products from one piece of equipment to another piece of equipment; and

- (4) Transport cottage cheese, cheese dressings, or cheese ingredients by methods which protect the product from contamination;
- m. Item 11p. Construction and repair of containers and equipment. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Use only multiuse containers and equipment, that may come in contact with any milk or milk products constructed of smooth, impervious, corrosion-resistant, and nontoxic materials; constructed for ease of cleaning; and kept in good repair;
- (2) Use only single-service containers, closures, gaskets, and other articles, that may come in contact with any milk or milk products, that are nontoxic and have been manufactured, packaged, transported, and handled in a sanitary manner;
- (3) Abstain from using more than once any articles intended for single-service use; and (4) Use only single-service containers, closures, caps, gaskets, and similar articles manufactured, packed, transported, and handled in a manner which complies with the requirements of Appendix J., "Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products--1991 revision" contained in the
- n. Item 12p. Cleaning and sanitizing of containers and equipment. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

"Grade A Pasteurized Milk Ordinance, 2005 revision";

- (1) Effectively clean and sanitize before each use the product-contact surfaces of all multiuse containers and equipment, utensils, and equipment used in the transportation, processing, handling, and storage of any milk or milk products;
- (2) Use only multi-use containers for packaging pasteurized milk and milk products that comply with the following: (i) the residual bacteria count on multi-use containers may not exceed one per milliliter of capacity when the rinse test is used, or the residual bacteria count on multi-use containers shall not exceed 50 colonies per eight square inches (one per square centimeter) of product-contact surface, when the swab test is used; in three-out-of-four samples taken at random on a given day; and (ii) all multi-use containers shall be free of coliform organisms; and
- (3) Use only single-service containers for packaging pasteurized milk and milk products that comply with the following: (i) the residual bacteria count of single-service containers shall not exceed 50 per container, when the rinse test is used, except that in containers less than 100 milliliters, the count shall not exceed 10, or the residual bacteria count of single-service containers shall not exceed 50 colonies per eight square inches (one per square centimeter) of product contact surface, when the swab test is used; in three-out-of-four samples taken at random on a given day; and (ii) all single-service containers shall be free of coliform organisms;
- o. Item 13p. Storage of cleaned containers and equipment. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products, shall after cleaning any multiuse milk or milk product

containers, utensils, or equipment, transport or store the multiuse milk or milk product containers, utensils, or equipment in a manner that assures complete drainage and in a manner that protects the multiuse milk or milk product containers, utensils, or equipment from contamination before use;

- p. Item 14p. Storage of single-service containers, utensils, and materials. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Purchase all single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk or milk products, in sanitary tubes, wrappings, or cartons;
- (2) Store in a clean dry place until used, single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk or milk products;
- (3) Store single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk or milk products in sanitary tubes, wrappings, or cartons; and
- (4) Handle single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk or milk products in a sanitary manner;

- q. Item 15p. Protection from contamination. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Locate the person's equipment and facilities and conduct milk plant operations to prevent any contamination of any milk or milk products, ingredients, equipment, containers, or utensils;
- (2) Discard all milk, milk products, or ingredients which have been spilled, overflowed, or leaked;
- (3) Perform the processing and handling of products other than milk and milk products in the person's milk plant to preclude the contamination of any milk or milk products;
- (4) Store, handle, or use any toxic material to preclude the contamination of any milk, milk product, or ingredient, and the milk product contact surfaces of all equipment, containers, or utensils; and
- (5) Clean, prior to use, all multi-use cases used to encase packaged milk or milk product containers;
- r. Item 16p. Pasteurization and ultra-pasteurization. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Perform perform pasteurization, or ultra-pasteurization, or aseptic processing as defined in 2 VAC 5-490-10 of this chapter; and

- (2) Perform aseptic processing in compliance with the provisions of 21 CFR 113, 21

  CFR 108, and the Administrative Procedures of Item 16p., 16p.(C), 16.p(D), and 16.p(E)

  of the "Grade A Pasteurized Milk Ordinance, 2005 revision";
- s. Item 17p. Cooling of milk. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Maintain all raw milk and milk products at a temperature of 45°F or cooler, but not frozen, until processed;
- (2) Immediately cool, except for milk or milk products to be cultured, all pasteurized or ultra-pasteurized milk or milk products prior to filling or packaging in approved cooling equipment to a temperature of 45°F or cooler, but not frozen;
- (3) Store, transport and deliver at a temperature of 45°F or cooler, but not frozen, all pasteurized or ultra-pasteurized milk or milk products; and
- (4) Equip with an accurate thermometer each of the rooms or tanks in which any milk or milk products are stored;
- t. Item 18p. Bottling and packaging. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Bottle or package all milk or milk products (except for cottage cheese, dry curd cottage cheese and lowfat cottage cheese) at the place of pasteurization in the grade A permit holder's milk plant and in approved mechanical equipment; and

- (2) Transport all cottage cheese, dry curd cottage cheese, or lowfat cottage cheese not creamed or packaged in the grade A permit holder's milk plant in sealed containers and in a protected, sanitary manner from the grade A permit holder's milk plant to another grade A permit holder's milk plant for creaming or packaging;
- u. Item 19p. Capping. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Cap or close all milk or milk product containers in a sanitary manner by use of approved mechanical capping or closing equipment; and
- (2) Use only caps or closures for all milk or milk products, which protect the pouring lip of a milk or milk product container to at least its largest diameter and, use with respect to fluid product containers, only caps or closures that the removal of the cap or closure cannot be made without detection;
- v. Item 20p. Personnel; cleanliness. No person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:
- (1) Permit any person in a milk plant to commence any plant function before the person has thoroughly washed the person's hands to remove soil and contamination or to permit any person in a milk plant to continue any plant function if the person's hands are not clean;
- (2) Permit any person in a milk plant to resume work after the person has visited the toilet room before the person has thoroughly washed the person's hands;

