



Milk Safety

Pennsylvania Regulations for Sale of Unpasteurized Milk

This handout is for educational purposes only

It is not legal for a person to sell raw milk within Pennsylvania unless they have a 'raw milk permit'. The Pennsylvania Department of Agriculture is responsible for the following:

- Issuing the permits to farmers selling raw milk for human consumption
- Administering and enforcing the 'Milk Sanitation Law' and the 'Food Act'
- Making sure the laws and regulations for production and sale of raw milk are followed

Regulations with information on 'raw milk for human consumption' include the '**Milk Sanitation Law**' - Title 7 of the Pennsylvania Code, Chapters 57 and 59 - and the '**Food Act**' - Title 7 of the Pennsylvania Code, Chapter 46. See www.pacode.com for the specific regulations.

What do these terms mean?

Raw milk for human consumption —this name is used to describe unpasteurized milk marketed to people without first being pasteurized. For ease of reading, the term 'raw milk' is used in this fact sheet to describe 'raw milk for human consumption'. It is not intended to confuse anyone with raw milk sold to a processor (milk plant) that is pasteurized and sold at the grocery store or other locations as the product most of us think of as **milk**.

Pasteurization – This name is used to describe heat treatment of a product for a set time. The concept and original process was developed by Louis Pasteur, a French scientist about 150 years ago. Pasteurization is intended to kill all the disease-causing bacteria in milk (and other foods) without significantly impacting its' nutrient quality.

Milk pasteurization is a process where each particle of milk is heated to 145 to 150 degrees Fahrenheit (F) for 30-minutes or to 164 to 168 degrees F for 15-seconds. The current pasteurization standard is to pasteurize milk to 161 degrees F for 15-seconds. Most processors heat milk to 175 degrees F and in some cases ultra-pasteurize milk, which involves heat treating milk to 282 degrees F. This is done so milk will last longer in your refrigerator, specifically to have a 'shelf-life' of 60 to 120 days. This is much longer than milk pasteurized according to traditional standards.

Again, 'raw milk sold for human consumption' is not pasteurized. Only by monitoring the farm sanitation, milk cooling, animal health, and testing milk on a regular basis can we have some degree of confidence the fresh raw milk product will be safe for **healthy** consumers to drink. That is the reason for only allowing sale of raw milk for human consumption to dairies with a raw milk permit and for close monitoring of the process by the Pennsylvania Department of Agriculture.

Current Laws relating to "Sale" of Raw Milk and Permits

- Raw milk can't be sold by a dairy farm or dairy producer without their having a current raw milk permit (issued by Pennsylvania Department of Agriculture).

- A dairy producer (dairy farm) can't sell raw milk without having 'good' test results (to be described later) and current and valid paperwork.
- Permits begin on September 1 on a calendar year and end the following August 31. Permits need to be renewed each year. It is the responsibility of the permit holder to apply to renew their raw milk permit in advance of the end date. Recent news reports should be evidence that the Department of Agriculture and law enforcement has acted to protect food safety and to try to prevent future violations when a few dairy producers repeatedly ignored these laws.
- In addition to raw milk (fluid product) for sale, the farm (person) may also choose to make and sell aged cheese. Sale of aged cheese also requires a permit with 'authorization' to sell aged cheese manufactured from raw milk. Farms that have a permit to sell aged cheese will also have a permit to sell raw milk.
- A law is pending in Pennsylvania which may allow manufacture of other products from raw milk in the future (H.B. 2597 pending June 2008). Currently, it is only legal to sell raw milk or aged cheese. The bill pending proposes manufacture and sale of butter, cheese (natural or processed), dry whole milk, nonfat dry milk, dry buttermilk, dry whey, evaporated milk (whole or skim), condensed whole and condensed skim milk (plain or sweetened), and other similar products from raw milk.

What does 'sale' of raw milk include?

