

Regulation 61-34

Raw Milk for Human Consumption

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S.C. Department of Health and
Environmental Control

2600 Bull Street | Columbia, SC 29201

Statutory Authority:

S.C. Code Sections 44-1-140(3) and 44-1-150

Regulation History as Published in State Register			
Date	Document Number	Volume	Issue
June 26, 2009	4017	33	6, Part 1
April 22, 2022	5033	46	4

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SECTION I. Definitions and Standards.

A. The following definitions shall apply in the interpretation and the enforcement of this Regulation:

1. Abnormalities of Milk means

a. Abnormal Milk: Milk that is visibly changed in color, odor, and/or texture.

b. Undesirable Milk: Milk that, prior to the milking of the animal, is known to be unsuitable for sale, such as colostrum.

c. Contaminated Milk: Milk that is not sellable or is unfit for human consumption following treatment of the animal with veterinary products, i.e. antibiotics, which have withhold requirements or treatment with medicines or insecticides not approved for use on dairy animals by the United States Food and Drug Administration (FDA) or the United States Environmental Protection Agency (EPA).

2. Adulterated: means raw milk or raw milk products are deemed to be adulterated if the product:

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

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

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

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

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

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

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

h. Contains any animal drug residues.

3. Automatic Milking Installation (AMI) means the entire installation of one (1) 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.

4. Buttermilk means a cultured dairy product that is produced by culturing milk or cream with characterizing microbial organisms and which contains at least 3.25% milkfat and at least 8.25% milk solids not fat.

5. Clean means the effective and thorough removal of product and/or contaminants from direct product contact surfaces.

6. Code of Federal Regulations (CFR) means the current Code of Federal Regulations.
7. Common Name means the generic term commonly used for domestic animals, i.e., cattle, goats, sheep, horses, water buffalo, etc.
8. Craft Usage means the use of raw milk to create products such as soap, candles, or other non-edible products.
9. Cream means a dairy product that is composed of the higher-fat layer separated from the top of milk and which contains at least 18% milkfat.
10. Dairy Farm means any place or premises where one (1) or more lactating animals (cows, goats, sheep, water buffalo, or other hooved mammals) are kept for milking purposes and from which a part or all of the milk or milk products are provided, sold, or offered for sale.
11. Department means the South Carolina Department of Health and Environmental Control and its representatives.
12. Drug means:
- a. A substance 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;
 - b. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease;
 - c. A substance (other than food) intended to affect the structure or any function of the body ; and
 - d. A substance intended for use as a component of a substance specified in clause a, b, or c but does not include devices or their components, parts, or accessories.
13. Goat Milk means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this Regulation.
14. Kefir means a cultured dairy product that is produced by fermentation of milk by *Lactobacillus bulgaricus*, *Lactobacillus acidophilus*, and *Lactobacillus caucasicus* and which contains not less than 3.5% milk fat or, if made from goat milk, not less than 2.8% milkfat.
15. Milk means the normal lacteal secretion of hooved mammals, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Regulation. Hooved mammals milk shall include bovine milk, goat milk, sheep milk, water buffalo milk, etc.
16. Milk or Milk Products Distributor means any person who offers for sale milk or milk products that have been packaged at a permitted location.
17. Milk or Milk Products Plant means any place, premises, or establishment where milk or milk products are collected, handled, processed, and stored or prepared for distribution.

18. Milk or Milk Products Producer means any person who operates a dairy farm and provides, sells, or offers milk or milk products for sale that were produced at the farm.

19. Misbranded Milk or Milk Product means any milk or milk product when:

- a. The product's container bears or accompanies any false or misleading written, printed, or graphic matter;
- b. The milk or milk product does not conform to the definitions as contained in this Regulation; or
- c. The product is not labeled in accordance with this Regulation.

20. Officially Designated Laboratory means a commercial laboratory authorized to do official work by the Department or a milk industry laboratory officially designated by the Department for the examination of producer samples of SC Grade A raw milk and raw milk products for human consumption and commingled milk tank truck samples of raw milk and raw milk products for drug residues and bacterial limits.

21. Person means any individual, producer, distributor, plant operator, partnership, corporation, company, firm, trustee, association, or institution.

22. Raw Milk means milk that has not received any heat treatment such as pasteurization or any other further processing.

23. Raw Milk Products means unpasteurized buttermilk, kefir, or cream.

24. Risk means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

25. 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 practical. Such treatment shall not adversely affect the equipment, the milk or milk product, or the health of consumers and shall be acceptable to the Department.

26. Sheep Milk means the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this Regulation.

27. Water Buffalo Milk means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this Regulation.

B. Standards.

All raw milk and raw milk products for human consumption shall be bottled, packaged, and sealed at the same location where they were produced, or, in the case of raw milk products, at a location under the direct control of the raw milk producer that has been approved by the Department, and all raw milk and raw milk products shall conform to the chemical, physical, bacteriological, and temperature standards as well as the sanitation requirements of this Regulation.

SECTION II. Adulterated or Misbranded Raw Milk or Raw Milk Products.

A. No person shall, within South Carolina or its jurisdiction, produce, provide, sell, offer, barter, or expose for sale, or have in possession with intent to sell any raw milk or raw milk product that is adulterated or misbranded.

B. Any adulterated or misbranded raw milk or raw milk product may be impounded by the Department and disposed of in accordance with applicable laws or regulations.

C. Raw milk and raw milk products will be examined by the Department in the course of routine or complaint inspections, outbreak investigations, or as otherwise deemed appropriate by the Department to determine that they are not adulterated or misbranded. The Department may, upon written notice to the owner or person in charge, place a hold order on any raw milk or raw milk product that it determines, or has probable cause to believe, to be unwholesome or otherwise adulterated or misbranded. Under a hold order, raw milk and raw milk products shall be permitted to be suitably stored. It shall be unlawful for any person to remove or alter a hold order, notice, or tag placed on raw milk or raw milk products by the Department, and neither such raw milk or raw milk products nor the containers thereof shall be relabeled, repacked, reprocessed, altered, disposed of, or destroyed without permission of the Department except if ordered by a court of competent jurisdiction.

