ARTICLE 12:81

BOTTLED RAW MILK FOR HUMAN CONSUMPTION

Chapter

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CHAPTER 12:81:01

DEFINITIONS

Section

12:81:01:01 Definitions

12:81:01:01. Definitions. Terms defined in SDCL 39-6-1 and SDCL 40-32-2 and in the Grade "A" Pasteurized Milk Ordinance have the same meanings when used in this article. In addition, terms used in this article mean:

(1) "Accredited Laboratory," a laboratory using the approved methods found in the Association of Official Agricultural Chemist (AOAC) and United States Food & Drug Administration Bacteriological Analytical Manual (FDA-BAM) for pathogen testing in milk, and successfully participates in a food pathogen testing proficiency program;

(2) "Adulterated milk and milk products," any milk or milk product which bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health; bears or contains any added poisonous or deleterious substances for which no safe tolerance has been established by state or federal regulation or in excess of any tolerance established; consists in whole or in part of any substance unfit for human consumption; has been produced, processed, prepared, packed, or held under unsanitary conditions; has a container composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health; or has any substance added to it or mixed or packed with it to increase its bulk or weight, reduce its quality or strength, or make it appear better or of greater value than it is;

(3) "Bottled raw milk for human consumption," milk that has not been pasteurized and is packaged for human consumption. The term, milk, includes cow's, goat's, sheep's, and other hoofed mammal's milk;

(4) "Misbranded milk and milk products," products whose containers bear or accompany any false or misleading written, printed, or graphic matter; products which do not conform to their definitions as contained in this article;

(5) "Officially Designated Laboratory," a commercial laboratory authorized to do official work by the department, or an official laboratory which is under the direct supervision of the department, or a milk industry laboratory officially designated by the department for the examination of producer samples of raw milk and commingled milk tank truck samples of raw milk for somatic cell limits, drug residues, and bacterial limits;

(6) "Official sample", milk or water sample collected by a sampler that is licensed by the department using the universal sampling system as defined in Appendix B of the PMO;

(7) "Pesticide," a substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; a substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; or a substance or mixture of substances intended to be used as a spray adjuvant;

(8) "PMO," "Grade "A" Pasteurized Milk Ordinance," the Grade "A" Pasteurized Milk Ordinance (PMO) and Appendices, 2011, except sections 16 and 17, United States Public Health Service.

Source:
General Authority: SDCL 39-6-9, 40-32-18.
Law Implemented: SDCL 39-6-9, 39-6-3, 40-32-18.

References: "Grade A Pasteurized Milk Ordinance", 2011, published by Public Health Service/Food and Drug Administration, U.S. Department of Health and Human Services, Washington, D.C. 20740-3835. Copies may be obtained from the Milk Safety Branch HFS-626, Division of Cooperative Programs, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835; no charge. This request must include a self-return label.

"The Official Methods of Analysis of the AOAC International", 19th edition, 2012, Dr. George Latimer, Jr. Editor, AOAC International 481 N. Frederick Avenue, Suite 500 Gaithersburg, MD 20877 USA.

"United States Food and Drug Administration Bacteriological Analytical Manual (BAM)", 8th Edition, 1998, Thomas Hammack, Peter Feng, Karen Jinneman, Patrick M. Regan, Julie Kase, Palmer Orlandi, William Burkhardt, Editors, may be obtained on line from
http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm.

CHAPTER 12:81:02
PERMITS FOR BOTTLED RAW MILK FOR HUMAN CONSUMPTION

Section	
12:81:02:01	Bottled raw milk for human consumption – Permits required.
12:81:02:02	Bottled raw milk for human consumption – Minimum permit requirements.

12:81:02:01. Bottled raw milk for human consumption - permits required.

No person may offer or provide bottled raw milk for human consumption unless the raw milk has been produced and packaged by a producer holding a permit issued by the secretary under SDCL 40-32-10.1 or SDCL 39-6-9, and the milk meets the standards in §§12:81:03:01 to 12:81:03:06, inclusive.

No milk producer may offer or provide bottled raw milk for human consumption on the farm premises unless the producer holds a producer's permit issued by the secretary and the milk meets the standards in §§12:81:03:01 to12:81:03:06, inclusive.