The sale of raw milk includes the sale or exchange of raw milk; delivery of raw milk; having raw milk with the intent to sell it, exchange, or deliver it; marketing raw milk (print, electronic, or other form of advertising), and exposing raw milk for sale. Raw milk and products (aged cheese) in Pennsylvania comes from dairy cows, dairy goats and dairy sheep.

What has to happen for a raw milk permit to be issued to a farm (person)?

A new raw milk permit – A milk sanitarian from the Pennsylvania Department of Agriculture will 'evaluate' a dairy farm after the producer fills out and submits an application to sell raw milk. Essentially, the purpose of the farm evaluation is to assess farm cleanliness, animal health, and potential food safety. Specifically, the milk sanitarian will inspect the dairy farm using a risk assessment checklist to make sure the dairy producer is following procedures in the Milk Sanitation Law. In addition, milk samples will be tested for hygiene, animal health, and presence of disease-causing bacteria (see more below). In many cases, this process should not be a difficult, as most farms seeking raw milk applications will also be selling a portion of their milk to a processing plant and will already be following similar procedures. The intention of the laws is to protect consumers from getting sick from consuming unpasteurized milk products. Similar laws are in place for sale of all other legally sold food products whether pasteurized or not, again with the intention of ensuring milk is healthy and nutritious and meets the needs and demands of the consumer, while reducing the risk of food-borne illness. This entire process protects the consumer and the farmer.

Continuing the raw milk permit – As mentioned previously, a raw milk permit is issued for a 1-year period of time. Before the permit expires (August 31), the permit holder may decide to continue selling raw milk and request to continue their permit for another year. Again, this should be an easy process. Providing all tests are current and 'good', an application for

continuing the raw milk permit is submitted, the raw milk permit is reissued, and the producer continues to sell or have the ability to sell raw unpasteurized milk directly from the farm, or farmer's market. The raw milk permit may be continued without the sanitarian doing another dairy farm inspection.

What testing is done to ensure that animals are healthy and risk to people is low?

Tests to evaluate animal health of a dairy herd are important to assure the consumer that animals are treated well but also to reduce the risk of animals transferring bacteria or viruses to people through their milk. Testing is done on milk that is pasteurized to ensure quality and is also important for 'raw milk sold to the consumer' without being pasteurized.

Tests for new raw milk permits – A dairy producer requesting a raw milk permit must provide proof to the Pennsylvania Department of Agriculture that the herd is free of brucellosis and tuberculosis. Although currently rare in the U.S., both diseases can be transferred directly from animals to people through the milk. Again, this precaution is in place to be proactive and reduce the chance of someone getting sick when choosing to drink or eat milk products that are not pasteurized.

A licensed veterinarian must examine the herd and provide the Pennsylvania Department of Agriculture with a written report that confirms that general health of the herd is good and free of diseases that may be transmitted to people through the milk.

Renewing raw milk permits – Dairy producers renewing a raw milk permit must provide test results or other confirmation that their herd is free of tuberculosis and brucellosis. Proof of annual blood tests for Brucellosis and Tuberculosis must be provided from the herd licensed veterinarian. In addition, a ring test result must be provided to PDA every 6-months.

A licensed veterinarian must examine the herd for general health and confirm on a yearly basis that the herd is in good health and is free of diseases that may be transmitted to people. The veterinary reports must be kept by the raw milk permit holder for at least a 3-year period and must be prepared to provide results to PDA upon request.

Why is water testing done?

Water testing is done as part of the permitting process for raw milk herds and is also done annually for herds selling milk to the processing plant. Water with high bacteria levels affects the ability to properly clean milk handling equipment and directly increases the risk of animals and people getting sick. 'Good' water test results help to reduce the risk of people getting sick when consuming unpasteurized milk products.

Tests for new raw milk permits – A dairy producer seeking a raw milk permit must provide proof to the Pennsylvania Department of Agriculture that the dairy is using water that has safe bacteria levels. If the water is supplied through a public or municipal water system, the farm is not required to provide these test results.

