

Subchapter F. RAW MILK FOR HUMAN CONSUMPTION

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§ 59a.401. Raw milk; General.

This subchapter prescribes the permitting, testing and inspection requirements that are applicable to persons seeking to sell raw milk for human consumption.

§ 59a.402. Raw milk; Prohibitions.

(a) *Sale of raw milk without permit.* A person may not sell raw milk for human consumption without having a current raw milk permit issued by the Department. The term "sell" includes the selling, exchanging, delivering, or having in possession, care, control, or custody with intent to sell, exchange, or deliver, or to offer or to expose for sale.

(b) *Actions authorized under a raw milk permit.* A raw milk permit authorizes the permitholder to lawfully produce and sell (within this Commonwealth) raw whole milk for human consumption. It also authorizes the permitholder to obtain an additional permit, issued by the Department under authority of 21 CFR 133.150 (relating to hard cheeses), authorizing the sale of aged cheese manufactured from raw milk.

(c) *Compliance with testing and documentation requirements.* A person may not sell raw milk without being in compliance with the testing and documentation requirements of this section.

§ 59a.403. Raw milk permit.

(a) *Application.* A raw milk permit application may be obtained by contacting the Department at the address set forth in § 59a.3 (relating to contacting the Department).

(b) *Duration.* A raw milk permit will be valid for no more than 1 year. Each raw milk permit will expire as of September 1 each year, unless revoked or suspended earlier by the Department.

(c) *Timing of filing to ensure Department review of an application for a successor raw milk permit.* If a raw milk permitholder wishes to obtain a raw milk permit to replace an expiring raw milk permit, the permitholder is encouraged, but is not required, to file an application for this successor raw milk permit with the Department by July 1 of the year in which the current raw milk permit is to expire. Compliance with this recommendation may help to prevent a lapse between the expiring raw milk permit and the effective date of the successor raw milk permit.

§ 59a.404. Requirements for the issuance of a raw milk permit.

(a) *Preissuance inspection.*

(1) *New raw milk permits.* Prior to issuing a raw milk permit, the Department will inspect the dairy farm that is the subject of a new raw milk permit application, to determine whether the dairy farm is in compliance with the act and this chapter. The dairy farm must be in passing condition to be eligible for a raw milk permit.

(2) *Successor raw milk permits.* If a raw milk permit-holder applies to the Department for a successor raw milk permit, the Department may issue the raw milk permit without conducting the dairy farm inspection described in paragraph (1).

(b) *Confirmation of Tuberculosis-free and Brucellosis-free status.*

(1) *New raw milk permits.* An applicant for a new raw milk permit shall provide the Department confirmation that the animal or herd from which the raw milk is to be produced has been determined to be free from brucellosis and free from tuberculosis, in accordance with the process described in § 59a.406 (relating to animal health). This confirmation shall be provided for the subject dairy farm to be eligible for a raw milk permit.

(2) *Successor raw milk permits.* An applicant for a successor raw milk permit shall, at intervals of no greater than 13 months, provide the Department confirmation that the animal or herd from which the raw milk is to be produced has been determined to be free from brucellosis and tuberculosis by annual tests in accordance with the process described in § 59a.406.

(c) *General herd health.*

(1) *New raw milk permits.* An applicant for a new raw milk permit shall have a licensed veterinarian examine the herd and provide the Department a written report of this examination.

The report must reflect that the herd is in good general health and free from communicable disease. This shall be done in accordance with § 59a.406.

(2) *Successor raw milk permits.* An applicant for a successor raw milk permit shall provide the Department a copy of a veterinary examination report as described in paragraph (1). The report must be dated within 1 year preceding the date of the application, and reflect that the herd is in general good health and free from communicable disease. The applicant shall continue to have this veterinary examination conducted on an annual basis, in accordance with § 59a.406.

(d) *Confirmation of safe water supply.*

(1) *New raw milk permits.* An applicant for a new raw milk permit shall have the dairy farm water supply tested, and provide the Department with confirmation that the water is bacteriologically safe, in accordance with § 59a.407 (relating to regular testing of water supply). Confirmation that the water supply is bacteriologically safe shall be provided for the subject dairy farm to be eligible for a raw milk permit. If the water supply is through a public or municipal water system, this testing requirement does not apply.

(2) *Successor raw milk permits.* An applicant for a successor raw milk permit shall provide the Department with a copy of a written laboratory report as described in paragraph (1). The report must be dated no earlier than 6 months preceding the date of the application, done in accordance with § 59a.407 and reflect that the dairy farm water supply is bacteriologically safe.