Source:
General Authority: SDCL 39-6-9 (1) to SDCL 39-6-9 (11), inclusive, 40-32-18 (2) to 40-32-18(7), inclusive, 40-32-18 (9).
Law Implemented: SDCL 39-6-3, 40-32-1, 40-32-4, 40-32-10.1, 40-32-10.3.

12:81:02:02. Bottled raw milk for human consumption – Minimum permit requirements.

Before any bottled raw milk may be offered or provided for human consumption, the producer shall submit or cause an official raw milk sample to be submitted to an officially designated laboratory for testing at the producer's expense for somatic cell count, drug residue, and bacteria. This sample shall be taken from the comingled raw milk supply such as the dairy farm bulk tank if the farm is using a bulk tank to store the farm's milk supply prior to packaging. The results shall be provided to the department. All such preliminary samples must be taken using the milk sampling procedures in Appendix B of the PMO as adopted by § 12:05:14:01. Testing the raw milk for somatic cell count, drug residue, and bacteria shall be conducted monthly at the producer's expense, and the results shall be provided to the department.

Before any bottled raw milk may be offered or provided for human consumption, the department shall collect an official bottled raw milk sample in the consumer container which will be submitted to an accredited laboratory approved by the department for testing for bacteria, coliform bacteria, pathogenic bacteria (Salmonella, Listeria Monocytogenes, Campylobacter spp., and E. Coli 0157:H7), and antibiotic residue. The department shall pay for this testing and the results shall be provided to the department. All such preliminary samples must be taken using the milk sampling procedures in Appendix B of the PMO as adopted by §12:05:14:01. The testing of the bottled raw milk for bacteria, coliform bacteria, pathogenic bacteria, and antibiotic residue shall be

conducted monthly at the department's expense, and the results shall be provided to the department.

Before any bottled raw milk may be offered or provided for human consumption, a producer with a private water supply used in the milking operation shall submit or cause an official water sample to be submitted to an officially designated or EPA certified laboratory for testing at the producer's expense for coliform bacteria. The results shall be provided to the department. All such preliminary samples must be taken using the water sampling methods adopted in Appendix G of the PMO as adopted by § 12:05:14:01 and test negative for coliform bacteria. The private water supply must be tested at a minimum of once every three years or immediately after any repairs have been made to the private water supply. The testing must be conducted at the producer's expense and the test results must be provided to the department.

No bottled raw milk may be offered or provided for human consumption if laboratory test results for bottled raw milk samples exceed the standards for milk in § 12:81:03:03.

Source:
General Authority: SDCL 39-6-9 (5), (11), (12), 40-32-18(2), (5), (6).
Law Implemented: SDCL 39-6-3, 40-32-1, 40-32-13, 40-32-22, 40-32-23.

CHAPTER 12:81:03
STANDARDS FOR BOTTLED RAW MILK FOR HUMAN CONSUMPTION

Section	
12:81:03:01	Bottled raw milk for human consumption – Packaging raw milk
12:81:03:02	Bottled raw milk for human consumption – Sample collection.
12:81:03:03	Bottled raw milk for human consumption - Standards.
12:81:03:04	Bottled raw milk for human consumption – Contamination.
12:81:03:05	Bottled raw milk for human consumption – Labeling.
12:81:03:06	Bottled raw milk for human consumption – Animal health.

12:81:03:01. Bottled raw milk for human consumption – Packaging raw milk.

Bottled raw milk for human consumption must be packaged on the farm where it is produced. There may not be any direct openings between the milk packaging area and milking operations. Packaging must be done in a sanitary manner with sanitary equipment.

Source:
General Authority: SDCL 39-6-9, 40-32-18 (4), (5), (6), (7).
Law Implemented: SDCL 39-6-3, 40-32-1.

12:81:03:02. Bottled raw milk for human consumption – Sample collection.

Bottled raw milk must, at a minimum, be tested monthly for bacteria, coliform bacteria, drug residue, and pathogenic bacteria (Salmonella, Listeria Monocytogenes, Campylobacter spp., and E.Coli 0157:H7) at an accredited laboratory approved by the department.
Additionally, bottled raw milk may be tested for pesticides, added water and other adulterants, as deemed necessary by the department.

The tests must be undertaken using the sampling methods in § 12:81:02:02 and must meet the standards in §12:81:03:03. Any such sample must be collected from the consumer container.

