Raw Milk

A Quick Guide for Producer-Processors

Healthy animals can carry illness-causing germs, such as Brucella, Campylobacter, Cryptosporidium, E.Coli, Listeria, Mycobacterium, Salmonella and others that can contaminate milk. Pasteurization is the most effective means of destroying or deactivating these germs.

Raw milk is unpasteurized milk produced for human consumption. In this guide you'll find recommended best practices to produce and distribute raw milk. Here are factors to consider:

- Although a market exists for raw milk, there are also potential health
 hazards associated with it. Bacteria or other pathogenic (disease-causing)
 microorganisms that can be found in raw milk include Campylobacter
 jejuni, Salmonella, Listeria monocytogenes, and E. coli 0157:H7. In
 addition, tuberculosis, undulant fever, and Q fever can be contracted
 from consuming raw milk. These pathogens can cause serious illness or
 death.
- Safe, clean, production, packaging and transport is critical. This will
 decrease the possibility of contamination and reduce the risk to the
 consumer, which is particularly important for protecting children, the
 elderly, pregnant women, and other individuals with weakened immune
 systems.
- In Montana, raw milk can be sold by small dairies as a homemade food.
 A producer must inform the consumer that the product has not been licensed, permitted, certified, packaged, labeled, or inspected per any official regulations.



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Testing Milk



Per SB199, a small dairy shall sample, test, and retest every six months for standard plate count, coliform count, and somatic cell count of milk or cream sold as a homemade food.

Records from tests must be maintained for two years.

More frequent testing is recommended as a best practice.

Herd Health

A successful raw milk operation requires healthy animals

All milking cows, goats, and other mammals should meet basic animal health requirements. Distributing milk or milk products from diseased animals could be dangerous.

Your animals should test negative for diseases that can be transmitted to people through raw milk. An accredited veterinarian can collect and submit official samples for animal health testing. The Montana Local Food Choice Act states every lactating cow, goat, or lactating sheep that is part of a small dairy shall be tested for Brucellosis annually. In addition:

- Animals should also be tested for tuberculosis and Q Fever (see chart, next page), as well as for any other diseases as recommended by the state veterinarian. (If new diseases emerge, the state veterinarian may suggest additional tests.)
- Your animals should be tested prior to being used to produce milk, and then annually after that.
- Additions to the herd should test negative for disease within the previous thirty days before introduction into the herd. This includes all fresh cows, calves, and other livestock (chickens, pigs, etc.)
- Animal health testing records should be kept for each animal that is used (or intended to be used) to produce raw milk or raw milk products.

There are other animal health requirements, too:

- Any animal showing chronic mastitis, whether producing abnormal milk or not, should be permanently excluded from the milking herd. Animals producing bloody, stringy, or otherwise abnormal milk, but with only slight inflammation of the udder should be excluded from the herd until re-examination shows that the milk has become normal.
- Ensure the herd stays clean. This is especially important during winter months when animals may be confined indoors. Using composted bed packs may help reduce filth.

Good herd inventory and animal health records provide information that helps monitor public health disease concerns.

Good herd management and biosecurity practices can help keep your animals healthy and productive. Having all the right equipment and facilities won't matter if your animals are sick, the milk they produce can make customers sick. Work with your accredited veterinarian to develop a herd health plan.



Having all the right equipment and facilities won't matter if your animals are sick.
Milk sick animals produce can make people sick.



Keeping Your Herd Healthy

Your vet can help you create a plan to address:

- Vaccination.
- Nutrition.
- Animal comfort and safety.
- Mastitis prevention.
- Early identification and treatment of ill animals.
- Effective and appropriate treatment protocols.