D. Adding water to raw milk will be considered a violation of this Regulation if the raw milk contains in excess of three percent (3%) water. A cryoscope shall be used to determine percentage of water by measuring the freezing point of the raw milk. When the freezing point of raw milk is greater than 32.945°F (-0.525°C), the farm shall be notified that the raw milk apparently contains added water. If a second violation of this freezing point standard occurs within two (2) years, milking or processing operations may be observed, and samples will be collected and analyzed. The freezing point obtained from raw milk collected during the observation shall be used to determine a definite freezing point standard from the farm. A violation of the determined freezing point standard for a specific operation by over three (3%) percent within two (2) years of setting the standard for the individual farm shall call for a two (2) calendar day permit suspension or equivalent.

E. When raw milk or raw milk products are found to be adulterated by the presence of drugs, pesticides, herbicides, or other poisonous substances, they shall be placed under a hold order and additional samples analyzed. Raw milk or raw milk products found to be adulterated shall be disposed of until analysis shows the product not to be adulterated. If testing reveals raw milk or raw milk products are positive for drug residues, the raw milk or raw milk products shall be disposed of in a manner that removes it from the human or animal food chain. The Department shall immediately suspend the producer's SC Grade "A" permit, or equally effective measures shall be taken, to prevent the sale or distribution of raw milk or raw milk products containing drug residues, and a penalty shall be imposed. Future sales or distribution are prohibited until subsequent testing reveals the raw milk or raw milk products are free of drug residue. The SC Grade "A" producer's permit may be reinstated to allow the sale or distribution of raw milk or raw milk products when a representative sample taken by the Department from the producer's raw milk or raw milk products is no longer positive for drug residue. Whenever a drug residue test is positive, a recall shall be initiated, and an investigation shall be made to determine the cause. The farm inspection must be completed by the Department to determine the cause of the residue and actions that need to be taken to prevent future violations, including on-farm changes in procedures necessary to prevent future occurrences.

SECTION III. Permits.

A. It shall be unlawful for any person who does not possess a permit from the Department to manufacture, bring into, send into, or receive into South Carolina or its jurisdiction, have in storage, sell, barter, or offer for sale therein, or offer to give away any raw milk or raw milk products defined in this Regulation, including but not limited to raw milk for craft usage.

B. Raw milk and raw milk products that have been manufactured under the provisions of this Regulation may be further distributed or sold at retail locations in South Carolina by distributors and retailers. Distributors and retailers are not required to have a permit, provided that the product has not been repackaged or relabeled.

C. Although distributors and retailers listed in Section III.B do not require a permit, the Department retains the authority to conduct an investigation in response to a complaint. The Department may require corrective action and issue orders as deemed necessary in response to food safety or health risks identified during the investigation.

D. Only a person who complies with the requirements of this Regulation shall be entitled to receive and retain a permit. Permits shall not be transferable to other persons and/or locations or used by a person other than the permit holder.

E. Every producer of raw milk or raw milk products for human consumption shall hold a valid permit issued by the Department prior to beginning operation. No permit shall be issued until all parts of the operation meet the requirements of this Regulation.

F. The production, distribution, storage, and sale of unpasteurized milk products other than the raw milk products defined in this Regulation (unpasteurized buttermilk, kefir, and cream) are prohibited in South Carolina and will be considered to be violations of this Regulation, except that aged raw milk cheese may be produced in accordance with the provisions of R.61-36, Manufactured Grade Dairy Products.

G. The addition of flavoring or other ingredients to raw milk or raw milk products other than cultures, citric acid, or salt needed for the processing of buttermilk and kefir is prohibited; provided, kefir may also contain harmless edible stabilizers subject to the limitations in VIII.C of this Regulation.

H. The Department may deny a permit to produce, distribute or sell raw milk or raw milk products for human consumption when the applicant or facility has a history of noncompliance with other standards, regulations, or statutes governing milk and milk products.

SECTION IV. Inspection of Dairy Farms and Plants Producing and Packaging Raw Milk and Raw Milk Products for Human Consumption.

A. Each dairy farm or plant manufacturing raw milk or raw milk products for human consumption shall be inspected by the Department prior to the issuance of a permit. Following the issuance of a permit, the Department shall inspect each dairy farm or plant at a frequency determined by the risk level assigned to the product(s) being manufactured or distributed, or as otherwise deemed necessary by the Department. Inspections of dairy farms will be made at milking time when possible.

B. The Department shall conduct inspections and investigations as are necessary for the enforcement of this Regulation.

C. The inspector will notify the owner or other responsible person of the intent to inspect upon arrival at the premises.

D. A copy of the inspection report will be provided, either electronically or in paper form, to the permit holder, manager, or other duly authorized representative.

E. Every raw milk producer shall, upon request of a Department representative, permit the Department access to all parts of the establishment or facilities to determine compliance with the provisions of this Regulation. A permit holder, manager, or other duly authorized representative shall furnish the Department, upon request and for official use only, a true statement of the actual quantities of raw milk or raw milk product purchased and sold, and a list of all sources of ingredients, records of inspections, records of tests, and cooling time and temperature records.

F. Should a violation of any requirement set forth in Section VII or Section VIII be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three (3) calendar days. Any violation of a requirement of Section VII or Section VIII may result in enforcement action pursuant to Section XII of this Regulation. When the Department at any time finds that a critical processing element violation involving conditions whereby direct contamination of raw milk or raw milk products is occurring, the Department shall take immediate action to prevent transfer from the vessel or location of such raw milk or raw milk products until such violations of critical processing element(s) have been corrected.

G. It shall be unlawful for any person who, in an official capacity, under the provisions of this Regulation obtains any information of disposition of milk, or results of inspections or tests thereof to use such information to his/her own advantage or to reveal it to any unauthorized person.