- (3) Permit any person in a milk plant to engage in the processing, pasteurization, handling, storage, or transportation of any milk, milk products, containers, equipment or utensils, unless the person is wearing clean outer garments;
- (4) Permit any person in a milk plant, to engage in the processing of any milk or milk products unless the person wears adequate hair covering; or
- (5) Permit any person in a milk plant, to engage in the processing of any milk or milk products if the person is using tobacco;
- w. Item 21p. Vehicles. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall use vehicles to transport pasteurized and ultra-pasteurized milk and milk products that are constructed and operated so that the milk or milk products are maintained at a temperature of 45°F or cooler, but not frozen and protected from sunlight, from freezing, and from contamination;
- x. Item 22p. Surroundings. Any Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall keep neat, clean, and free from conditions which might attract or harbor flies, other insects, rodents, or which otherwise constitute a nuisance, the area surrounding any milk plant;
- y. Any Each grade A permit holder's receiving station shall comply with subdivisions C 1
  a 2 VAC 5-490-220(C)(1)(a) through q 2 VAC 5-490-220(C)(1)(q) of this section,
  inclusive, and subdivisions C 1, s, v, and x 2 VAC 5-490-220(C)(1)(s), 2 VAC 5-490-

220(C)(1)(v), and 2 VAC 5-490-220(C)(1)(x) of this section, except that the partitioning requirement of C 1 g 2 VAC 5-490-220(C)(1)(g) of this section shall not be deemed to apply;

- z. Any Each grade A permit holder's transfer station shall comply with subdivisions C-1 a, d, f, g, h, i, j, k, l, m, n, v, and x 2 VAC 5-490-220(c), 2 VAC 5-490-220(f), 2 VAC 5-490-220(f), 2 VAC 5-490-220(g), and 2 VAC 5-490-220(g) of this section; and as climatic and operating conditions require, the provisions of subdivisions C-1 b and c 2 VAC 5-490-220(d) and 2 VAC 5-490-220(e) of this section; except that each person shall provide overhead protection for a transfer station;
- a1. Any Each grade A permit holder's facilities for the cleaning and sanitizing of bulk tanks which transport milk and milk products in the grade A permit holder's milk plant, receiving station, or transfer station shall comply with subdivisions C 1 a, d, f, g, h, i, j, k, l, m, n, v, and x 2 VAC 5-490-220(C)(1)(a), 2 VAC 5-490-220(C)(1)(f), 2 VAC 5-490-220(C)(1)(p), 2 VAC 5-490-220(C)(1)(p), 2 VAC 5-490-220(C)(1)(p), 2 VAC 5-490-220(C)(1)(q), 2 VAC 5-490-220(C)(1)(v), and 2 VAC 5-490-220(C)(1)(x) of this section; and as climatic and operating conditions require, the provisions of subdivisions C 1 b and c 2 VAC 5-490-220(C)(1)(d) and 2 VAC 5-490-220(C)(1)(e) of this section except that each grade A permit holder shall provide overhead protection for facilities for the cleaning and sanitizing of bulk tanks which transport milk and milk products in the grade A permit holder's milk plant, receiving station, or transfer station.

FOOTNOTE 7 The bacteria limit standard is not applicable to cultured milk products.

FOOTNOTE 8 The phosphatase standard is not applicable to bulk shipped heat treated milk products.

FOOTNOTE 9 "Grade A Pasteurized Milk Ordinance -1989 Recommendations" is available from U.S. Food and Drug Administration, Milk Safety Branch, HFF-346, 200 "C" St., S.W., Washington, D.C. 20204.

FOOTNOTE 10 "Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products," 1991 revision, is available from the U.S. Food and Drug Administration, Milk Safety Branch, HFF-346, 200 'C' St., S.W., Washington, D.C. 20204.

# Part VII - Animal health

2 VAC 5-490-60. 2 VAC 5-490-230. Animal health.

<u>A.</u> No person may produce, provide, manufacture sell, offer for sale, store in the Commonwealth, or, bring, send, or receive into the Commonwealth any milk, milk product, or condensed and dry milk product for use in the commercial preparation of grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk product unless the person complies with the following requirements:

1. Milk for pasteurization or ultra-pasteurization or aseptic processing <u>from cows, goats, sheep, water buffalo, and other mammals</u> shall be from a herd <u>or flock</u> that complies

with the "Uniform Methods and Rules; Bovine Tuberculosis Eradication-effective February 3, 1989," January 1, 2005, 9 CFR Part 77, and Each herd or flock shall be located in a Modified Accredited Tuberculosis Area or an Area Accredited Free of Bovine Tuberculosis as defined in "Uniform Methods and Rules; Tuberculosis Eradication-effective February 3, 1989 January 1, 2005," and certified by the U.S. Department of Agriculture or shall have passed an annual tuberculosis test:

- 2. Milk for pasteurization or ultra-pasteurization or aseptic processing <u>from bison and cattle</u> shall be from a herd that complies with "Uniform Methods and Rules; Brucellosis Eradication-effective <u>May 6, 1992 October 1, 2003</u>," <sup>42</sup> 9 CFR Part 78; and the following:
- (a) Each herd shall be located in a Certified Brucellosis-Free Area or a Modified Certified Brucellosis Area as defined in "Uniform Methods and Rules; Brucellosis Eradication-effective May 6, 1992 October 1, 2003," and certified by the United States Department of Agriculture and enrolled in a testing program for the Certified Brucellosis-Free Area or the Modified Certified Brucellosis Area; or
- (b) Each herd shall meet the requirements for an individually certified herd as defined in "Uniform Methods and Rules; Brucellosis Eradication-effective May 6, 1992 October 1, 2003"; or
- (c) Each herd shall participate in a milk ring testing program meeting the requirements specified in "Uniform Methods and Rules; Brucellosis Eradication-effective May 6, 1992 October 1, 2003," in an area that conducts a milk ring testing program at least four two

times per year at approximately equal intervals, and any herd with a positive milk ring test result shall be blood tested within 30 days from the date of the positive milk ring test; or