(e) *Sampling and testing.*

(1) *New raw milk permits.* An applicant for a new raw milk permit shall demonstrate its ability to produce raw milk for human consumption through the following process:

(i) The applicant shall have an approved sampler draw three separate samples of commingled milk. The samples shall be drawn at least 7 days apart, and be taken on an unannounced basis.

(ii) Each of these three samples described in subparagraph (i) shall be submitted to a Pennsylvania-approved dairy laboratory or the Department for analysis.

(iii) The analysis described in subparagraph (ii) will determine whether the sample meets the standards in § 59a.408 (relating to regular testing of raw milk).

(iv) If any of the three analyzed samples described in subparagraph (iii) violates or exceeds a standard in § 59.408, the three-sample process shall repeat itself until three successive samples are in compliance with the referenced standards.

(v) If the first of the three required samples is tested as described in subparagraph (iii), and concludes that no pathogenic bacteria are present, the second and third samples need not be tested for the presence of pathogenic bacteria. If a sample test concludes that pathogenic bacteria are present, a raw milk permit will not be issued until two separate consecutive tests, from samples drawn at least 7 days apart, conclude that no pathogenic bacteria are present.

(2) *Successor raw milk permits.* An applicant for a successor raw milk permit shall demonstrate its ability to produce raw milk for human consumption through the regular sampling and testing process described in § 59.408.

(f) *Location of packaging-related facilities and equipment.*

(1) *Containers owned by the customer.* If a dairy farm that is the subject of a raw milk permit or raw milk permit application packages raw milk for sale in containers that are owned by the customers, rather than by the permitholder, the Department will consider a milk room facility as being adequate for the packaging of this raw milk.

(2) *Containers owned by the raw milk permitholder.* If a dairy farm that is the subject of a raw milk permit or raw milk permit application packages raw milk for sale in containers that are owned by the permitholder, such as in prepackaged containers for consumer purchase, the dairy farm shall have separate rooms for bottling, single service container storage, and bottle washing. A mechanical means of filling and capping bottles shall be utilized for prepackaging, and the closure must protect the pouring lip to its largest diameter.

§ 59a.405. Sanitation.

A raw milk permitholder shall maintain and operate the subject dairy operation in compliance with the same sanitation and handling standards that are applicable to the production of milk for pasteurization, as set forth in § 59a.19 (relating to standards for grade "A" raw milk for pasteurization, ultra-pasteurization or aseptic processing) except to the extent any of those provisions are inconsistent with this subchapter. The provisions of the Grade "A" PMO and, in particular, the *Standards for Grade "A" Raw Milk for Pasteurization, Ultrapasteurization or Aseptic Processing* set forth in that document and section 7 of the Grade "A" PMO, regarding standards for Grade "A" milk and milk products, are incorporated by reference as regulations authorized under the act, to the extent they do not conflict with the act or this subchapter. This includes the items listed under the referenced Grade "A" PMO provisions, including the following:

- (1) Item 1r. Abnormal milk.
- (2) Item 2r. Milking Barn, Stable or Parlor--Construction.
- (3) Item 3r. Milking Barn, Stable or Parlor--Cleanliness.
- (4) Item 4r. Cowyard.
- (5) Item 5r. Milkhouse--Construction and Facilities.
- (6) Item 6r. Milkhouse--Cleanliness.
- (7) Item 7r. Toilet.

(8) Item 8r. Water Supply, with the additional requirement that a plate heat exchanger or tubular cooler installed and in use on a dairy farm shall be equipped with a backflow prevention device.

(9) Item 9r. Utensils and Equipment--Construction.

(10) Item 10r. Utensils and Equipment--Cleaning.

(11) Item 11r. Utensils and Equipment--Sanitization.

(12) Item 12r. Utensils and Equipment--Storage.

(13) Item 13r. Milking--Flanks, Udders and Teats.

(14) Item 14r. Protection from Contamination.

(15) Item 15r. Drug and Chemical Control.

(16) Item 16r. Personnel--Handwashing Facilities.

(17) Item 17r. Personnel--Cleanliness.

(18) Item 18r. Raw Milk Cooling, with the exception that raw milk for pasteurization shall be cooled to 4° C (40° F) within 2 hours after the completion of milking.

(19) Item 19r. Insect and Rodent Control.