SECTION V. The Examination of Raw Milk and Raw Milk Products for Human Consumption.

A. Samples of raw milk or raw milk products for human consumption may be taken for analysis for public health purposes, at any reasonable time or place, and examined for any other public health reason by the Department.

B. Samples of raw milk and raw milk products for human consumption shall be collected and tested prior to a permit being issued. No permit shall be issued until the milk and milk products meet the requirements of Section VII and Section VIII.

C. The producer shall provide to the Department satisfactory pathogenic testing results prior to:

1. receiving a permit and beginning production and/or distribution; or

2. reinstatement of a permit that has been suspended because of positive results of testing for pathogenic organisms in association with a suspected outbreak of disease. In testing associated with a suspected outbreak of disease, the Department shall provide up to two (2) tests at no cost to the producer; pathogen testing required beyond these two (2) tests shall be the responsibility of the producer.

D. Samples of raw milk and raw milk products shall be collected by the producer or the Department, as directed, at a frequency that is deemed appropriate by the Department based on the level of risk of the product. The Department will require sampling for bacterial counts, somatic cell counts, coliform, cooling temperatures, drugs, pesticide residue, and/or pathogenic organisms as deemed appropriate by the Department. Sampling will be conducted in accordance with Department standard operating procedures for sampling of raw milk and raw milk products.

E. Whenever two (2) of the last four (4) consecutive bacterial counts, somatic cell counts, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the raw milk or raw milk products as defined in this Regulation, the Department shall send written notice thereof to the person concerned. This notice shall be in effect so long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) calendar days of the sending of such notice, but not before the lapse of three (3) calendar days. The Department shall suspend the permit in accordance with Section XII whenever the standard is violated by three (3) of the last five (5) bacterial counts, coliform determinations, cooling temperatures, or somatic cell counts.

F. When sampling for pathogenic organisms is conducted in association with a suspected outbreak of disease, and the samples test positive for pathogenic organisms, such positive finding of pathogenic organisms shall be considered an imminent health hazard, and the product involved shall be disposed of and not be offered for sale. The Department shall immediately suspend the permit. The permit shall remain suspended until a representative sample containing a minimum of two (2) consecutive milkings are found to be free of pathogenic organisms.

G. Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the latest edition of Standard Methods for the Examination of Dairy Products (SMEDP) of the American Public Health Association, and the latest edition of Official Methods of Analysis (OMA) of the Association of Official Agricultural Chemists (AOAC) International. Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance with the Evaluation of Milk Laboratories.

H. All violations of bacteria, coliform, somatic cell counts, and cooling temperature standards shall be followed by inspection, if needed, to determine and correct the cause.

SECTION VI. Labeling.

A. All bottles, containers, and packages enclosing raw milk or raw milk products for human consumption shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act as amended, the Nutrition Labeling and Education Act (NLEA) of 1990 and regulations developed thereunder, and the Code of Federal Regulations, and shall comply with the applicable requirements of this section.

B. No person shall use any misleading marks, words, or endorsements upon the label. The Department may permit the use of registered trade designs or similar terms on the bottle cap or label when, in its opinion, they are not misleading and are not used to obscure the labeling required by the Regulation.

C. All bottles, containers, and packages enclosing raw milk or raw milk products for human consumption shall be conspicuously marked with:

1. The word "Raw" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.

2. The identity of the farm where packaged. This identity shall include the name and the Department Permit Number.

3. The following consumer advisory, in print no smaller than six (6) point font, shall be included on the package: "This is a raw milk product that is not pasteurized. Consuming raw milk products may increase your risk of foodborne illness."

4. The common name of the hooved mammal producing the milk shall precede the name of the milk or raw milk product when the product is made from other than cattle’s milk. As an example, “Goat,” “Sheep,” “Water Buffalo,” or “Other Hooved Mammal” milk, respectively.

D. Raw milk that has had cream separated from it must also be labeled as per Section VIII.B.3.

E. The term Grade “A” Raw may only be used with the designation of SC to read “SC Grade ‘A’ Raw”. Other grade designations may not be used.

F. Descriptive labeling terms such as “wholesome” or “healthy” must not be used. The label must not be false or misleading. The use of the term “cultured” is allowed and optional for buttermilk and kefir.

G. A permit holder’s label and Department permit number are not transferable and may only be used by that permit holder.

SECTION VII. Standards for Raw Milk and Raw Milk Products for Human Consumption.

A. General

1. All raw milk and raw milk products for human consumption shall be produced to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of this section.

2. No process or manipulation other than appropriate refrigeration shall be applied to raw milk or raw milk products for the purpose of removing or deactivating microorganisms.

SC GRADE “A” RAW MILK AND RAW MILK PRODUCTS FOR HUMAN CONSUMPTION	Temperature	Raw milk: Cooled to 10°C (50°F) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45°F) or less within two (2) hours after milking, provided, that the blend temperature after the first and subsequent milkings does not exceed 10°C (50°F). Raw milk and raw milk products: All finished, processed, and packaged raw milk and raw milk products shall be maintained at 7°C (45° F) or less after processing, during storage, and during transportation. Production of buttermilk shall also meet the requirements of Section VIII.A.3.
	Bacterial Limits	Individual producer raw milk and raw milk products not to exceed 10,000 per mL
	Drugs	No positive results on drug residue detection methods
	Somatic Cell Count*	Individual producer raw milk not to exceed 500,000 per mL.
	Coliform	Not to exceed 10 per gram.

	Pathogenic Organisms: **Escherichia Coli	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms
	**0157:H7	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms
	**Salmonella	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms
	**Listeria Monocytogenes	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms
	**Campylobacter	Individual producer: raw milk and raw milk products not to exceed zero (0) organisms

*Goat Milk 1,000,000 per mL: when greater than 1,000,000, additional confirmatory or screening tests will be used.

**Pathogenic testing required before permitting and in association with a foodborne disease outbreak. See Section V.C.1, V.C.2, and V.F.