- (d) Each cow, bull, heifer, calf, and bison in the herd shall be individually tested by an "official" blood test as defined in "Uniform Methods and Rules; Brucellosis Eradication" for the detection of brucellosis annually;
- 3. Goat's milk and , sheep's milk, water buffalo milk and milk from other mammals(except bison and cattle) for pasteurization or ultra-pasteurization or aseptic processing shall be from a herd or flock which:
- (a) has Has passed an annual whole-herd tuberculosis and brucellosis test; and or
  (b) Has passed an initial whole herd or flock brucellosis test, followed by the testing of
  all replacement animals or any animals entering the milking group or sold as dairy
  animals on a continuing basis; or
- (c) Has passed an annual random blood-testing program sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found. The following table provides the random sampling size needed to achieve a 99% confidence with a P value of 0.05:

Herd/Flock Size	Sampling Size	Herd/Flock Size	Sampling Size
<u>20</u>	<u>20</u>	<u>500</u>	<u>82</u>
<u>50</u>	41	<u>600</u>	<u>83</u>

<u>100</u>	<u>59</u>	<u>700</u>	<u>84</u>
<u>150</u>	<u>67</u>	800	<u>85</u>
200	<u>72</u>	<u>1000</u>	<u>86</u>
<u>250</u>	<u>75</u>	<u>1400</u>	<u>87</u>
300	<u>77</u>	<u>1800</u>	<u>88</u>
<u>350</u>	<u>79</u>	<u>4000</u>	<u>89</u>
400	<u>80</u>	10000	<u>89</u>
<u>450</u>	<u>81</u>	<u>100000</u>	<u>90</u>

<u>; or</u>

- (d) Has passed a USDA approved bulk milk Brucellosis test certified for use in each species of mammal and at the USDA recommended frequency for testing; and
- 4. For diseases of cows, sheep, or goats, water buffalo or other mammals which might affect human health, other than brucellosis and tuberculosis, the State Regulatory Authority may require physical, chemical, or bacteriological examinations or other tests as may be deemed necessary by a licensed veterinarian or a veterinarian in the employ of the State Regulatory Authority to diagnose the disease. Each grade A permit holder shall dispose of any diseased animal disclosed by testing in a manner which prevents the spread of the disease to other animals or humans.
- B. Each grade A dairy farm permit holder shall test his whole herd of milking mammals for Brucellosis using a test method acceptable to a licensed veterinarian or a

veterinarian in the employ of the State Regulatory Authority within thirty days after each positive screening test result on a milk ring test.

effective February 3, 1989," is available from Veterinary Services, Animal and Plant
Health Inspection Service, U.S. Department of Agriculture, Federal Center Building,
Hyattville, Maryland, 20782 or Federal Veterinarian in Charge, VS, APHIS, USDA, Sixth
Floor, Washington Building, 1100 Bank St., Richmond, VA 23219.

FOOTNOTE 12 "Uniform Methods and Rules; Brucellosis Eradication-effective May 6, 1992" is available from Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Center Building, Hyattville, Maryland, 20782 or Federal Veterinarian in Charge, VS, APHIS, USDA, Sixth Floor, Washington Building, 1100 Bank St., Richmond, VA 23219.

Part VIII – Milk and milk products which may be sold 2 VAC 5-490-70. 2 VAC 5-490-240. Milk or milk products which may be sold.

A. Except as specified in subsection B of this section from and after the date this chapter are effective, a person may sell, offer for sale, or expose for sale in the Commonwealth only grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products to the final consumer, or to restaurants, soda fountains, and grocery stores.

B. No person may sell, offer for sale, or expose for sale in the Commonwealth any pasteurized, ultra-pasteurized, or aseptically processed milk or milk products which have not been graded or the grade of which is not known to the final consumer, or to restaurants, soda fountains, and grocery stores unless the Commissioner of Agriculture and Consumer Services makes a finding in writing (which the Commissioner of Agriculture and Consumer Services may renew for terms not to exceed 90 days per term, without limitation) that the supply of grade A raw milk for pasteurization, ultra-pasteurization, or aseptic processing is not adequate to meet the nutritional needs of any person who secures milk in Virginia; or the supply of pasteurized, ultra-pasteurized, or aseptically processed milk or milk product at retail is not available for purchase by any person who secures milk in Virginia.

C. No person may sell, offer for sale or, expose for sale in, or possess in the Commonwealth any pasteurized, ultra-pasteurized, or aseptically processed milk or milk products under the provision of subsection B of this section unless the milk or milk product is labeled "ungraded."

2 VAC 5-490-250. Mandatory pasteurization for all milk, milk products, condensed milk, condensed milk products, dry milk, and dry milk products in final package form intended for direct human consumption.

No person shall cause to be delivered into intrastate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in intrastate commerce any milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product in final package form for direct human consumption unless the product has been pasteurized or is made from milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product that has all been pasteurized, except where alternative procedures to pasteurization are provided for under 21 CFR part 133 for curing of certain cheese varieties.

2 VAC 5-490-260. Sale of unpasteurized milk for human consumption prohibited.

No person may offer to sell or sell, barter, trade, or accept any goods or services in exchange for unpasteurized milk if the unpasteurized milk is intended for human consumption.

2 VAC 5-490-80. 2 VAC 5-490-270. Transferring, delivery containers, cooling.

A. No person, except as authorized in this chapter, may transfer any milk or any milk product from one container or tank truck to another container or tank truck in any place except a milk plant, receiving station, transfer station, or milkhouse especially used for that purpose and no person may dip or ladle any milk or milk product;

B. No person may sell or serve to the public any milk or fluid milk product except in the individual, original container received from the milk distributor, or from an approved bulk

dispenser. Nothing in subsection A of this section prohibits any person from transferring milk from one container to another container for the purpose of mixing drinks, if the amount of milk required is less than one-half pint of milk; or using an original container of not more than one-half gallon capacity or an approved bulk dispenser to serve cream, whipped cream, or half-and-half, which is to be sold or served to the public;

C. No person may sell or serve to the public any pasteurized or any ultra-pasteurized milk or milk product which has not been maintained at a temperature of 45°F or cooler, but not frozen. No person may store any pasteurized or ultra-pasteurized containers of milk or milk products in ice unless the container is properly drained.