Source:
General Authority: SDCL 39-6-9 (1), (5), 40-32-18(2).
Law Implemented: SDCL 40-32-1, 40-32-23.

12:81:03:03. Bottled raw milk for human consumption - Standards.

Bottled raw milk must be produced and handled to conform to the following chemical, bacteriological, and temperature standards.

(1) Temperature: Maintained at 45 degrees Fahrenheit (7 degrees Celsius) or less;

(2) Antibiotics: No positive results on drug residue detection methods that are currently validated by United States Food & Drug Administration-Center for Veterinarian Medicine (FDA-CVM) or any other drug detection methods, as deemed necessary by the department;

(3) Bacteria Limits: Not to exceed 20,000 per ml;

(4) Coliform: Not to exceed 10 per ml;

(5) Pathogen: No pathogenic bacteria present.

Source:
General Authority: SDCL 39-6-9 (1), (5), 40-32-18(2).
Law Implemented: SDCL 40-32-1.

12:81:03:04. Bottled raw milk for human consumption – Contamination.

If official laboratory test results indicate that a sample of bottled raw milk for human consumption contains pathogenic bacteria, the milk producer must be notified immediately; the bottled raw milk must immediately be removed from supplies intended for human consumption; and the milk producer's permit is suspended immediately to prohibit the provision of bottled raw milk direct to the consumer. The department shall reinstate the milk producer's permit to allow the milk producer to only market raw milk

to a licensed milk buyer. The department shall notify the public. An official sample of bottled raw milk must be collected within two working days by the department upon the faxed, emailed, or written request of the milk producer. This sample must be tested, at the producer's expense, at an accredited laboratory approved by the department, for the contamination that caused the permit suspension.

Following this initial sampling, the department shall collect an additional sample no sooner than 24 hours and no later than 48 hours after the previous sample collection. The sample must also be tested, at the expense of the producer, at an accredited laboratory approved by the department to determine whether the contamination that caused the permit suspension is still present in milk produced at the permitted facility. The department shall reinstate the milk producer's permit if both samples meet the standards outlined in §12:81:03:03 and §12:81:02:02 and the milking facility successfully passes an inspection.

Source:
General Authority: SDCL 39-6-9 (1), (2), (5), 40-32-18(2).
Law Implemented: SDCL 39-6-15, 40-32-1; SDCL 40-32-10.4, 40-32-26, 40-32-33.

12:81:03:05. Bottled raw milk for human consumption – Labeling.

All bottles, containers and packages containing bottled raw milk for human consumption must be labeled in accordance with the requirements provided in this section.

The warning label type size must be consistent with the type size of other required labeling, but not less than one-sixteenth inch in height. The warning label must be conspicuous and in contrasting color from other labeling. The warning label must be prominently displayed on the container's principal display panel. The warning label must be clearly readable.

All bottles, containers and packages containing bottled raw milk for human consumption must be conspicuously marked with:

(1) The identity of the farm where the raw milk is produced and packaged;

(2) The words "RAW MILK";

(3) The date of bottling.

The raw milk container must also bear the following labeling:

"WARNING: This product has not been pasteurized and may contain harmful bacteria. Pregnant women, infants, children, the elderly and persons with lowered resistance to disease have the highest risk of harm from use of this product."

Source:
General Authority: SDCL 39-6-9 (3), 40-32-18(7).

Law Implemented: SDCL 39-6-3, SDCL 40-32-1.

12:81:03:06. Bottled raw milk for human consumption - Animal health.

Before offering or providing bottled raw milk for human consumption, the producer shall complete a herd test at the producer's expense for tuberculosis and brucellosis on animals that are used for raw milk production and on beef and non-milking hoofed mammals housed with, or in close proximity to, the milking herd. Following this initial test, complete herd tests must then be conducted at the producer's expense every 12 months. All additional animals must be tested before entering the herd. Testing must be completed by a USDA accredited veterinarian. A certificate identifying each animal and the test results, signed by the veterinarian, must be submitted to the department within 15 days of completion. Failure to complete and submit required herd tests will result in immediate suspension of the milk producer's permit until the tests are completed and test results submitted. If any animal has a positive test result, the producer's permit is immediately suspended until a complete herd test shows no positive test results.
The producer may apply for tuberculosis accredited free herd status and certified brucellosis free herd through the South Dakota Animal Industry Board in lieu of annual herd testing.