B. Sanitation Requirements for SC Grade “A” Raw Milk and Raw Milk Products for Human Consumption.

1. Milk with Abnormalities

a. Lactating animals which show evidence of the secretion of milk with abnormalities in one (1) or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment and the milk shall be discarded as the Department may direct.

b. Lactating animals that have been treated with, or have consumed, chemical, medicinal, or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the Department, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Department may direct.

c. Raw milk or raw milk products from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, shall not be offered for sale for such period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

d. Raw milk or raw milk products from lactating animals treated with or exposed to insecticides not approved for use on dairy animals by the United States Environmental Protection Agency shall not be offered for sale.

e. The Department may require additional tests for the detection of milk with abnormalities as it deems necessary.

f. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, shall be handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

g. Lactating animals secreting milk with abnormalities shall be milked last or in separate equipment which effectively prevents the contamination of the wholesome supply. Milking equipment used on animals with abnormalities in their milk shall be maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animals.

h. Equipment, utensils, and containers used for the handling of milk with abnormalities shall not be used for the handling of raw milk or raw milk products to be offered for sale, unless they are first cleaned and effectively sanitized.

i. Processed animal waste derivatives used as a feed ingredient for any portion of the total ration of the lactating dairy animal shall:

(1) Be properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and

(2) Not contain levels of deleterious substances, harmful pathogenic organisms, or other toxic substances which are secreted in the milk at any level that may be harmful to human health.

j. Unprocessed poultry litter and unprocessed recycled animal body discharges shall not be fed to lactating dairy animals.

2. Milking Barn, or Parlor Construction

A milking barn or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations.

a. All floors must be constructed of concrete or equally impervious material. Floors shall be easily cleaned and shall be graded to drain and maintained in good repair and free of excessive breaks or worn areas that may create pools.

b. Walls and ceilings shall be smooth, painted, or finished in an approved manner, and be in good repair. Ceilings shall be dust-tight; approved materials include wood, tile, smooth-surfaced concrete, cement plaster, brick, or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair; and surfaces shall be refinished whenever wear or discoloration is evident. Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable, or parlor. If a hay opening is provided from the loft into the milking portion of the barn, such opening shall be provided with a dust-tight door which shall be kept closed during milking operations.

c. Separate stalls or pens for horses, calves, and bulls shall be provided. Such portions of the barn that are not separated by tight partitions shall comply with all requirements of this item.

d. Natural and/or artificial light well distributed for day and/or night milking must be provided to ensure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten (10) foot-candles (110 lux) of light in all working areas shall be provided.

e. Sufficient air space and air circulation to prevent condensation and excessive odors must be provided.

f. There must be no overcrowding by the presence of calves, cows, or other barnyard animals in walk or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn.

g. There must be dust-tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed. A dust-tight partition, provided with doors that are kept closed except when in actual

use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored. When conditions warrant, the Department may approve a barn without four (4) walls extending from floor to roof, or a shed-type barn provided the requirement of Section VII.B.3, which prohibits animals and fowl from entering the barn, is satisfied. Lactating animal-housing areas (stables without stanchions, such as loose housing stables, pen stables, resting barns, free stall barns, holding barns, loafing sheds, and wandering sheds) may be of shed-type construction, provided no milking is conducted therein. (These structures are classified as part of the cowyard under Section VII.B.4.)

h. The Department may grant a variance or waiver from one or more of the requirements of paragraphs VII.B.2.a through VII.B.2.g when, in the opinion of the Department, a health hazard or nuisance will not result from the variance or waiver.

3. Milking Barn, Stable, or Parlor Cleanliness

a. The interior of the milking barn, stable, or parlor shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be free of filth and/or litter and shall be clean. Outside surfaces of pipeline systems located in the milking barn, stable, or parlor must be kept reasonably clean.

b. Gutter cleaners must be kept reasonably clean.

c. Swine and fowl shall be kept out of the milking barn.

d. Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor (as in covered, dust-tight boxes or bins). Open feed dollies or carts may be used for distributing the feed, but not storing food, in the milking area.

e. Food mangers shall be kept clean so as not to attract flies; leftover feed in feed mangers must appear fresh and not be wet or soggy.

4. Cowyard

a. The cowyard, which is interpreted to be the enclosed or unenclosed area approximately adjacent to the milking barn in which the lactating animals may congregate, including animal-housing areas and feed lots, shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes.

b. Wastes from the barn, milkroom, or processing room shall not be allowed to pool in the cowyard. Depressions and soggy areas shall be filled, and lactating animal lanes kept reasonably dry. Cowyards which are muddy due to recent rains should not be considered as violating this item.

c. Manure, soiled bedding, and waste feed shall not be stored or permitted to accumulate in such a manner as to permit the soiling of lactating animals' udders and flanks. Animal-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered part of the cowyard. Manure packs shall be solid to the footing of the animal.

d. In loafing or lactating animal housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating animal's udder and flanks.

e. Waste feed shall not be allowed to accumulate.

f. Swine shall be kept out of the cowyard.

g. Cowyards shall be kept reasonably free of animal droppings. Animal droppings shall not be allowed to accumulate in piles that are accessible to the animals.