2 VAC 5-490-90. 2 VAC 5-490-280. Milk and milk products from beyond the limits of routine inspection.

No person may provide, sell, offer for sale or, store in the Commonwealth or, bring, send, or receive, in the Commonwealth any condensed milk, condensed milk product, dry milk, dry milk product, milk or milk product from outside the Commonwealth unless the condensed milk, condensed milk product, dry milk, dry milk product, milk or milk products are produced and pasteurized, ultra-pasteurized, or aseptically processed under regulations which are substantially equivalent to this chapter and the supply of the milk er and the milk plant that produced the condensed milk, condensed milk product, dry milk, dry milk product, milk or milk product has been awarded a milk sanitation compliance rating of at least 90 and an enforcement compliance rating of at

least 90, or awarded an acceptable HACCP listing made by a state milk sanitation rating listing officer certified by the United States Public Health Service. The State Regulatory Authority may impound any condensed milk, condensed milk product, dry milk, dry milk product, milk or milk product within the Commonwealth of Virginia if it does not comply with the requirements of this section.

Part IX – Construction plans for dairy farms and milk plants 2 VAC 5-490-100. 2 VAC 5-490-290. Construction plans for dairy farms and milk plants.

No grade A permit holder may construct, reconstruct, or modify a milkhouse, milking barn, stable, or parlor, transfer station, receiving station, or milk plant regulated under this chapter without submitting to the State Regulatory Authority written plans for review and approval before construction work is begun.

2 VAC 5-490-300. Equipment and facilities - accessibility for inspection.
Each grade A permit holder shall ensure that their facilities and equipment are accessible for inspection by complying with the following:

1. Concrete lids, covers and access doors to each well house, water supply, or pump house shall be easily lifted or opened by a single person and require the person to lift no more than eighty pounds to gain free access to the facilities for inspection;

- 2. If the permit holder locks any portion of their facilities requiring inspection; the permit holder; upon request, shall provide the State Regulatory Authority with keys to open the facilities or the combination code for each lock to unlock the facilities or the permit holder shall ensure that he or his agent is always available on the premises to provide access to the locked facilities during all normal inspection times;
- 3. If the permit holder installs floor mats on cow standing surfaces in the milking parlor or barn; the entire area of the floor underneath of the floor mats shall be accessible for inspection by a single person working continuously for twenty minutes including the time necessary to lift and replace the floor mats on the floor;
- 4. If the permit holder installs any equipment that requires a tool or tools to be disassembled for inspection; the permit holder shall provide the tool or tools freely accessible to the State Regulatory Authority during all normal inspection times;
- 5. If the permit holder installs any equipment requiring inspection in an attic, loft, pit, or other area requiring a ladder for access; the permit holder shall provide a ladder convenient to each of these areas during all normal inspection times; and
  6. If the permit holder installs any milk lines or other milking equipment, milk
  transfer or wash solution lines in an attic, loft, pit, or other area not visible from
  below by the State Regulatory Authority; the permit holder shall ensure that all

fittings and joints are welded and contain no gaskets or joints that could leak and that the interior surfaces of all milk lines or other milking equipment, milk transfer or wash solution lines is fully accessible for inspection from outside the attic, loft, pit, or other area not visible from below.

2 VAC 5-490-310. New or test facilities and equipment; equipment design, construction and approval process.

A. At the request of any grade A permit holder the State Regulatory Authority may allow the temporary installation of equipment or the temporary construction of dairy facilities that the State Regulatory Authority has no or limited regulatory experience with; on a trial basis, to determine if the equipment or dairy facilities can comply with the requirements of this chapter under normal conditions of use. The State Regulatory Authority will at a minimum evaluate the equipment or facilities for compliance with the requirements of this chapter when newly installed, as well as, complete a separate evaluation of the inspection record during the trial of the equipment or facilities to comply with the requirements of this chapter over time under normal conditions of use.

B. At the conclusion of each trial the State Regulatory Authority shall inform the grade A permit holder in writing if the equipment or facilities or both the equipment and facilities comply with the requirements of this chapter. If the equipment or facilities do not comply or both the equipment and facilities do not comply with the requirements of this chapter the State Regulatory Authority shall inform the grade A permit holder in

writing to alter or remove his equipment or facilities or to alter or remove both his
equipment and facilities within a maximum of six months from the date of receipt of the
written decision by the permit holder.

- C. The State Regulatory Authority shall not renew or extend any temporary installation of equipment or the temporary construction of dairy facilities beyond the time specified in the written agreement between the grade A permit holder and the State Regulatory Authority for more than one year after the time specified in the written agreement for any reason. The State Regulatory Authority shall not accept any agreement between the grade A permit holder and the State Regulatory Authority for the temporary installation of equipment or the temporary construction of dairy facilities that proposes to be evaluated for a period longer than one year.
- D. If the State Regulatory Authority agrees to allow the temporary installation of equipment or the temporary construction of dairy facilities, the State Regulatory

  Authority and the grade A permit holder installing the equipment or constructing the facilities shall each sign a written agreement that at a minimum includes:
  - A description of the equipment or facilities and detailed plans for their installation acceptable to the State Regulatory Authority;
  - 2. The name of the grade A permit holder and the physical address where the equipment or facilities will be installed;
  - 3. The name and contact information for the person or persons who will be installing the equipment or constructing the facilities;

### 4. A detailed plan including:

- A description of the items to be evaluated by the State Regulatory
   Authority;
- b. Criteria to judge the acceptability of performance by which each
   item being evaluated will be measured by the State Regulatory Authority;
- A time table specifying the length of the trial, the minimum number
   of inspections and time periods between inspections;
- d. How inspection findings will be documented and reviewed with the permit holder and at what frequency;
- e. A provision for the State Regulatory Authority to end the temporary installation agreement before the completion of the timeline and reject the equipment or facilities as not complying with the requirements of this chapter if continuation of the trial will not substantially affect the decision of the State Regulatory Authority;
- f. A provision that at the end of the timeline specified in the agreement; the permit holder will remove or alter the equipment or facilities within a maximum of six months from the date he receives written instruction to do so from the State Regulatory Authority to comply with the requirements of this chapter if the State Regulatory Authority does not approve the equipment or facilities; and

g. A provision that the permit holder's failure to remove or alter the equipment or facilities to comply with the requirements of this chapter within six months after receipt of written instructions from the State Regulatory Authority shall be considered sufficient cause for permit suspension.