DISEASES, TESTS, AND PREVENTION AND CONTROL

DISEASE		SUGGESTED TESTS	PREVENTION and CONTROL
Brucellosis	One of the most serious livestock diseases. Mostly affects cattle but may affect other animals. Brucellosis can be transmitted to humans through the consumption of raw milk. In humans it causes undulant fever, a chronic disease characterized by recurrent fever and general malaise.	Lactating animals must be tested for Brucellosis annually. The test is a blood test in which the sample must be drawn by an accredited veterinarian and tested at a state-approved laboratory.	Vaccination of young animals and annual testing of adult livestock can reduce the prevalence of Brucellosis in cattle.
Tuberculosis	A contagious disease of cattle and other animals. It has a wide range of hosts and can also be contagious to humans. Tuberculosis can be transmitted to humans through the consumption of raw milk. Tuberculosis affects mainly the respiratory system but may affect other organs.	Animals should be tested for Tuberculosis within the previous 12 months. The test is a skin sensitization test in which 0.1 ml of tuberculin is injected into the skin at the base of the tail. The area is observed 72 hours after injection for the detection of any response. An accredited veterinarian must perform the test.	Control in livestock can be accomplished by annual testing.
Q Fever	Q fever (Query fever) is an infectious disease that spreads from animals to humans. Q fever is caused by a microbe called "Coxiella burnetii" and is highly infectious to humans. This microbe can survive for months and even years in dust or soil. Infected animals also release the microbe in milk and manure. People usually get Q fever by breathing in this contaminated barnyard dust. Occasionally, people can get Q fever from drinking contaminated raw milk or from tick bites.	Animals should be tested for Q Fever within the previous 12 months. Seriologic testing detects the presence of antibodies to Coxiella burnetii antigens. The test is a blood test in which the sample must be drawn by an accredited veterinarian and tested at a state-approved laboratory.	Appropriately dispose of placenta, birth products, fetal membranes, and aborted fetuses at facilities housing sheep and goats. Control in livestock is accomplished by annual testing. Surfaces, floors, and walls contaminated with fluids or dust from animals should be disinfected using procedures established for infection control.

Facilities and Equipment

Many of the decisions you'll make about your raw milk operation involve facilities and equipment:

- How and where the animals are housed.
- How and where the animals are milked.
- How the milk gets from the animals to the bottling/packaging facility.
- How and where the milk gets packaged.
- How and where the milk gets stored.

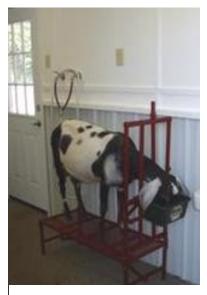
In a raw milk operation, these decisions are particularly important because you must take special care to reduce and prevent contamination. **Separation and sanitation** are two of the most important considerations when choosing facilities and equipment.

Facilities

A raw milk operation needs facilities for both **production and processing**. Although a raw milk processing plant is located on the same site as the dairy farm, milk production and processing (bottling) activities should remain separate to reduce potential contamination.

For example, milking production equipment should not be stored or cleaned in the milk processing plant. Milk processing rooms designed as processing plants may have a milk tank installed. All other traditional milk house activities should be done separately (i.e., equipment cleaning). Also, it is highly recommended that the milk house is not used for storing or selling the bottled milk, in order to reduce foot traffic in the milk house and thus reduce potential contamination.

All farms vary in layout and design, but by building clear separation into the design of your facilities from the start, you can make it easier to prevent contamination.



Some facilities and equipment will need to accommodate your animals and protect the milk from contamination.



Milk processing facilities need to be easy to clean and dedicated to milk processing only.

Some Facility Basics

Keep in mind these best practices for the operation:

- Floors are concrete or other impervious material, so they are easily cleanable.
- Walls are washable and finished light in color.
- Doors and windows are tight-fitting and screened when open.
- Lighting and ventilation are adequate.
- The space is large enough to handle maximum milk production and milk processing.
- Product contact areas are accessible for cleaning and inspection.
- Hot and cold water are plumbed for handwashing and cleaning.

Remember: Bare or unfinished wood encourages bacteria survival and growth.



Light-colored walls and good lighting make it easier to see "dirt" that could contaminate your product.

What facilities do I need? Do I need separate buildings, or can I have one building with separate areas?

The recommended best practice is to have facilities for each of the four main functions. See chart below. Ideally, to prevent contamination of your product, there will be four separate and distinct areas. They all can be in one building or separated into individual buildings. The design of your facility can be creative and still meet the recommendations. There is no one-size-fits-all model.

Barn	Where the animals are housed.		
Milking Parlor	Where the animals walk in to be milked.		
Milk House	Where milking equipment from the parlor is washed, rinsed, sanitized and stored in a clean condition between milking.		
	This room needs at least a 2-compartment or 3-compartment sink and may house a bulk milk storage (holding) tank, or other milk cooling equipment and cold storage for the milk prior to bottling.		
Milk	Where the raw milk is handled for the final time and filled into the finished product container.		
Processing Plant/Room	Sanitation and good employee practices are of utmost importance in this room. Foot traffic through this area should be limited to the bare minimum that is needed to accomplish the final processing or bottling operation. It is highly recommended that doorways in and out of this room should not lead directly into the milk house, the milking parlor or barn area. A hallway or other closed area that separates these rooms helps minimize the potential for contamination in the processing or bottling area.		
	Wash facilities for the washing, bottling, and filling equipment, bottles, and a hand-washing sink are usually located in this room, in addition to a cold storage unit or refrigerator for the bottled milk.		