5. Milkroom or Processing Room—Construction and Facilities

a. A separate milkroom and/or processing room of sufficient size shall be provided, in which the cooling, handling, further processing, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted, except as provided for in Section VII.B.12 of this Regulation.

b. Every milkroom and processing room shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Floors shall be sloped to drains so that there are no pools of standing water. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

c. The joints between floors and walls shall be watertight.

d. The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner. Surfaces and joints shall be tight and smooth. Acceptable materials include sheet metal, tile, cement block, brick, concrete, cement plaster, or similar materials of light color. Surfaces up to splash height shall be non-absorbent and easily cleanable.

e. Every milkroom and processing room shall have adequate natural and/or artificial light and be well ventilated. A minimum of twenty (20) foot-candles (220 lux) of light shall be provided at all working areas from natural and/or artificial light for milkroom and processing room operations.

f. The milkroom and processing room shall be used for no other purpose than milkroom and processing room operations; there shall be no direct opening into any barn, stable, parlor or into a room used for domestic purposes. A direct opening between the milkroom or processing room and milking barn, stable or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting is provided and opens outward from the milk room. A vestibule, if used, must comply with the applicable milkroom and processing room construction requirements. Screened vents in the wall between the milkroom or processing room and a breezeway, which separates the milkroom or processing room from the milking parlor, are permitted, provided animals are not housed within the milking facility.

g. Water under pressure shall be piped into the milkroom and/or processing room.

h. Every milkroom and processing room shall be adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.

i. Vents, if installed, and lighting fixtures shall be located to preclude the contamination of bulk milk tanks or clean utensil storage area.

j. The milkroom and/or processing room shall be equipped with a wash-and-rinse vat having at least two (2) compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The cleaning-in-place vat for milk pipelines and milk machines may be accepted as one (1) part of the two (2)-compartment vat; provided that the cleaning-in-place station rack in or on the vat and milking machine inflations and appurtenances are completely removed from the vat during the washing, rinsing, and/or sanitizing of other utensils and equipment. Where mechanical cleaning/recirculated systems

eliminate the need for handwashing of equipment, the presence of the second wash vat compartment may be optional if so determined by the Department on an individual farm basis.

k. Each milkroom and/or processing room shall be provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils.

6. Milkroom and Processing Room – Cleanliness

a. The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils, and equipment, and other milkroom or processing room equipment shall be kept clean. Vestibules, if provided, shall be kept clean.

b. Only articles directly related to milkroom or processing room activities shall be permitted in the milkroom or processing room.

c. The milkroom and processing room shall be kept free of trash, animals, and fowl.

d. Incidental articles such as desks, refrigerators, and storage cabinets may be in the milkroom or processing room provided they are kept clean, ample space is available to conduct the normal operations in the milkroom or processing room, and they will not cause contamination of the milk.

7. Toilet

a. Every dairy farm shall be provided with one (1) or more toilets, conveniently located and properly constructed, operated, maintained and utilized in a sanitary manner. There shall be at least one (1) flush toilet connected to a public sewer system or to an individual sewage-disposal system, or if occupied for less than two (2) hours per day, a portable chemical toilet may be used. Such sewage systems shall be constructed and operated in accordance with applicable Department regulations and statutes.

b. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply.

c. The toilet room, including all fixtures and facilities, shall be kept clean and free of insects and odors.

d. Where flush toilets are used, doors to toilet rooms shall be tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of insects.

8. Water Supply

a. Water for milkroom or processing room and milking operations shall be from an approved supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

b. No cross-connection shall exist between a safe water supply and any unsafe or questionable water supply, or any other source of pollution.

c. There shall be no submerged inlets through which a safe water supply may be contaminated.

d. The well or other source of water shall be located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy, or other source of pollution can reach such water supply.

e. New individual water supplies and water supply systems that have been repaired or otherwise become contaminated shall be thoroughly disinfected before being placed in use. The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

f. All containers and tanks used in the transportation of water shall be sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the dairy farm, a suitable pump, hose, and fittings shall be provided. When the pump, hose, and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material provided with a dust and rainproof cover, as well as with an approved-type vent and roof hatch. All new reservoirs, or reservoirs which have been cleaned, shall be disinfected prior to placing them into service.

g. Samples for bacteriological examination shall be taken upon the initial approval of the physical structure based upon the requirements of this Regulation, when any repair or alteration of the water supply system has been made, and at least every year.

h. Bacteriological examinations shall be conducted in a laboratory acceptable to the Department.

i. Current records of water test results shall be retained on file with the Department or as the Department directs.

9. Utensils and Equipment – Construction

a. All multiuse containers, equipment, and utensils that are exposed to raw milk or raw milk products, or from which liquids may drip, drain or be drawn into raw milk or raw milk products, and used in the handling, storage, or transportation of milk shall be made of smooth, non-absorbent, corrosion-resistant, nontoxic materials, and shall be constructed to be easily cleaned. Acceptable materials include:

(1) Stainless steel of the AISI (American Iron and Steel Institute) 300 series, or equally corrosion-resistant, nontoxic metal;

(2) Heat-resistant glass; or

(3) Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent, and relatively insoluble; do not release component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

b. All containers, utensils, and equipment shall be in good repair and shall be free of breaks, corrosion, pits, cracks, or inclusions.

c. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Seamless hooded pails having an opening not exceeding one-third the area of that of an open pail of the same size shall be used for hand milking and hand stripping.

d. Strainers, if used, shall be constructed of perforated metal design, or single-service strainer media should be utilized. Multiple-use woven material shall not be used for straining milk.

e. All single-service articles shall be manufactured, packaged, transported, stored, and handled in a sanitary manner and shall comply with the applicable requirements of Section IX. Articles intended for single-service use shall not be reused.

f. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of Section VII.B.9.a, g, and h.

g. Mechanically cleaned milk pipelines and return-solution lines shall be self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in Section VII.B.9.a.(3), and shall be of such design, finish, and application as to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks, and inclusions.

h. Mechanically cleaned milk pipelines and return solution lines installed after the effective date of this Regulation shall have welded ferrule/flange fittings; rolled fittings shall not be used.

i. Detailed plans for cleaned-in-place pipeline systems shall be submitted to the Department for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Department.

j. All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces shall be constructed to be easily cleaned and inspected. Pipelines, milking equipment, and appurtenances that require a screwdriver or special tool shall be considered easily accessible for inspection, provided the necessary tools are available at the milkroom or processing room. Milking systems shall not have components incorporated in the return solution lines that by design do not comply with the criteria for product-contact surfaces, such as:

(1) Ball type plastic valves;

(2) Plastic tees with barbed ridges to better grip the plastic or rubber hoses; and

