

SOUTH DAKOTA
DEPARTMENT OF AGRICULTURE AND
NATURAL RESOURCES

EDUCATIONAL GUIDE

SALE OF RAW MILK FOR HUMAN
CONSUMPTION



Educational Guide

Sale of Raw Milk for Human Consumption

The South Dakota Department of Agriculture and Natural Resources (DANR) interest in bottled raw milk for human consumption is to protect consumers and producers in the state by enforcing the established rules and regulations. The DANR carries out this work through inspections, testing, and technical assistance. This guide is not a substitute for the laws and rules regarding bottled raw milk, but provides assistance to the producer wishing to sell bottled raw milk.

"Raw milk for human consumption" is the lacteal secretion, practically free from colostrum, obtained by the milking of one or more healthy cows, goats, sheep, or other hooved mammals that has not been pasteurized or homogenized and is packaged for human consumption. The term also includes raw cream intended for human consumption.

Raw milk for human consumption can be purchased for personal use at the farm where the milk is produced or delivered directly to the consumer by the producer. No raw milk for human consumption may be sold at a farmers market or farmer-owned retail store not located on the producer's farm.

Laws and Rules

Bottled raw milk producers need to be familiar with the state laws and rules that regulate the production and sale of bottled raw milk.

Codified Laws	SDCL 40-32 Milk Plants, Producers, and Distributors SDCL 39-6 Milk and Milk Product Grades and Standards
Administrative Rules	ARSD 12:17 Dairy Plants and Manufactured Grade Milk ASRD 12:05 Grade A Milk and Milk Products ASRD12:81 Sale of Bottled Raw Milk for Human Consumption

Permits, Licenses, and Fees

A permit and license is required for any producer of milk who is selling raw milk for human consumption directly to the consumer. Each license is valid for one year, or any fraction thereof, and is \$50 to renew every December 31st.

An inspection service fee is collected annually by July 1st and is \$50. Inspection to ensure compliance with the rules and statute occurs once a year.

A valid sampler license may also be required for farms who take their own monthly samples to submit for testing. This license is valid for one year and is \$50 to renew every July 1st.

Testing of raw milk for somatic cell count, drug residue, and bacteria is conducted monthly at the producer's expense.

Testing of raw milk for pathogens from the consumer container is conducted monthly at the DANR's expense.

Private water sources are tested every three years at the producer's expense.

Labeling and Recordkeeping



All final consumer bottles, containers, and packages containing 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" or "RAW CREAM";
- (3) The date of bottling.

Producers engaged in the selling of raw milk for human consumption shall maintain records of the consumers who purchase raw milk. The records shall contain the consumer name, phone number, and date of sale. Records shall be maintained for a period of 90 days.

Standards and Testing

Raw milk for human consumption must be produced and handled to conform to the following standards:

- ✓ **Temperature:** Maintained at 45°F (7°C) or less.
- ✓ **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 DANR.
- ✓ **Bacteria Limits:** Not to exceed 30,000 per ml.
- ✓ **Pathogen:** No pathogenic bacteria present.
- ✓ **Somatic Cell Count:** Not to exceed 750,000 per ml in cow milk. Not to exceed 1,500,000 per ml in goat milk.

Raw milk for human consumption samples may be tested for pesticides by the secretary at least once a year or at a frequency which the secretary determines to be adequate to protect the consumer. The samples may not exceed tolerances established in 45 C.F.R. § 180 Subpart C (July 1, 2014).

One sample per month is taken as the official producer sample, by a licensed sampler to be tested for standard plate count, somatic cell counts, and drug residue at an accredited laboratory approved by the DANR.

One sample per month is taken from the consumer container to be tested for coliform and pathogenic bacteria (*Salmonella* spp., *Listeria monocytogenes*, *Campylobacter jejuni*, and Shiga toxin-producing *E. coli*) at an accredited laboratory approved by the DANR.