Toilet Facilities

All employees should have access to plumbed toilets that are convenient and maintained. Flush toilets should be provided for use by employees involved in bottling of the milk. The door to the toilet room should be tight and self-closing. Windows should be screened.

If only members of the immediate family work in your operation, the home bathroom may be used if it is located on the premises, is easily available for use and adequately satisfies the requirement.

Hand-Washing Facilities

Hand-washing sinks must be plumbed for hot and cold or tempered water. Sinks should have soap and single-service hand toweling, and a covered trash can should be provided. A hand-washing sink should be provided and accessible for after using the restroom. Additional hand sinks are highly recommended for use in the milk house and any milk processing areas where milk is handled.

Equipment

Equipment—especially equipment that comes in direct contact with the milk—should be made of food-grade material that is easily cleanable and has smooth, impervious surfaces. Accumulations in even tiny cracks and crevices can host undesirable bacterial growth, contaminating your equipment and the milk.





Self-closing doors and separate hand-washing sinks reduce the risk of contamination.

Milk containers and other utensils should:

- Have flush joints and seams, if any.
- Have smooth, easily cleaned, and accessible surfaces.
- Be made of durable, non-corrodible material such as 300 series stainless steel, glass or food grade rubber, silicone, or hard plastics.

Milk pipelines, if used, should be rigid design and supported so as to maintain slope to allow proper draining. This is true for the piping used to supply cleaning and sanitizing solutions to the milk pipeline as well.

Single-service articles that are not manufactured and/or handled in a sanitary manner may contaminate the milk or milk contact surfaces.

An effective cleaning process for milking equipment and bulk tanks includes:

- 1. Flush with lukewarm water; rinse away all milk and organic debris.
- 2. Hot alkaline wash; remove bacteria, protein, fat, and biofilms from equipment surfaces.
- 3. Warm acid rinse; lower the pH of equipment surfaces to create unfavorable environment for harmful bacteria.
- 4. Dry; remove moisture to make it hard for bacteria to grow.
- 5. Sanitize just prior to milking; inactivate any bacteria that has grown in the system in between each milking.



Look for smooth seams and welds.



Stainless steel is a common material for dairy equipment.

Production and Processing Practices

Good practices are an essential part of a well-run raw milk operation. Poor practices can undermine the safeguards built into a well-designed facility and good equipment. Preventing contamination relies on the procedures you and your employees follow.

While there is no way to guarantee the safety of raw milk, try to identify steps in your process that will help you to produce it as safely as possible. Look at all stages, from milking through processing. Look at the order of how things are done, the route the milk takes and how it is handled, what equipment is used and who does what. Then establish practices and procedures such as the following:

- Restrict traffic through the processing areas.
- Do not work in plant facilities when you are ill, such as with diarrhea, vomiting, or fever.
- Wash your hands twice after using the toilet once in the restroom, and then again when you return to the processing area.
- Properly use gloves or utensils instead of bare hands when processing.
- Wash, rinse, and sanitize all equipment used for production with appropriate cleaners and sanitizers.

You should identify areas where there is potential for cross-contamination and ways to make the process safer—from production to packaging. Some key requirements for various stages of the process are outlined below.

Milking

To prevent contamination during milking, the animals, equipment, and milking personnel all must be clean.

Be careful, too, with the process of transferring the milk from the animals to any room where it will be cooled and bottled. The separation between these facilities can be breached by dirt/manure on shoes or clothing. Equipment used to transfer the milk must be kept clean as well.

Pre-milking udder preparation is especially important since dirty udders are the most probable source for pathogens to contaminate raw milk. Udder preparation may include:

- 1. Brushing and cleaning udders; use a clean towel for each animal
- 2. Pre-dip each teat in an iodine or hydrogen peroxide-based teat dip
- 3. Wipe off the teat dip
- 4. Strip each teat and inspect milk for abnormalities
- 5. Apply milking machine
- 6. After milking, apply iodine-based post-dip to each teat



Cleanliness and sanitation are important throughout production and processing.

Properly clean the productcontact surfaces of all containers, equipment, and utensils used in the handling or storage of milk after each use. Milk cannot remain clean and free of contamination if permitted to come into contact with unclean containers, utensils or equipment.

Sanitize all product-contact surfaces before each use. Cleaning alone does not insure the removal or destruction of all potentially present disease organisms.