(3) PVC water type piping.

k. Milk cans shall have umbrella-type lids.

l. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of this Regulation.

m. During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill and top fill bulk milk storage tanks, when needed for functional purposes. Such hoses shall be drainable, be as short as practical, have sanitary fittings, and be supported to maintain uniform slope and alignment. The end fittings of such hoses shall be permanently attached in such a manner that will assure a crevice-free

joint between the hose and the fitting and can be cleaned by mechanical means. The hoses shall be included as part of a mechanical cleaning system.

n. Transparent flexible plastic tubing (up to 150 feet in length) used in connection with milk transfer stations shall be considered acceptable if it meets the “3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20” and if it remains sufficiently clear that the interior surfaces can be properly inspected. Short lengths of flexible plastic tubing (eight [8] feet or less) may be inspected for cleanliness by sight or by use of a “rod.” The transparency or opacity of such tubing under this condition is not a factor in determining cleanliness.

o. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it shall be free of oil, dust, rust, excessive moisture, extraneous materials, and odor.

10. Utensils and Equipment—Cleaning

a. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of raw milk and raw milk products shall be cleaned after each milking or once every twenty-four (24) hours for continuous operations.

b. There shall be a separate wash manifold for all mechanically cleaned milk pipelines in all new or extensively remodeled facilities.

11. Utensils and Equipment – Sanitization

a. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of raw milk and raw milk products shall be sanitized before each usage.

b. Sanitization shall be achieved by use of the following methods:

(1) Complete immersion in hot water at a temperature of at least 77°C (170°F), for at least five (5) minutes, or exposure to a flow of hot water at a temperature of at least 77°C (170°F), as determined by the use of a suitable accurate thermometer (at the outlet) for at least five (5) minutes;

(2) Complete immersion for at least one (1) minute in or exposure for at least one (1) minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces must be wetted by the sanitizing solution, and piping so treated must be filled. Sanitizing sprays may be used. Chemical solutions, once used, shall not be reused for sanitizing but may be reused for other purposes; or

(3) By any method which has been demonstrated to be equally effective and approved by the FDA, EPA, or the Department.

12. Utensils and Equipment – Storage

a. All containers, utensils, and equipment used in the handling, storage, or transportation of raw milk and raw milk products, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use, except that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers, milk pumps, and AMI milking equipment which are designed for mechanical cleaning and other equipment, as accepted by FDA, which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed, and operated to protect the product and solution-contact surfaces from contamination at all times.

b. Strainer pads, parchment papers, gaskets, and similar single-service articles shall be stored in a suitable container or cabinet and protected against contamination.

13. Utensils and Equipment—Handling

After sanitization, all containers, utensils, and equipment shall be handled in a manner that prevents contamination of any product-contact surface.

a. Sanitized product-contact surfaces, including farm cooling holding tank openings and outlets, shall be protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation, and other sources of contamination.

b. Any sanitized product-contact surface which has been otherwise exposed to contamination shall be cleaned and sanitized before being used.

14. Milking—Flanks, Udders, and Teats

a. Milking shall be done in the milking barn or parlor.

b. The flanks, udders, bellies, and tails of all milking cows shall be free from visible dirt. All brushing shall be completed prior to milking.

c. The udders and teats shall be cleaned and treated with a sanitizing solution just prior to the time of milking, and shall be relatively dry before milking. Sanitizing solutions shall be used in accordance with manufacturer specifications and recommendations.

d. Wet hand milking is prohibited.

e. Flanks, bellies, tails, and udders shall be clipped as often as necessary to facilitate cleaning of these areas.

15. Drug and Chemical Control

a. Cleaners and Sanitizers

(1) Cleaners and sanitizers shall be stored in dedicated end-use containers which properly identify the contents.

(2) Bulk cleaners and sanitizers that are transferred from the manufacturer's or distributor's container shall be stored only in an end-use container that is properly labeled with the container's contents.

(3) The manufacturer's or distributor's label for each cleaner and sanitizer, including the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor, shall be maintained on the premises and be readily accessible for reference or inspection.

b. Drugs

(1) Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for over-the-counter (OTC) drugs or veterinary practitioner dispensing the product for prescription and extra label use drugs. Drug labels shall also include:

- (a) Directions for use and prescribed withholding times;
- (b) Cautionary statements, if needed; and
- (c) Active ingredient(s) in the drug product.

(2) Drugs dispensed by a pharmacy on the order of a veterinarian shall have labeling that includes the name of the prescribing veterinarian and the name and address of the dispensing pharmacy; the address of the prescribing veterinarian may be included on the labeling.

(3) Drugs intended for treatment of non-lactating dairy animals shall be segregated from those drugs used for lactating animals in separate shelves in cabinets, refrigerators, or other storage facilities.

(4) Unapproved drugs shall not be used and shall not be stored in the milkroom, processing room, milking barn, stable, or parlor.

(5) Animal drugs and drug administration equipment shall be stored in such a way that milk, milking equipment, wash vats, and hand sinks are not subject to contamination by the drugs.

(6) Equipment used to administer drugs shall not be cleaned in the wash vats.

(7) Topical antiseptics and wound dressings, unless intended for direct injection into the teat, vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements, except when it is determined that they are stored in such a manner that they may contaminate the raw milk or raw milk product-contact surfaces of containers, utensils, or equipment.

16. Milking—Transfer and Protection of Milk

a. Each pail or container of milk shall be taken immediately from the milking barn or parlor to the milkroom or processing room. No milk shall be strained, poured, transferred, or stored outside the milkroom or processing room.

b. The milk receiving receptacle shall be raised above the floor.