Part X – Personnel health

2 VAC 5-490-110. 2 VAC 5-490-320. Personnel health.

A. No person affected with any disease in a communicable form, or while a carrier of a communicable disease, may work at any dairy farm or milk plant in any capacity which brings the person into contact with the production, handling, storage, or transportation of milk or milk products, or into contact with milk or milk product containers, equipment, or utensils.

- B. No person holding a grade A permit may employ any person having, or suspected of having, any disease in a communicable form, or of being a carrier of a communicable disease.
- C. Any grade A permit holder who produces or distributes milk or milk products, or condensed or dry milk products upon whose dairy farm, or in whose milk plant any communicable disease occurs, or who suspects that any employee has contracted any disease in a communicable form, or has become a carrier of a communicable disease, shall notify the State Regulatory Authority immediately.

2 VAC 5-490-120. 2 VAC 5-490-330. Procedure when infection is suspected.

When reasonable cause exists to suspect the possibility of transmission of infection of a communicable disease from any person concerned with the handling of milk or milk products to any other person, the person concerned with the handling of milk or milk products and the person holding the grade A permit shall comply with the following measures:

- 1. The immediate exclusion of that person from milk handling;
- 2. No grade A permit holder may sell or offer for sale any milk or milk products that have been handled by or exposed to a person who is suspected of having a communicable disease or being a carrier of a communicable disease; and
- 3. Any Each person who is suspected of having a communicable disease or being a carrier of a communicable disease and his associates, at the discretion of the State Regulatory Authority, shall submit to medical and bacteriological examination by a licensed physician in the Commonwealth sufficient to make a medical diagnosis.

2 VAC 5-490-130. Grade A condensed and dry milk products and condensed and dry whey.

No person may produce, provide, manufacture, sell, offer for sale, or store in the Commonwealth, or, bring, send, or receive in, the Commonwealth any condensed and dry milk product for use in the commercial preparation of grade A pasteurized, ultra-

pasteurized, or aseptically processed milk or milk product if the person does not comply with:

1. The following sections of Part II of the "Grade A Condensed and Dry Milk Products and Condensed and Dry Whey - Recommended Sanitation Ordinance for Condensed and Dry Milk Products and Condensed and Dry Whey used in Grade A Pasteurized Milk Products - Supplement I to the Grade A Pasteurized Milk Ordinance - 1978

Recommendations of the United States Public Health Service Food and Drug Administration, 1978 Edition"13 and "Supplement I - 1978 Grade A Condensed & Dry Milk Ordinance (DMO)": 14

- Section 2;
- Section 4;
- Section 7 (except that the temperature standard for grade A raw milk for pasteurization shall be 40°F or cooler, but not frozen);
- Section 8;
- Section 9;
- Section 10;
- Section 11; and
- 2. The following appendices contained in the "Grade A Condensed and Dry Milk

  Products and Condensed and Dry Whey Recommended Sanitation Ordinance for

  Condensed and Dry Milk Products and Condensed and Dry Whey used in Grade A

  Pasteurized Milk Products Supplement I to the Grade A Pasteurized Milk Ordinance -

1978 Recommendations of the United States Public Health Service Food and Drug Administration, 1978 Edition:"

Appendices A, B, C, D, E, F, and H.

Pry Whey", supplement I to the "Grade A Pasteurized Milk Ordinance", 1978

recommendations, is available from U.S. Food and Drug Administration, Milk Safety

Branch, HFF-346, 200 "C" St., S.W., Washington, D.C. 20204.

FOOTNOTE 14 "Supplement I--1978 Grade A Condensed & Dry Milk Ordinance (DMO)" was issued December 11, 1992 and is available from U.S. Food and Drug Administration, Milk Safety Branch, HFF-346, 200 "C" St., S.W., Washington, D.C. 20204.

# Part XI - Voluntary HACCP program

## 2 VAC 5-490-340. HACCP program participation voluntary.

A. Participation in the HACCP program is voluntary for each person who operates a dairy plant, receiving station or transfer station and the State Regulatory Authority responsible for the permitting and auditing of each person's dairy plant, receiving station or transfer station. No person operating a milk plant, receiving station or transfer station may participate in the voluntary HACCP program unless the State Regulatory Agency

responsible for the permitting and auditing of each person's dairy plant agrees to participate in the voluntary HACCP program also.

- B. Each person volunteering to operate their milk plant, receiving station or transfer station under the voluntary HACCP program shall provide a written commitment to the State Regulatory Authority responsible for their milk plant, receiving station or transfer station that they will supply the necessary resources to support participation in the voluntary HACCP program.
- C. Each State Regulatory Authority volunteering to participate in the voluntary HACCP program shall provide a written commitment to the person requesting to operate a milk plant, receiving station or transfer station under the voluntary HACCP program that the State Regulatory Authority will supply the necessary resources to support participation in the voluntary HACCP program.
- D. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall have a minimum of sixty days of HACCP System records prior to a HACCP listing audit. Each milk plant, receiving station or transfer station shall be inspected and permitted initially by the State Regulatory Authority and shall be regulated initially under the requiremetrs of this chapter without taking into consideration the provisions of Part XI Voluntary HACCP program until the State Regulatory Authority conducts an acceptable HACCP listing audit documenting the successful implementation of a fully functioning HACCP System in the person's milk plant, receiving station or transfer station.