Source:
General Authority: SDCL 39-6-9 (6).
Law Implemented: SDCL 39-6-15, 40-32-1, 40-32-10.4, 40-32-23.

CHAPTER 12:81:04
ENFORCEMENT FOR BOTTLED RAW MILK FOR HUMAN CONSUMPTION

Section

12:81:04:01	Enforcement.
12:81:04:02	Notice or suspension if quality standards are exceeded.
12:81:04:03	Drug or pesticide residues.
12:81:04:04	Reinstatement of permit suspension due to quality standards
12:81:04:05	Reinstatement of permit suspended for drug residue.

12:81:04:01. Enforcement.

Dairy farms that are issued a Manufacturing Grade farm permit shall comply with ARSD 12:17:02:03, 12:17:02:05 to 12:17:02:09 inclusive, 12:17:02:11, 12:17:02:13, 12:17:02:14, 12:17:02:16, 12:17:02:17, 12:17:03:09, 12:17:03:11, 12:17:03:16, 12:17:03:21, 12:17:03:22, 12:17:03:22.02, 12:17:03:24, 12:17:04:01, 12:17:04:04 to 12:17:04:14 inclusive, 12:17:04:16 to 12:17:04:19 inclusive.

Dairy farms that are issued a Grade A farm permit shall comply with ARSD 12:05:03:02 to 12:05:03:04 inclusive, 12:05:07:04, and 12:05:14:01.

Source:
General Authority: SDCL 39-6-9 (1) to SDCL 39-6-9 (11), inclusive, 40-32-18 (2) to 40-32-18(7), inclusive.
Law Implemented: SDCL 39-6-3, 39-6-15, 40-32-1, 40-32-4, 40-32-10.1, 40-32-10.3, 40.32-10.4, 40-32-22, 40-32-23.

12:81:04:02. Notice of suspension if quality standards are exceeded.

If two of the last four consecutive bacterial and coliform counts or cooling temperatures exceed the limit of the standard for bottled raw milk, the secretary shall send a written notice to the permit holder. The notice remains effective as long as two of the last four consecutive samples exceed the limit of the standard. The secretary shall suspend the producer's permit immediately if the standard is violated by three of the last five bacterial counts, coliform counts, or cooling temperatures.

Source:
General Authority: SDCL 39-6-9 (2), (5), 40-32-18 (2).
Law Implemented: SDCL 39-6-15, 40-32-1, 40-32-10.4.

12:81:04:03. Notice of suspension for drug or pesticide residues.

If a drug or pesticide residue test is positive, milk must be disposed of in a manner that removes it from the human food chain. The secretary shall immediately suspend the producer's permit. For a third violation of drug residue in 12 months, the secretary shall hold a hearing pursuant to SDCL 1-26 to revoke the producer's permit.

Source:
General Authority: 39-6-9 (2), (5), 40-32-18 (2).
Law Implemented: 39-6-15, 39-6-16, 40-32-1, 40-32-10.4, 40-32-10.5.

12:81:04:04. Reinstatement of permit suspension due to quality standards.

If the permit suspension is due to a violation of bacterial counts, coliform counts, or cooling temperature, the secretary shall within one week after the receipt of notification for reinstatement and receipt of acceptable results of an official resampling of the producer's milk supply, issue a three-week temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. An official sample must be taken, and analyzed at an officially designated laboratory, at the producer's expense at a rate of at least one per week for three weeks. If any sample is not in compliance during the three-week temporary permit period, the producer's permit is immediately suspended. The secretary shall reinstate the permit upon compliance with the applicable standards set in chapter 12:81:03.

Source:
General Authority: 39-6-9 (2), (4), (5), 40-32-18 (2).
Law Implemented: 39-6-15, 40-32-1, 40-32-10.4, 40-32-23, 40-32-26.

12:81:04:05. Reinstatement of permit suspension for drug or pesticide residues.

The secretary shall reinstate the producer's permit after an official sample taken from the producer's milk supply is no longer positive for drug or pesticide residues.

Source:
General Authority: 39-6-9 (2), (5), 40-32-18 (2).
Law Implemented: 40-32-1, 40-32-10.4, 40-32-23.