17. Personnel

a. Adequate handwashing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent, and individual sanitary towels, or other approved hand drying devices, convenient to the milkroom, processing room, milking barn, stable, parlor and flush toilet, and shall be used for no other purpose. Utensil wash and rinse vats shall not be considered as handwashing facilities.

b. Hands shall be washed clean and dried with an individual sanitary towel or other approved hand drying device immediately before milking, before performing any milkroom or processing room function, and immediately after the interruption of any of these activities. Milkers shall wear clean outer garments while milking or handling raw milk, raw milk products, milk containers, utensils, or equipment.

c. No person who by medical examination or supervisory observation is shown to have or appears to have an illness, open lesion (including boils, sores, or infected wounds) or any other abnormal source of microbial contamination shall work at any dairy farm in any capacity that brings them into contact with the production, handling, storage, or transportation of raw milk, raw milk products, containers, equipment, and/or utensils.

d. When reasonable cause exists to suspect the possibility of transmission of infection or disease from any person associated with the handling of raw milk or raw milk products, the Department may:

(1) Order the immediate exclusion of that person from raw milk handling or handling of raw milk products;

(2) Order the immediate exclusion of the raw milk or raw milk products concerned from distribution and consumption;

(3) Order adequate medical and bacteriological examination of the person to determine if an infection or disease is present; or

(4) Order any combination of the previous measures.

18. Cooling

a. Raw milk shall be cooled to 10°C (50°F) or less within four (4) hours or less of the commencement of the first milking, and to 7°C (45° F) or less within two (2) hours after the completion of milking, and shall be maintained at that temperature, including during packaging and transportation; except that, the blend temperature after the first milking and subsequent milking shall not exceed 10°C (50°F).

b. All finished, processed, and packaged raw milk and raw milk products shall be maintained at 7°C (45° F) or less after processing, during storage, and during transportation.

c. Recirculated cold water that is used in plate or tubular coolers or heat exchangers shall be from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards set by the Department.

19. Vehicles.

Vehicles used to transport raw milk and raw milk products shall be constructed and operated to protect their contents from sun, freezing, and contamination. Such vehicles shall be kept clean, inside and out; no substance capable of contaminating raw milk or raw milk products shall be transported with raw milk or raw milk products.

20. Insect and Rodent Control.

a. Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents, and by chemicals used to control such vermin.

b. Milkrooms and processing rooms shall be free of insects and rodents.

c. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents.

- d. Feed shall be stored in such a manner that it will not attract birds, rodents, or insects.
- e. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds, and free-stall housing shall be properly bedded and managed to prevent fly breeding.
- f. Milkrooms and processing rooms shall be effectively screened or otherwise protected against the entrance of vermin, including hose ports and floor drains through walls.
- g. Outer milkroom and processing rooms doors shall be tight and self-closing. Screen doors shall open outward.
- h. Only pesticides approved for use by the Department and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.
- i. Pesticides shall be used only in accordance with manufacturer's directions.

SECTION VIII. Standards for Further Processing of Raw Milk Products.

A. Buttermilk

- 1. All equipment used for the production and processing of buttermilk must be smooth, non-absorbent, and easily cleanable.
- 2. All ingredients must come from an approved source.
- 3. The pH of the buttermilk must be maintained at 4.6 or below following production and at the time of packaging, or the product must be maintained at 7°C (45° F) or below. All finished, processed, and packaged buttermilk must meet the requirements of VII.B.18.b.

B. Cream

- 1. All equipment used for the production and processing of cream must be smooth, non-absorbent, and easily cleanable.
- 2. Cream must be removed from the raw milk vat by the use of a separator or other method approved by the Department. The hand skimming of cream is prohibited.
- 3. Raw milk that has had the cream removed shall be labeled as "Raw Milk with Cream Removed."
- 4. All finished, processed, and packaged cream must meet the requirements of VII.B.18.b.

C. Kefir

- 1. All equipment used for the production and processing of kefir must be smooth, non-absorbent, and easily cleanable.
- 2. All ingredients must come from an approved source.
- 3. The product may contain harmless edible stabilizers not to exceed six-tenths of 1 percent (0.6%). Kefir shall contain no more than 10 coliform bacteria per gram and shall be free of molds, yeasts, and other fungi, and other objectionable bacteria that may impair the quality of the product.

4. Conformance with the requirements of I.A.14 and VIII.C.3 shall be demonstrated by a product assessment conducted by a third-party process authority and provided to the Department by the raw milk processor if requested by the Department.

5. All finished, processed, and packaged kefir must meet the requirements of VII.B.18.b.

SECTION IX. Bottling, Packaging, Container Filling, and Container Closure/Sealing.

A. Bottling, Packaging, and Container Filling.

1. Bottling, packaging, and container filling of raw milk and raw milk products shall be done at the place of production in a sanitary manner by approved mechanical equipment. Bottling, packaging, and container filling of raw milk or raw milk products may be conducted in the milkroom and processing rooms or room.

2. Bottling or packaging machine supply tanks and bowls shall have covers which are smooth and easily cleanable and shall be constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

3. A drip deflector shall be installed on each filler valve. The drip deflector shall be designed and adjusted to divert condensation away from the open container.

4. All containers, seals, and caps shall be from an approved Interstate Milk Shippers listed facility.

5. All containers, seals, and caps shall be handled in a sanitary manner and protected against undue exposure during the operation.

6. When any lubricant is applied to the filler equipment or other milk contact surfaces, the lubricant shall be food grade and applied in a sanitary manner.

7. Containers shall be closed immediately after being filled.

B. Container Closure/Sealing.

1. All container caps, sealers, and closures shall be stored in a clean, dry place protected from insects, rodents, dust, splash, or other contamination.

2. Only new containers, container caps, sealers, and closures shall be used. Reusable glass containers must be approved by the Department prior to use.

3. All container closure/sealing shall be done at the place of production in a sanitary manner by approved mechanical equipment.

4. Hand capping or sealing of containers is prohibited.

5. If suitable mechanical equipment for the capping or closing of specific container(s) of 12.8 liters (three [3] gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by the Department. Approval of such methods shall be obtained prior to beginning operation.

6. Bottles and packages which have been imperfectly capped, sealed, or closed shall have the contents emptied immediately into approved sanitary containers that are protected from contamination and maintained at 7°C (45°F) or less; when handled and stored properly, the contents may be repackaged in new containers at a later time.