Hand Milking

Hand milking is an option for raw milk production. Take extra care when meeting the requirements because raw milk is a ready-to-eat food.

Best practices for hand milking include:

- · Milker's hands are clean.
- Proper hand-washing facilities are convenient to milking operations, including hot and cold water under pressure and plumbed. Soap and single-service towels are available.
- Dry hands with a clean towel before milking.
- Do not practice wet-hand milking; it will increase the likelihood of contaminating the milk.
- Use a properly designed pail for capturing milk. Covered pails are preferred for protection against contamination.

Additional recommendations include:

- Repeat cleaning and drying process after any interruptions in the milking process.
- Rinse hands with a bactericidal solution.
- Remove all excess hair and maintain udder cleanliness by following the udder preparation stated previously.

Quick Cooling

Milk should reach 40° Fahrenheit within 1 hours of milking. Proper recording of temperature and time demonstrates that this is met. A hand-written log can be used.

The most efficient way of achieving quick cooling of the milk is by using a water or ice bath. Do not plan on using refrigeration as your main cooling method; it takes too long and may never reach temperatures low enough. Effective agitation of the milk will also assist in reaching the cooling recommendations. Using smaller containers such as half gallons will cool more quickly.



Monitor temperatures to assure effective cooling.





Use clean, dry, single-use towels and covered pails.

Filling

Bottling and capping should be done in a sanitary manner by means of appropriate equipment and operations. This could mean one machine with integral filling and capping or be as simple as hand pouring through a funnel and hand capping.

Hand Filling and Hand Capping

If you plan to bottle your raw milk using only hand filling and hand capping, the guidelines established in 21 Code of Federal Regulations (CFR), Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food could be applied. This covers such areas of concern as handwashing, protective clothing, employee health, and education and training.

Containers

Packaging material should protect the product from contamination and should not impart any toxic or harmful substances to the product. The use of metal lids on milk jars may rust and feed pathogen growth, therefore plastic caps or lids may be best.

The cap or cover must cover the pouring lip to at least its largest diameter. You may want to consider using a tamper-proof cap. Purchase caps in a sanitary container and store them in clean and dry location until ready for use.

Single-service or reusable containers both offer advantages; consider your marketing plan to decide which would be better for your operation.

Remember: If you are reusing returnable containers, proper cleaning and sanitation are your responsibility. Realize that these containers have been out of your control in a variety of storage conditions. Cleaning, sanitizing and thorough inspection of the individual glass containers is in your best interest. Lids should not be reused.





Choose containers and a fill method that meet the standards, work for your operation, and protect your product.

Can I hot fill after milking?

Yes. However, you should not do partial fills (i.e., you could not partially fill a container, chill it and then hot fill into that same container). Chill milk from each milking process before blending. Remember that all milk should reach 40° Fahrenheit within 2 hours of milking.

Labeling

It is recommended that you label all containers. Foodborne illness outbreaks associated with raw milk or raw milk products occur every year. This is why properly labeled raw milk intended for human consumption is ideal for any sale. It is recommended that raw milk products be labeled with this warning, or something similar:

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

Additional labeling suggestions include name and location of business, contact information, pull dates, product identity (use common name), and volume. When milk has been hand-skimmed, the resulting products are cream and a lower fat milk. The label should reflect the cream or lower fat milk product.

Perishable packaged food products with a projected shelf life of thirty (30) days or less should state the pull date on the package label. The pull date should be stated in day and month, and in a style and format that is readily decipherable by consumers. Also, when products require refrigeration either before or after opening, such information should be on the label.



Raw Goat's Milk

64 FL.OZ. (1/2 GAL.) 1.89 L Whole Goat's Milk

PULL DATE: __month/day/year_

Keep Refrigerated at 40° F or below

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

X.Y.Z. Dairy

Address - City - State - Zip

Sample label

Sales and Distribution

In Montana, you can only sell your raw milk directly to the end consumer. You can't sell your product to grocery stores, but you can sell it at farmers markets, at on-farm stores and through delivery.

You may not sell your raw milk to restaurants or institutions such as schools, nursing homes or hospitals, and Federal regulations prohibit selling raw milk products across state lines. You cannot donate milk to community social events.

A producer must inform the consumer that the product has not been licensed, permitted, certified, packaged, labeled, or inspected per any official regulations.



Definitions

A small diary is a place where no more than 5 lactating cows, 10 lactating goats, or 10 lactating sheep are kept for producing milk.

Small dairies may sell milk or cream as a homemade food.