- E. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:
  - Comply with all of the provisions applicable to the voluntary HACCP program contained in:
    - a. Section 7. Standards for grade "A" milk and milk products;
    - b. <u>Item 16p. Pasteurization and aseptic processing</u>;
    - c. <u>Item 16p(E) Pasteurization and aseptic processing records, equipment tests and examinations;</u>
    - d. Section 13. Personnel health;
    - e. Section 14. Procedure when infection or high risk of personnel health;
    - f. Appendix H. Pasteurization Equipment and procedures;
    - g. Appendix I. Pasteurization equipment and controls tests;
    - h. Appendix K. HACCP Program; and
    - i. Appendix R. Determination of Time/Temperature Control for Safety of Milk and Milk Products contained in the "Grade A Pasteurized Milk Ordinance,
       2005 revision;
    - 2. <u>Prepare their HACCP Plan based on the following HACCP principles:</u>
      - a. Conduct a hazard analysis;
      - b. <u>Determine the critical control points</u>;
      - c. Establish critical limits;
      - d. Establish monitoring procedures;

- e. Establish corrective actions;
- f. Establish verification procedures; and
- g. <u>Establish record-keeping and documentation procedures</u>;
- 3. Prior to the implementation of a HACCP Plan develop, document and successfully implement written prerequisite programs which provide the basic environment and operating conditions that are necessary for the production of safe, wholesome food.
- 2 VAC 5-490-350. Implementation of a HACCP System; Prerequisite programs.
- A. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:
  - 1. Provide complete, up-to-date process flow diagrams for all grade A milk, milk products, condensed milk, condensed milk products, dry milk or dry milk products prior to developing the HACCP Plan;
  - 2. Provide a brief written description or checklist for each prerequisite program that can be audited against to endure compliance. Each prerequisite program shall include procedures that can be monitored; records that specify what is monitored; and how often it will be monitored;
  - 3. <u>Develop and implement prerequisite programs that address conditions and</u> practices before, during, and after processing;
    - 4. Develop and implement prerequisite programs that address:

- a. Safety of the water that comes into contact with milk, milk products,
   condensed milk, condensed milk products, dry milk, dry milk products or
   product-contact surfaces, including steam and ice;
- b. <u>Condition and cleanliness of equipment product-contact surfaces;</u>
- c. Prevention of cross-contamination from unsanitary objects and or practices to milk, milk products, condensed milk, condensed milk products, dry milk, dry milk products or product-contact surfaces, packaging material and other food-contact surfaces, including utensils, gloves, outer garments, etc, and from raw product to processed product;
- d. Maintenance of hand washing, hand sanitizing, and toilet facilities;
- e. Protection of milk, milk products, condensed milk, condensed milk

  products, dry milk, dry milk products, packaging material, and product-contact

  surfaces from adulteration with lubricants, fuel, pesticides, cleaning

  compounds, sanitizing agents, condensate and other chemical, physical and

  biological contaminates;
- f. Proper labeling, storage, and use of toxic compounds;
- g. Control of employee health conditions, including employee exposure to high risk situations, that could result in the microbiological contamination of milk, milk products, condensed milk, condensed milk products, dry milk, dry milk products, packaging materials, and product-contact surfaces; and
- h. <u>Pest exclusion from the milk plant, receiving station or transfer station;</u>

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- 5. In addition to the required prerequisite programs specified in this section, any other prerequisite programs that are being relied upon in the Hazard Analysis to reduce the likelihood of hazards such that they are not reasonably likely to occur, shall also be monitored, audited, and documented as required prerequisite programs.
- B. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:
  - 1. Monitor the conditions and practices of all required prerequisite programs with sufficient frequency to ensure conformance with those conditions and that are appropriate both to the milk plant, receiving station or transfer station and to the safety of the milk, milk products, condensed milk, condensed milk products, dry milk or dry milk products being processed;
  - 2. <u>Document the correction of those conditions and practices that are not in conformance with all prerequisite programs;</u>
  - 3. <u>Determine the frequency of calibration for indicating thermometers, recording thermometers, and other devices used to monitor prerequisite programs and ensure that they are properly calibrated to assure accuracy at the determined frequency; and</u>
  - 4. <u>Maintain records that document the monitoring and corrections required by</u> their prerequisite programs for review by the State Regulatory Authority.

2 VAC 5-490-360. Implementation of a HACCP System; Hazard analysis.

- A. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:
  - 1. Develop, or have developed for it, a written hazard analysis to determine whether there are hazards that are reasonably likely to occur for each type of milk, milk product, condensed milk, condensed milk product, dry milk, dry milk product processed or handled by the milk plant, receiving station or transfer station and to identify the control measures that the milk plant, receiving station or transfer station can apply to control those hazards;
  - 2. Include in the hazard analysis, hazards that can be introduced both within and outside the milk plant, receiving station or transfer station environment, including hazards that can occur during handling, transportation, processing and distribution;
  - 3. Evaluate milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product hazards that are reasonably likely to occur and at a minimum, giving consideration to the following:
    - a. Microbiological contamination;
    - b. Parasites;
    - c. Chemical contamination;
    - d. Unlawful drug and pesticide residues;
    - e. Natural toxins;
    - f. Unapproved use of food or color additives;

- g. Presence of undeclared ingredients that may be allergens; and
- h. Physical hazards.

## 2 VAC 5-490-370. Implementation of a HACCP System; HACCP Plan.

- A. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall develop and implement a written HACCP Plan whenever a hazard analysis reveals one or more hazards that are reasonably likely to occur.
- B. <u>Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall ensure the person's HACCP Plan complies with the following:</u>
  - 1. The HACCP Plan shall be developed by one or more individuals who have been trained in accordance with the requirements of this chapter;
  - 2. The HACCP Plan shall be subject to the record keeping requirements of this chapter; and
  - 3. The HACCP Plan shall be specific to each location and milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product;
- C. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall ensure the person's HACCP Plan shall at a minimum:

- Include complete up-to-date process flow diagrams for all milk, milk products,

  condensed milk, condensed milk products, dry milk and dry milk products

  manufactured;
- 2. <u>List all hazards that are reasonably likely to occur as identified in the hazard</u> analysis and that must be controlled for each type of milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product;
  - 3. List the Critical Control Points for each of the identified hazards, including:
    - a. <u>Critical Control Points designed to control hazards that could occur or</u>
       could be introduced in the milk plant, receiving station or transfer station
       environment;
    - b. Critical Control Points designed to control hazards introduced outside the

      milk plant, receiving station or transfer station environment, including hazards

      that occur before arriving at the milk plant, receiving station or transfer station;

      and
    - c. A list of Critical Limits that shall be met at each of the Critical Control