7. All caps, seals, and closures shall be designed and applied so that the sealed container is tamper-evident (removal cannot be made without detection), and the pouring lip shall be protected to at least its largest diameter.

8. Caps, sealers, and closures shall not be left in the equipment at the end of an operating period. Caps, sealers, and closures remaining in the chute between the hopper and the capping device shall be discarded.

9. Loose caps, sealers, and closures may be returned to storage by enclosing them in a clean, protective wrap, plastic bag, or container approved by the Department.

SECTION X. Animal Health.

A. All raw milk and raw milk products for human consumption within South Carolina shall be from healthy animals. Raw milk and raw milk products from unhealthy animals shall not be offered for sale, barter, or be given away, or combined with other raw milk or raw milk products for human consumption.

B. All animals producing raw milk or raw milk products for human consumption shall be free of brucellosis and tuberculosis. Animals showing positive by lesions or a positive test shall be reported to the Department and shall also be reported to the State Veterinarian office in accordance with applicable law.

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

D. Animals shipped into South Carolina for additions to herds shall have been tested for tuberculosis and brucellosis within thirty (30) calendar days prior to being brought into the state, except that this shall not apply, with regard to brucellosis, to those cattle that have been vaccinated for brucellosis and are under thirty (30) months of age.

E. Records supporting the tests required in this section shall be made available to the Department and be validated with the signature of a licensed veterinarian.

SECTION XI. Recall.

Each producer and distributor of raw milk and raw milk products for human consumption shall develop and maintain procedures for the notification of regulatory officials, consumer notification, and product recall, and shall implement any of these procedures as necessary with respect to any product for which the producer, distributor, or the Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. If the Department determines, based upon representative samples, risk analysis, information provided by the producer or distributor, and other information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the producer or distributor to initiate a level of product recall or, if appropriate, issue a form of notification to customers. The producer or distributor shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem.

SECTION XII. Enforcement.

A. General.

This Regulation is issued under the authority of Sections 44-1-140(3) and 44-1-150, S.C. Code of Laws, 1976, as amended. It shall be enforced in accordance with interpretations and public health reasons approved by the Department.

B. Penalties.

Any person found to be in violation of this Regulation, in noncompliance with the issued permit, or in violation of an order issued by the Department shall be subject to civil monetary penalties, permit suspension, and/or permit revocation. Each day of continued violation shall be a separate offense.

C. Suspension of Permit.

1. The Department may temporarily suspend a permit whenever:

- a. It has reason to believe that a public health hazard exists;
- b. The permit holder has violated any of the requirements of this Regulation;
- c. The permit holder has violated its permit or an order of the Department, including but not limited to, a hold order;
- d. The permit holder has interfered with the Department in the performance of its duties, including willful refusal to allow an authorized inspection/audit; or
- e. The permit holder exhibits hostile behavior toward a representative of the Department during the performance of duty.

2. The Department may, without warning, notice, or hearing, immediately suspend the permit of any producer of raw milk or raw milk products whenever, in the opinion of the Department, an imminent health hazard exists. An imminent health hazard may include, but is not limited to, a willful refusal to permit authorized inspection, serious or repeated violations of bacterial, coliform, somatic cell, or cooling temperature standards, violation of drug residue test standards, or the presence of pathogenic organisms. Upon such suspension of the permit, all processing, bottling, and/or distribution activities shall immediately cease and remain ceased while the permit is suspended. The suspension of permit shall remain in effect until the imminent health hazard has been corrected to the satisfaction of the Department.

3. A suspension of permit shall remain in effect until any violation has been corrected to the satisfaction of the Department.

D. Revocation of Permit.

The Department may revoke a permit for serious or repeated violations of any of the requirements of this Regulation, the permit, or an order of the Department, or for interference with the Department or its representatives in the performance of its duties, including willful refusal to allow an authorized inspection/audit. Notwithstanding any other provisions of this Regulation, the permit may be revoked if

any Department representative is threatened with bodily harm or physical interference in the performance of inspectional duties.

E. Reinstatement of Permit.

1. Any producer whose permit has been suspended may submit a written application for the reinstatement of the permit. Any application for the reinstatement of a suspended permit must be in writing and must address all violations underlying the suspension and explain the steps taken to correct those violations.

2. Within seven (7) business days of the receipt of such an application, the Department shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine whether the conditions cited in the notice of suspension no longer exist. When the findings justify, the permit shall be reinstated.

3. When the permit suspension has been due to a violation of any of the bacteriological, coliform, somatic cell, cooling temperature, or drug residue test standards, the Department may issue a temporary permit whenever resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section VII. Samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3)-week period, and the Department shall reinstate the permit upon compliance with the appropriate standards as determined in accordance with Section V of this Regulation.

4. When a permit has been revoked, the holder of the revoked permit may submit a written application for a new permit; however, the Department may deny a new permit based upon past history, including previous enforcement, suspension, or revocation history.

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

SECTION XIII. Delayed Implementation.

Existing raw milk or raw milk products permit holders in operation prior to the effective date of the below listed requirements of this Regulation may use labels that do not comply with those requirements (but which meet all labeling requirements previously in effect) until their existing supply of labels as of the effective date of the below requirements is exhausted or for no more than one (1) year from the effective date of these requirements, whichever is sooner:

1. As provided in Section VI.C.3, all labels shall include the following consumer advisory, in no smaller than six (6) point font: "Consuming raw milk products may increase your risk of foodborne illness."

2. As provided in Section VI.E, labels may only use the term Grade "A" Raw in conjunction with the designation of "SC," to read "SC Grade 'A' Raw". Other grade designations may not be used.

Raw milk or raw milk products permit holders permitted after the effective date of the requirements referenced in Section XIII.1 and XIII.2 above must comply with all of the labeling requirements of Section VI without any delayed implementation.

SECTION XIV. Severability Clause.

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