Renewing raw milk permits – Dairy producers renewing their permits must provide lab results done in the last 6-months (before permit expires) to show that the dairy farm water supply is bacteriologically safe. In addition, the water supply must be retested anytime there is a repair or change made to the water system.

The required water test measures coliform level and is reported as 'Most Probable Number of Coliform Organisms (MPN). Water can be tested using one of two tests. If water is measured using the 'multiple tube fermentation method' then it must test below 2.2 cfu/100 ml. If water is tested by the 'membrane filter technique' it must test below 1.0 cfu/ml.

The raw milk permit holder needs to keep water test results on file at the farm and be able to provide them to PDA upon request.

What tests are needed to check for good farm hygiene and reduce risk for food-borne illness from consuming unpasteurized milk?

New raw milk permits – Three milk samples from mixed herd milk must be collected by an approved person and be tested by an approved laboratory. The milk samples must be collected at least 7-days apart and at an unannounced time.

If any of the 3-milk samples doesn't meet or isn't better than the standards (See Table 1), the 3-sample process has to be repeated. There must be 3 successive samples that meet or are better than the standards before the raw milk permit can be issued.

If the first of the 3-milk samples meets or is better than the requirement, the other 2-milk samples do not need to be tested.

If disease causing bacteria are present in a milk sample, the raw milk permit won't be issued until 2 consecutive milk samples are free of the disease causing bacteria. Again, these 2 milk samples must be taken at least 7-days apart.

What requirements are there for packaging raw milk?

If containers are owned by the customer of the raw milk farm, the milk room (milk house) is an acceptable location for packaging the raw milk. It is suggested that the 'packages' be very clean and made from food grade material and be no larger than 1-gallon in size. Again, this recommendation is to improve safety and freshness of the milk product.

If containers are owned by the raw milk permit holder, the dairy farm must have separate rooms for bottling, single service container storage, and/or bottle washing ability. Also, in order to prepackage the milk, there must be a mechanical way of filling and capping any milk bottles used. The cap must completely protect the pouring lip of the container.

What is considered a violation of the raw milk permit and what can the producer do if there is a violation?

If 2 of the last 4 tested raw milk samples don't meet the standards for bacteria count, somatic cell count, or coliform count, and/or temperature (cooling) requirements, the raw milk permit holder will receive a written notice of the problem (violation).

If 3 of the last 5 raw milk samples don't meet standards listed above, the PDA will suspend or end the raw milk permit until the problem can be fixed.

Other:

If a raw milk sample is positive for a pesticide, the permit holder needs to do the following:

- Stop the sale of raw milk immediately

- Take a second milk sample and test for pesticides
- Determine the cause of pesticide contamination, correct the cause, and report findings to PDA
- Provide negative results to PDA and seek approval to resume raw milk sales

If a raw milk sample is positive for a growth inhibitor, the raw milk permit holder must follow a similar process to the one for pesticide residues. Raw milk sales can't restart until the problem is fixed and PDA approves restarting sales.

If a raw milk sample is positive for disease causing organisms such as Salmonella, Listeria monocytogenes, Campylobacter or E. coli O157:H7, the permit holder must do the following:

- Stop selling raw milk immediately
- Investigate the cause, fix the source of the contamination and report results to PDA
- After at least 2-days of ending raw milk sales (and hopefully fixing the problem), have an approved person take another milk sample and test for presence of disease-causing bacteria.
- Have another milk sample taken at least 1-day later. There must be at least 2 consecutive samples taken at least 1-day apart showing that the dairy is free of disease causing bacteria.
- Again, PDA must give approval for the raw milk permit holder to restart sale of raw milk.

What labels must be attached to raw milk containers?

Labels on containers provided by the raw milk permit holder must be approved by PDA. The container must be labeled as 'RAW MILK' and must include the net weight plus name and address of the distributor or producer

The label must also have a consumer advisory statement to let consumers know of the increased risk of consuming milk and other dairy products that haven't been pasteurized.