When collecting official samples Appendix B of the Pasteurized Milk Ordinance (PMO) must be followed. This includes:

- ✓ Samplers shall practice good hygiene; maintain a neat and clean appearance; and not use tobacco in the milk house.
- ✓ Samplers must wash hands thoroughly and dry with a clean individual sanitary towel.
- ✓ Samplers must use a sample dipper or other approved aseptic sampling devices of sanitary design and material.
- ✓ Any single use sample containers shall be properly stored.
- ✓ Samplers must use a calibrated pocket thermometer, certified for accuracy every six months. The thermometer must have an accuracy of within 2°F ($\pm 1^\circ\text{C}$) for recording temperature.
- ✓ Samplers must use an approved sanitizing agent and if necessary applicable sanitizer test kit to test the strength of the agent.
- ✓ Samplers must use a device for timing milk agitation if using a bulk tank.
- ✓ A temperature control sample shall be taken with each official sample. This sample shall be labeled with the collection time (military time (24 hour clock) is acceptable), date, temperature, and producer and bulk milk hauler/sampler identification.

Risks

Raw milk for human consumption can carry many bacteria that can be potentially harmful when consumed. Children, the elderly, pregnant women, and immunocompromised individuals are most at risk. The DANR uses a variety of testing analysis to ensure this product is as safe as possible. While the risk may never be completely eliminated, it is crucial every producer understands the tests and analysis provided to them. By keeping an eye on the results of these tests and analyses, producers can help reduce the risk from raw milk for human consumption.

A standard plate count (SPC) is the indication of the total number of aerobic bacteria present. The most common causes of high SPCs is poor cleaning of the milking system. The lower the SPC the better. The DANR requires the bacteria to be less than 30,000 per mL. Generally, if the SPC is less than 5,000 colony forming unit (cfu) per mL, sanitation is good and cooling is adequate (Jones, et al.).

The somatic cell count (SCC) is an indicator of udder health and milk quality. The limit for raw milk is less than 750,000 cells per mL. High SCC is associated with udder inflammation and indicates that an immune response has been generated by the animal. Mastitis is a very common reason for a high SCC (Li, 2014).

All antibiotic tests have to be negative. No amount of antibiotic is ever acceptable in any milk product.

A coliform count is done to determine the presence of bacteria that are commonly associated with manure or environmental contamination. Counts above 50 indicate poor milking hygiene or other sources of contamination (Murphy, 2008). Possible sources and causes of contamination can be the exterior of the udder; environmental contaminants such as bedding, manure, feeds; and not using sanitizer.

Below is a table listing disease-causing pathogens that can be present in raw milk, bold items are currently tested for monthly. The test must be negative for compliance.

Pathogen	Illness Associated
<i>Salmonella</i> spp.	Gastrointestinal (GI) illness; Typhoid fever
<i>Campylobacter jejuni</i>	Campylobacteriosis
Enterohemorrhagic <i>Escherichia coli</i> (E.Coli O157:H7)	GI illness; kidney failure; death
<i>Listeria monocytogenes</i>	Noninvasive GI illness; Meningitis if enters bloodstream
<i>Brucella</i> spp.	Brucellosis
<i>Coxiella burnetii</i>	Q Fever (Chronic Q Fever can lead to death)
<i>Staphylococcus aureus</i>	Staphylococcal food poisoning
<i>Mycobacterium bovis</i> / <i>Mycobacterium tuberculosis</i>	Tuberculosis

(Bad Bug Book, 2012)

Safe Handling

Cleanliness in milking, transporting, and packaging is vital to reducing chances of harmful bacteria entering the final product. Bacteria grow very quickly in unsanitary conditions or even when the milk is slowly cooled. The quickest, most efficient, way to cool milk is using an ice bath. Do not use a refrigerator as the main cooling method due to the length of time to reach proper temperature. Some tips for farm operations and packaging are as follows:

Milking guidelines	Packaging guidelines
<ul style="list-style-type: none">✓ Provide adequate bedding to ensure animal cleanliness.✓ Use hot wash water (155°-170°F).✓ Check gaskets and rubber parts for cracks.✓ Ensure teatcup liners are smooth.✓ Use separate and clean equipment when milking fresh and treated animals.✓ Follow proper udder preparation protocols (i.e. clean, sanitize, dry).✓ Refrain from wet hand milking.✓ Clean equipment after each use.	<ul style="list-style-type: none">✓ Transport cans using tight fitting lids.✓ Filter milk using an approved single serve article before cooling and storage.✓ Strain within a clean overhead environment.✓ Sanitize all surfaces milk comes into contact with.✓ Enforce proper handwashing.✓ Rapidly cool milk to 45°F or less.✓ Do not submerge tops of containers in water bath after packing.