§ 59a.406. Animal health.

(a) *General.* A raw milk permitholder shall monitor the health of the animals from which the raw milk is produced, to ensure that they are in general good health and free of tuberculosis and brucellosis.

(b) *Confirmation of brucellosis-free status.*

(1) *Annual blood tests.* A raw milk permitholder shall, at intervals of no greater than 13 months, provide the Department confirmation from a licensed veterinarian that the animal or herd from which the raw milk is produced has been determined to be free from brucellosis by annual blood tests conducted in accordance with Chapter 7 (relating to brucellosis regulations).

(2) *Ring tests at intervals of 6 months or less.* A raw milk permitholder shall, at intervals of no greater than 6 months, provide the Department confirmation of the results of a brucellosis ring test conducted with respect to the animal or herd from which the raw milk is produced.

(c) *Annual confirmation of tuberculosis-free status.* A raw milk permitholder shall, at intervals of no greater than 13 months, provide the Department confirmation from a licensed veterinarian

that the animal or herd from which the raw milk is produced has been determined to be free from tuberculosis by annual tests conducted in accordance with Chapter 9 (relating to control and eradication of tuberculosis of livestock).

(d) *Annual veterinary examination.* A raw milk permit- holder shall, at intervals of no more than 1 year, have a licensed veterinarian examine the herd and issue a written report of this examination. The report must reflect that the herd is in good general health and free from communicable disease. The raw milk permitholder shall retain a copy of the written veterinarian's report for at least 3 years and shall, upon request of the Department, make the report available for inspection.

§ 59a.407. Regular testing of water supply.

(a) *General requirement of safe and sanitary water.* The water supply for a dairy operation that produces raw milk under a raw milk permit must be safe and sanitary.

(b) *Testing frequency.* The water supply for a dairy operation that produces raw milk under a raw milk permit shall be tested at least once every 6 months, and whenever any repair or alteration is made to the water supply system. This testing shall be at the raw milk permitholder's expense. If the water supply is through a public or municipal water system, this testing requirement does not apply.

(c) *Testing standards.* The water tests described in this section shall be conducted at a qualified laboratory. The testing must include bacteriological examinations to determine whether the water is bacteriologically safe. The water supply must contain a Most Probable Number of Coliform Organisms (MPN) of less than 2.2-per-100-milliliters by the multiple tube fermentation method or less than 1-per-100-milliliters by the membrane filter technique or the chromogenic substrate technique. The water must otherwise be safe and sanitary.

(d) *Water test records.* The raw milk permitholder shall retain all records of required water tests, and make these available for inspection upon request of the Department.

§ 59a.408. Regular testing of raw milk.

(a) *Responsibility.* A raw milk permitholder shall be responsible to arrange for the regular sampling and testing required with respect to the raw milk permit, and to pay for this testing.

(b) *Testing laboratories.* Raw milk samples submitted for testing shall be analyzed at an official laboratory or a Pennsylvania-approved dairy laboratory.

(c) *Testing schedule and standards.* A raw milk permit- holder shall coordinate raw milk testing on the following schedule, and the raw milk samples shall meet the following standards:

Raw Milk Testing Schedule and Standards

Required	Type of Action or Test	Standard
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Action Interval	Required	
At all times	Maintain raw milk temperature in accordance with raw milk temperature standards.	Raw milk shall be cooled to 40° F (4° C) or less within 2 hours after milking, provided that the blend temperature after the first and subsequent milking does not exceed 50° F (10° C).
At least twice each month, in conjunction with the tests for coliform count and for the presence of drugs (including growth inhibitors), described in this subsection	Bacterial count	Bacteria may not be present in excess of 20,000 per milliliter. NOTE: Tested in conjunction with a drug residue/ inhibitory substance test.
At least twice each month, in conjunction with the tests for bacterial count and for the presence of drugs (including growth inhibitors), described in this subsection	Coliform count	Coliform may not exceed 10 per milliliter. NOTE: Tested in conjunction with a drug residue/ inhibitory substance test.
At least twice each month	Somatic cell count	The somatic cell count may not exceed 750,000/milliliter.
At least twice each month, in conjunction with the tests for bacterial count and for coliform count, described in this subsection	Test for presence of drugs (including growth inhibitors)	There may be no positive results for drug residue, using drug residue detection laboratory techniques referenced in the current Grade "A" Pasteurized Milk Ordinance developed by the United States Department of Health and Human Services, Food and Drug Administration.
At least twice annually	Test for presence of pathogenic bacteria including <i>Salmonellae</i> , <i>Listeria monocytogenes</i> , <i>Camphylobacter</i> , and <i>E. Coli</i> 0157:H7	There may be no pathogenic bacteria present.