      Points;
- 4. <u>List the procedures and the frequency with which they are to be performed</u>
  that will be used to monitor each of the Critical Control Points to ensure compliance
  with the Critical Limits;

- 5. Include any corrective action plans that have been developed in accordance with the corrective action requirements as described in this chapter, and that are to be followed in response to deviations from Critical Limits at Critical Control Points;
- 6. List the verification and validation procedures, and the frequency with which they are to be performed, that the milk plant, receiving station or transfer station will use in accordance with verification and validation requirements as described in this chapter;
- 7. Provide a record keeping system that documents the monitoring of the Critical

  Control Points in accordance with the record requirements as described in this

  chapter; and
- 8. <u>Create records that contain only actual values and observations obtained</u> during monitoring.
- 2 VAC 5-490-380. Implementation of a HACCP System; Corrective actions.
- A. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall take corrective action as described in subsection B or subsection C of this section whenever a deviation from a Critical Limit occurs.
- B. <u>Before a deviation occurs each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program:</u>

- 1. May develop written corrective action plans, which become a part of their

  HACCP Plan. These corrective action plans may predetermine the corrective

  actions that milk plants, receiving stations and transfer stations will take whenever
  there is a deviation from a Critical Limit;
- 2. Shall develop corrective action plans that are appropriate for each particular deviation and that:
  - a. <u>Describes the steps to be taken;</u>
  - b. Assigns responsibility for taking those steps to ensure that:
    - (1) No milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product is allowed to enter commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; or
    - (2) If such milk, milk product, condensed milk, condensed milk product,

      dry milk or dry milk product has entered commerce, it is expeditiously

      removed; and
    - (3) The cause of the deviation is corrected.
- C. When a deviation from a critical limit occurs and a corrective action plan that is appropriate for that deviation does not exist, each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:

- 1. <u>Segregate and hold the affected milk or milk product, at least until the</u> requirements of subsection C(2) and subsection C(3) of this section have been met;
- 2. Perform or obtain a review to determine the acceptability of the affected milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product for distribution. The review shall be performed by an individual or individuals qualified by training or experience to perform such a review;
- 3. Take corrective action, when necessary, with respect to the affected milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product to ensure that no milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product is allowed to enter commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
- 4. <u>Take corrective action, when necessary, to correct the cause of the deviation;</u> and
- 5. Perform or obtain timely validation by a qualified individual or individuals to determine whether modification of the HACCP Plan is required to reduce the risk of recurrence of the deviation and modify the HACCP Plan as necessary.
- D. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall ensure that all corrective actions taken in accordance with this section are fully documented in records that are subject to verification.

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2 VAC 5-490-390. Implementation of a HACCP System; Verification and Validation.

A. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall verify that the HACCP System is being implemented according to design, except that critical factors for aseptically processed Grade "A" milk and milk products, as determined by the process authority and listed on the scheduled process under 21 CFR 113 shall be managed separately from the voluntary HACCP program, even if identified as a Critical Control Point in the hazard analysis. Critical factors identified in the scheduled process shall be monitored under the operating supervision of an individual who has successfully completed an approved course of instruction in low-acid canned foods as required by 21 CFR 108.35.

B. Each person operating a milk plant, receiving station or transfer station and

1. The calibration of Critical Control Point process-monitoring instruments;

participating in the voluntary HACCP program shall include in their verification activities:

- 2. At the option of the person operating a milk plant, receiving station or transfer station, the performance of periodic end-product or in-process testing;
- 3. A review, including signing and dating, by an individual who has been trained in accordance with the training requirements of this chapter, of the records that document:
  - a. The monitoring of Critical Control Points;
  - b. The taking of corrective action; and

- c. The calibrating of any process monitoring instruments used at Critical

  Control Points and the performance of any periodic end-product or in-process

  testing that is part of HACCP Plan verification activities;
- 4. The taking of corrective action procedures whenever any verification procedure establishes the need to take a corrective action; and
- 5. The calibration of Critical Control Point process-monitoring instruments, and the performance of any periodic end-product and in-process testing, in accordance with subsection B(3)(a) and B(3)(b) of this subsection, shall be documented in records and maintained as required by this chapter.
- C. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:
  - 1. Validate that the HACCP Plan is adequate to control hazards that are reasonably likely to occur at least once within twelve months after implementation of the HACCP System and annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP Plan;
  - 2. Ensure the validation is performed by a qualified individual or individuals trained in accordance with the requirements of this chapter;
  - 3. Ensure the validation is documented and the records maintained as required by this chapter; and
  - 4. Ensure the HACCP Plan is modified immediately whenever a validation reveals that the HACCP plan is no longer adequate.

D. Whenever a milk plant, receiving station or transfer station does not have a HACCP Plan, because a hazard analysis has revealed no hazards that are reasonable likely to occur, the person operating the milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall reassess the adequacy of the hazard analysis whenever there are any changes in the process that could reasonably affect whether a hazard exists.

#### 2 VAC 5-490-400. Implementation of a HACCP System; Records.

- A. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:
  - Use consistent terminology to identify each piece of equipment, record,

    document, or other program throughout their written HACCP System;
    - 2. Maintain the following records documenting the HACCP System:
      - a. Records documenting the ongoing application of the prerequisite
         programs, including a brief written description, monitoring and correction
         records;
      - b. The written hazard analysis;
      - c. The written HACCP Plan;
      - d. <u>A Table of Contents and centralized list of the HACCP program records,</u>
        by title, documenting the ongoing application of the HACCP System;
      - e. A document change log;