Herd Health

Animals must meet the requirements for tuberculosis and brucellosis, found in ARSD 12:17:04:02 and ARSD 12:17:04:03, as well as for any other diseases as required by the state veterinarian.

Animals which show evidence of the secretion of abnormal milk in one or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. Selling or delivering bottled raw milk from diseased animals is illegal.

Farm Requirements

Milking facility requirements:

- ✓ Clean, well-lit, and ventilated.
- ✓ Floors must be made of impervious material, sloped to drain, and in good repair.
- ✓ No animals present in the milking facility except for the milking herd.

Milk room requirements:

- ✓ Conveniently located near the milking facility.
- ✓ One or more outside walls with smooth and easily cleanable surfaces.
- ✓ Floor must be concrete or made of impervious material, graded to drain to a trapped floor drain.
- ✓ Well-lit and ventilated.
- ✓ Heated to above freezing.
- ✓ No animals or storage of items not directly related to the milking operation.
- ✓ Doors must be solid, tight-fitting, and self-closing; doors must swing outward.
- ✓ All openings must be screened.
- ✓ Equipped with a two compartment wash vat.
- ✓ Must have water under pressure to a thermostatically controlled hot water tank.

Milk storage requirements:

- ✓ Each farm bulk tank must be emptied for visual inspection at least once every 72 hours.
- ✓ Milk must be cooled to 45° F or lower within two hours after milking. The blend temperature after the first milking and subsequent milkings may not exceed 50° F. Each bulk tank, if the farm is using a bulk tank to store the farm's milk supply, must be equipped with a thermometer that is in good working condition.
- ✓ Utensils and equipment must be maintained in good condition, free from rust, open seams, milkstone, or other unsanitary conditions.
- ✓ Utensils and equipment must be washed, rinsed and sanitized, and drained after each milking. Sanitization must also occur immediately before use with 50 parts per million chlorine solutions or its equivalent.

Drugs and medicines must be stored in a manner that prevents contamination of the milk, utensils, or equipment. Products must be labeled to include the following:

- ✓ The name and address of the manufacturer or distributor for over-the-counter drugs, or the veterinary practitioner dispensing the product for prescription and extra-label-use drugs;
- ✓ Directions for use;
- ✓ The prescribed withholding times;
- ✓ Cautionary statements, if needed; and
- ✓ The active ingredient of the product.

Unapproved or improperly labeled drugs may not be used to treat animals and may not be stored in the milk house, milking barn, stable, or parlor. Drugs appropriate for lactating and non-lactating animals must be separated.

Contact

Producers are strongly encouraged to contact the DANR for the complete rules regarding the production, bottling, and selling of bottled raw milk.

South Dakota Department of Agriculture and Natural Resources
Dairy/Egg Program
Alfred Dairy Science Hall
Box 2104
Brookings, SD 57007
Phone: 605.688.6455

References

- Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins.* Food and Drug Administration, 2nd ed., 2012.
www.fda.gov/downloads/food/foodsafety/foodborneillness/foodborneillnessfoodbornepathogensnaturaltoxins/badbugbook/ucm297627.pdf
- Jones, G.M. "Testing Bulk Tank Milk Samples." Virginia Cooperative Extension, 2009.
https://pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/404/404-405/404-405_pdf.pdf.
- Li, N. et al. "Role of Somatic Cells on Dairy Processes and Products: A Review." Dairy Science & Technology, 2014. www.ncbi.nlm.nih.gov/pmc/articles/PMC4180028/
- Murphy, S.C. et al. *Sources and Causes of High Bacteria Counts, An Abbreviated Review.* Cornell University, 2008.
<https://articles.extension.org/pages/11811/sources-and-causes-of-high-bacteria-counts-in-raw-milk:-an-abbreviated-review>
- Pasteurized Milk Ordinance.* U.S. Department of Health and Human Services, Food and Drug Administration, Washington D.C, 2017.
<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/UCM612027.pdf>