§ 59a.409. Violations of raw milk testing standards.

(a) *Bacterial count, somatic cell count, coliform count or cooling temperature tests.*

(1) If two of the last four tested raw milk samples exceed the bacterial count, somatic cell count or coliform count standards or cooling temperature requirements described in § 59a.408

(relating to regular testing of raw milk), the Department will provide the raw milk permit- holder with written notice that it is in violation of the requirements of the act and this chapter.

(2) If three of the last five tested raw milk samples exceed the bacterial count, somatic cell count or coliform count standards or cooling temperature requirements described in § 59a.408, the Department will proceed to revoke or suspend the raw milk permit, and the raw milk permitholder shall be subject to summary criminal prosecution under the act.

(b) *Pesticides*. If a raw milk sample tests positive for the presence of a pesticide, the raw milk permitholder shall do all of the following:

- (1) Immediately cease the sale of raw milk for human consumption.
- (2) Take a second sample and submit it for testing for pesticide residue.
- (3) Investigate and determine the cause of the contamination, report the result of that investigation to the Department, and correct that cause of contamination.
- (4) Refrain from selling raw milk until and unless the second test shows the sample to be free of pesticide residue, or to be below the actionable levels established for the residue, and the Department reviews these test results and approves the resumption of raw milk sales.

(c) *Growth inhibitor*. If a raw milk sample tests positive for the presence of a growth inhibitor, the raw milk permitholder shall do the following:

- (1) Immediately cease the sale of raw milk for human consumption.
- (2) Investigate and determine the cause of the contamination, report the result of the investigation to the Department, and correct the cause of contamination.
- (3) Have a second sample collected by an approved sampler and tested at a Pennsylvania-approved dairy laboratory.
- (4) Refrain from selling raw milk until the second test shows the sample to be free of growth inhibitor residue, or to be below the actionable levels established for the residue, and the Department reviews these test results and approves the resumption of raw milk sales.

(d) *Disease-producing organisms*. If a raw milk sample tests positive for the presence of pathogenic bacteria or other disease-producing organisms such as *Salmonellae*, *Listeria monocytogenes*, *Camphylobacter* or *E. Coli* 0157:H7, the raw milk permitholder shall do the following:

- (1) Immediately cease the sale of raw milk for human consumption.
- (2) Investigate and determine the cause of the contamination, report the result of that investigation to the Department, and correct that cause of contamination.

(3) Wait at least 2 days from the cessation of raw milk sales, or until conformance can reasonably be assured, and then have an approved sampler collect a second sample and submit it to a Pennsylvania-approved dairy laboratory to be tested for the presence of pathogenic bacteria.

(4) Following the initial sampling described in the preceding requirement, have an approved sampler collect an additional sample, at least 1 day after the previous sample, and submit it to a Pennsylvania-approved dairy laboratory for testing for the presence of pathogenic bacteria.

(5) Refrain from selling raw milk until and unless two consecutive tests, from samples drawn at least 1 day apart, show that raw milk produced at the dairy operation that is the subject of the raw milk permit is free from disease-producing organisms, and the Department reviews these test results and approves the resumption of raw milk sales.

§ 59a.410. Location of raw milk packaging facilities on the dairy farm.

(a) *Containers owned by the raw milk permit holder.* If raw milk is packaged for sale in containers that are owned by the raw milk permit holder (such as in prepackaged containers for consumer purchase), the dairy farm shall have separate rooms for bottling, single service container storage, and bottle washing, as applicable. A mechanical means of filling and capping bottles shall be utilized for prepackaging, and the closure must protect the pouring lip to its largest diameter.

(b) *Containers owned by the customer.* If raw milk is packaged for sale in containers that are owned by the consumer, the Department will consider a milk room facility as being adequate for the packaging of this raw milk.

§ 59a.411. Label content review by the Department.

(a) *Raw milk in containers owned by the raw milk permit holder.*

(1) *General label statements.* If raw milk is packed for sale in containers that are owned by the raw milk permit holder, the labeling on these containers and caps shall be submitted to the Department and approved by the Department prior to use in commerce. The container must be labeled as raw milk, and include the net weight as well as the name and address of the distributor or producer and the words "Keep Refrigerated." It may not be misbranded or contain any false or misleading statements.