- f. Records documenting the ongoing application of the HACCP Plan that include:
  - (1) Monitoring of Critical Control Points and their Critical Limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP Plan;
  - (2) Corrective actions, including all actions taken in response to a deviation;
  - (3) A centralized deviation log; and
  - (4) Plan validation dates;
- g. Required HACCP documents and forms specified in subsection A(2)(a)

  through A(2)(c) of this subsection shall be dated or identified with a version

  number and each page shall be marked with a new date or version number

  whenever that page is updated; and
- h. Records documenting verification and validation of the HACCP System, including the HACCP Plan, hazard analysis and the prerequisite programs.
- B. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall ensure all required records include:
  - 1. The identity of the milk plant, receiving station or transfer station;
  - 2. The date and time of the activity that the record reflects;
  - 3. The signature or initial of the person or persons performing the operation or creating the record;

- 4. Where appropriate, the identity of the milk or milk product and the production code, if any;
- 5. Processing and other information entered on the records at the time that it is observed; and
  - 6. Only the actual values and observations obtained during monitoring.
- C. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall ensure all required records specified in 2 VAC 5-490-400A(2)(a) through 2 VAC 5-490-400(A)(2)(c):
  - 1. Have been signed and dated by the most responsible individual onsite at the milk plant, receiving station or transfer station to signify that the records have been accepted by the firm; and
    - 2. Are signed and dated upon initial acceptance;
      - a. Upon any modification; and
      - b. Upon verification and validation.
- D. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:
  - 1. Ensure all records required by this section for perishable or refrigerated products are retained for one year after the date that such products were prepared, and in the case of frozen, preserved, or shelf-stable products, for two years after the date that the products were prepared or the for the shelf-life of the product, whichever is greater;

- 2. Ensure all records that relate to the adequacy of equipment or processes used, such as commissioning or process validation records, including the results of scientific studies and evaluations, shall be maintained at the milk plant, receiving station or transfer station facility for a least two years after the date that the milk plant, receiving station or transfer station last used such equipment or process;
- 3. Ensure that all processing records stored off-site are a minimum of six months old from the date that the monitoring occurred and can be retrieved and provided on-site within twenty-four hours after a request by the State Regulatory Authority. Electronic records shall be considered accessible on-site if they can be accessed on-site; and
- 4. Ensure all records required by this subsection shall be available for review by the State Regulatory Authority at all reasonable hours.

2 VAC 5-490-410. Implementation of a HACCP System; Training.

Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall ensure that each person who is responsible for:

(i) developing a hazard analysis; (ii) delineating control measures; (iii) developing a HACCP Plan that is appropriate for the specific milk plant, receiving station or transfer station; (iv) validating and modifying the HACCP Plan; or (v) performing required HACCP Plan record reviews has received basic HACCP training and an orientation to

the HACCP requirements contained in Appendix K of the "Grade A Pasteurized Milk" Ordinance, 2005 revision".

## Part XII - Interpretation and enforcement

2 VAC 5-490-140. 2 VAC 5-490-420. Interpretation and enforcement.

- A. This chapter is based on the "Grade A Pasteurized Milk Ordinance-1989 2005 recommendations." Except as otherwise provided in this chapter, the provisions of this chapter shall be interpreted in a manner consistent with interpretations accorded the "Grade A Pasteurized Milk Ordinance-1989 2005 recommendations."
- B. The administrative procedures used to conduct case decisions under this chapter shall conform to the provisions of the Virginia Administrative Process Act.
- C. The State Regulatory Authority shall comply with the following administrative procedures when summarily suspending a grade A permit as specified in <del>2 VAC 5-490-30 C 2 VAC 5-490-60(B)</del> of this chapter:
- 1. The State Regulatory Authority shall serve upon the grade A permit holder a written notice of suspension. The written notice of suspension shall specify the violations in question and inform the grade A permit holder of the right to appear before the State Regulatory Authority in person, by counsel, or by other qualified representative at a fact-finding conference for the informal presentation of factual data, arguments, and proof to appeal this determination of violation;

- 2. Upon receipt of written application from any person whose grade A permit has been summarily suspended (within 30 days after the effective date of the summary suspension) the State Regulatory Authority shall within seven days after the date of receipt by the State Regulatory Authority of a written application from any person whose grade A permit has been summarily suspended proceed to hold an informal fact-finding conference to ascertain the facts of the violations in question and upon evidence presented at the informal fact-finding conference shall affirm, modify, or rescind the summary suspension;
- 3. The State Regulatory Authority shall, unless the parties consent, ascertain the fact basis for their decisions of cases through informal conference proceedings. Such conference proceedings include the rights of parties to the case to have reasonable notice thereof, to appear in person or by counsel or other qualified representative before the State Regulatory Authority for the informal presentation of factual data, argument, or proof in connection with any case, to have notice of any contrary fact basis or information in the possession of the agency which can be relied upon in making an adverse decision, to receive a prompt decision of any application for license, benefit, or renewal thereof, and to be informed, briefly and generally in writing, of the factual or procedural basis for an adverse decision in any case;
- 4. No person whose grade A permit has been summarily suspended may be granted an informal fact-finding conference by the State Regulatory Authority unless the State

Regulatory Authority receives the person's written application within 30 days after the effective date of the summary suspension;

5. From any adverse decision of an informal fact-finding conference, the State

Regulatory Authority grade A permit holder may request a formal hearing under § 96.14:12 §2.2-4020 of the Code of Virginia by writing the Director of Division of Dairy and

Foods Program Manager of the Office of Dairy and Foods within 30 days stating the

request and by providing the State Regulatory Authority with a statement of the issues

in dispute. If the request for a formal conference is denied, the State Regulatory

Authority shall notify the grade A permit holder in writing and further may affirm or

modify the decision of the informal fact-finding conference; and

6. If a formal fact-finding conference is denied, the State Regulatory Authority shall

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notify the grade A permit holder of the right to file an appeal in the circuit court.

Documents Incorporated by Reference

- National Uniform Coding System For Packaging Identification of Milk and Milk Product Processing Plants.

Standards For the Fabrication of Single-Service Containers and Closures For Milk and Milk Products -- 1991 revision.

- Uniform Methods and Rules; Bovine Tuberculosis Eradication -- eff. 2/3/89.
- -Grade A Condensed and Dry Milk Products and Condensed and Dry Whey, supplement I to the Grade A Pasteurized Milk Ordinance, 1978 recommendations.

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