An example of a label statement considered acceptable by PDA follows:

'Raw milk has not been processed to remove pathogens that can cause illness. The consumption of raw milk may significantly increase the risk of foodborne illness in persons who consume it – particularly with respect to certain highly-susceptible populations such as preschool-age children, older adults, pregnant women, persons experiencing illness, and other people with weakened immune systems.'

Labels don't need to be attached to containers provided by customers. An advisory does need to be posted visible to the location where the containers will be filled. See the example above.

Table 1. Tests done for new, existing, and renewal raw milk permits to reduce risk of illness from consuming unpasteurized milk

Test	Requirement	Frequency of Testing	Description/Rationale
Temperature	Raw milk must be cooled to 40 degrees F or less within 2-hours after milking. In addition, the blend temperature of the milk after the first (and subsequent) milkings is not greater than 50 degrees F	All the time	Milk temperature requirements are the same as for milk intended for sale and consumption as pasteurized product. These temperature and time requirements are designed to keep milk fresh for the longest period of time and are intended to keep bacteria associated with milk quality at a low level until the milk is consumed.
Bacteria Count	Bacteria must be less than or equal to 20,000 colony forming units per milliliter (cfu/ml)	At least 2-times each month. This test is done along with testing for coliform count and presence of drug residues	Bacteria count is used as a measure of animal health and sanitation practices on a farm. Bacteria counts above this requirement are associated with faster breakdown of nutrients in milk. In addition, this test combined with results from other tests can be used to evaluate risk that the milk is produced from unhealthy animals or that consumption of this farm's raw milk may increase risk of getting sick from drinking this farm's raw milk.
Coliform Count	Coliform count must be less than or equal to 10 cfu/ml	At least 2-times each month.	Coliform count is a specific measure of a group of bacteria found to be associated with food-borne illness. E. coli are a type of bacteria in the coliform group of bacteria. This measure is also used to evaluate if there is manure in the milk (e.g., measure of farm hygiene and cleanliness).
Somatic Cell Count	Somatic Cell Count must be less than 1,000,000 cells/ml	At least 1-time each month	Somatic cell count (SCC) is similar to white blood cell count in people and is used to measure infection of the mammary gland. Generally, the greater the infection in the udder, the higher the SCC in the milk. In addition, the more cows with udder infections in a herd, the higher the SCC in the bulk tank or herd milk sample. The legal limit for pasteurized milk is 750,000 cells/ml. The average SCC for herds on record systems in Pennsylvania is approximately 306,000 cells/ml. Raw milk herds have a higher legal limit for cell count because goats may have a higher SCC normally than cows and for simplicity one standard is used.

Table 1. Continued

Test	Requirement	Frequency of Testing	Description/Rationale
Test for presence of drugs – including growth inhibitors	There should be no positive results for drug residues	At least 2-times each month	Drug residue tests for raw milk are the same as those used for pasteurized milk. The main purpose of testing is to ensure that if animals are treated with antibiotics that the milk is withheld from milk for human consumption until the residue is not detectable. Inability for drugs used in human medicine and allergic responses are concerns and are the rationale for the testing system.
Test for presence of Pathogenic Bacteria including Salmonella, Listeria monocytogenes, Camphylobacter, and E. coli 0157:H7	There should be no pathogenic bacteria present	At least 2-times per year	These bacteria are major ones associated with consumption of unpasteurized raw milk consumption and food illness in people. Because of this, testing is conducted to ensure none of these bacteria are present in the test samples drawn from dairy farm milk supplies.

This fact sheet is based on the following materials:

PDA Bureau of Food Safety and Laboratory Services. Mar 20, 2008. "Guidance Document: Permits allowing the sale of raw milk for human consumption".

The General Assembly of Pennsylvania. House Bill No. 2596. <http://legis.state.pa.us>. Accessed June 23, 2008.

The General Assembly of Pennsylvania. House Bill No. 2597. <http://legis.state.pa.us>. Accessed June 23, 2008.

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