Other Considerations

Biosecurity

"Biosecurity" is about preventing infectious diseases from spreading to and from livestock. Good biosecurity can help protect not only your herd, but also your business and the consumer's food supply.

Federal agencies work to keep new animal diseases from entering the country. The USDA, USFDA, Montana Department of Livestock, and Montana Fish Wildlife and Parks work to protect animals and humans from contagious animal diseases.

Biosecurity is not just a matter for government agencies. Measures you take can prevent highly infectious animal diseases in your livestock:

Know who is on your farm at all times.

Limit access of nonessential people.

Keep things clean.

- Require livestock and feed haulers to clean and disinfect their vehicles before hauling livestock or feed to or from your operation.
- Provide disinfectant and appropriate disposable footwear.

Keep disease away.

- Develop and enforce a policy for family members and employees who visit other livestock facilities.
- Be careful when you buy livestock. Isolate new stock for observation.
- Be careful where you buy feed and equipment.
- Use separate equipment for healthy and sick animals. Prevent contact between healthy animals and those suffering from illness.
- Keep dogs, cats, and other animals confined to the farm. Do not feed or encourage wildlife to come onto your farm.
- Control rodents and insects.
- Keep livestock away from raw household waste, bones or swill.

Look for and report changes.

Call your veterinarian immediately if you observe unusual disease symptoms in livestock. Your veterinarian and state or federal veterinarians can help diagnose and prevent a disease from spreading.



Employee Training

If you have employees, it is important to work with them to ensure safe food handling practices and a clean environment.

Your efforts to create a successful raw milk operation can be undermined if your employees develop bad habits or don't know the proper procedures to follow. Training for new and existing employees can make a difference and help prevent product contamination.

Consider what new employees need to know and what existing employees need to stay on-track and up-to-date.

Recall Plan

When an unsafe or otherwise violative (violates the legal standard) food product has left the control of the manufacturer, it must be removed from the market. When the producer-processor does this voluntarily, the process of removing the product is called a *recall*.

Despite careful production and processing, there is a chance that, someday, you may need to recall your raw milk.

If you needed to remove a product from the market right now,

- Would you be able to do it?
- Would you be able to remove the product quickly?
- Would you be able to remove all of the product?

A **recall plan** can make the difference. The plan can be designed in a way that will work for you and your customers. The key idea is to be able to identify the product(s) affected and how much was involved, and then be able to locate it and let the customer know as soon as possible.

Your plan needs to be specific to the product in question. Here are some general tips:

- A good record keeping system is important to help identify particular codes, lots and quantities.
- Pick the person you want to have in charge. This could be the owner, a manager or someone who knows the operation well.
- Be able to organize a list of customers. This could be based on invoices, phone orders, etc. Have an idea before you contact them if you want the product returned, thrown away or held for pickup.
- Be proactive. Be willing to notify the local health department when you suspect a problem and ask for assistance.

Risk to the Consumer Creates Risk for the Producer-Processor

Any person with a compromised immune system, children, the elderly and pregnant women are especially at risk from foodborne illnesses associated with raw milk consumption.

United States product liability law allows people harmed by unsafe products, including food contaminated by microbial pathogens, to take legal action to claim monetary damages for their injuries.

Talk with your insurance agent or lawyer for more information on liability and liability protection.

Testing

A best practice is testing your raw milk at least once a month; however, at a minimum, you must test at least once every six months. Tests must be performed for standard plate count, coliform count, and somatic cell count.

 Aiming for 3-month average of <5,000 cfu/mL for standard plate count and <10 cfu/mL for coliforms is best.

Performing water testing annually can ensure water is safe for cleaning, washing, etc.

Records of test results must be maintained for two years. These records can be requested by The Department of Livestock if the department suspects a dairy is involved in a foodborne outbreak.

Technical Assistance

Talk with a food safety consultant about developing a Hazard Analysis Critical Control Plan (HACCP) to help you identify different areas of risk and their control points. HACCP is defined as a system to identify and correct errors as they occur throughout the flow of food and a process of assuring food safety. Because raw milk is a ready-to-eat food, use a risk-based inspection for identifying where Sanitation Standard Operating Procedures (SSOPs) can address areas of concern.

Pasteurization is the best way to eliminate disease causing germs from milk and milk products.

Producers of raw milk can reduce their probability of causing foodborne illness by doing the following:

- Promote good employee hygiene.
- Have separation between production and processing areas.
- Use food-grade equipment.
- Develop standard operating procedures to clean and sanitize equipment and work areas.
- Work with a food safety consultant to develop a HACCP plan.
- Have milk tested frequently.
- Test herd annually.