(2) *Consumer advisory for raw animal-derived foods that have not been processed to remove pathogens.*

(i) In addition to the information described in paragraph (1), the label must contain a consumer advisory statement to notify consumers of the increased risks (particularly to certain highly susceptible populations) associated with the consumption of raw animal-derived foods that have not been processed to remove pathogens. An acceptable notice would be as 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.

(ii) The Department will consider alternative written means of notification of consumers of the potential risks associated with the consumption of raw milk by highly-susceptible populations.

(3) *Label requirement: milk dating.*

(i) *Requirement.* The cap of the raw milk container, or the container itself, must be conspicuously and legibly marked in a contrasting color with the designation of the "sell-by" date--the month and day of the month after which the raw milk may not be sold or offered for sale. The designation may be numerical--such as "8-15"--or with the use of an abbreviation for the month, such as "AUG 15" or "AU 15." The words "Sell by" or "Not to be sold after" must precede the designation of the date, or the statement "Not to be sold after the date stamped above" must appear legibly on the container. This designation of the date may not exceed 17 days beginning after midnight on the day on which the raw milk was produced.

(ii) *Prominence of sell-by date on label.* The sell-by date must be separate and distinct from any other number, letter or intervening material on the cap or container.

(iii) *Prohibition.* Raw milk may not be sold or offered for sale for human consumption if the raw milk is sold or offered for sale after the sell-by date designated on the container.

(iv) *Monitoring by the Department.*

(A) The Department will periodically sample containers of raw milk in the possession of the raw milk permit- holder or a distributor. This sampling may occur at any time before the raw milk is delivered to the customer. The Department will take at least one sample of raw milk from each raw milk permitholder each calendar year.

(B) The samples described in clause (A) shall be analyzed by the Department or a Pennsylvania-approved dairy laboratory, to determine whether bacterial test results exceed the bacterial limits for raw milk described in the Raw Milk Testing Schedule and Standards set forth in § 59a.408 (relating to regular testing of raw milk) prior to the expiration of the sell-by date designated on the raw milk container.

(C) When two or more samples demonstrate a raw milk permitholder cannot produce raw milk that remains consistently within the bacterial limits referenced in clause (B) through the sell-by date marked on the container, the Department will require a raw milk permit- holder to use a shorter sell-by date specified by the Department. The Department will calculate this revised sell-by date so that bacterial growth in the raw milk will not exceed the referenced bacterial limits within that sell-by period if the raw milk is maintained in accordance with the temperature

requirements for raw milk set forth in the Raw Milk Testing Schedule and Standards in § 59a.408.

(D) A raw milk permitholder may submit samples to the Department for analysis to obtain approval to resume a 17-day sell-by period for the raw milk sampled. The Department will approve resumption of a 17-day sell-by period when analysis of a sample demonstrates that bacterial growth in the raw milk will not exceed the referenced bacterial limits within that sell-by period if the raw milk is maintained in accordance with the temperature requirements for raw milk set forth in the Raw Milk Testing Schedule and Standards in § 59a.408.

(b) *Raw milk in customer-owned containers.*

(1) *Container labeling and caps.* If raw milk is packed for sale in containers that are owned by the consumer, Departmental review of the labeling on the container or caps is not required. The Department recommends, but does not require, that customer owned containers be clean, food-grade containers of 1 gallon or smaller capacity.

(2) *Consumer advisory.* If raw milk is packed for sale in containers that are owned by the consumer, the raw milk permitholder shall post a consumer advisory at the location where the customer owned containers are filled, or in close proximity to that location, to provide consumers notice of increased risks associated with the consumption of raw animal-derived foods that have not been processed to remove pathogens by certain highly susceptible populations. An acceptable notice would be as described in subsection (a)(2). The Department will consider alternative written means of notification of consumers of the potential risks associated with the consumption of raw milk by highly-susceptible populations.

§ 59a.412. Inspection, sampling and testing by the Department.

A raw milk permitholder shall allow the Department and its personnel to inspect the dairy operation that is the subject of the permit, review records, draw samples, conduct tests and take other actions necessary to the Department's performance of its responsibilities under the act, the Food Act or any other applicable statute or regulation. If a raw milk permitholder fails to allow this inspection and sampling by the Department, the Department may take steps to revoke or suspend the raw milk permit.

§ 59a.413. Enforcement: Suspension or revocation of a raw milk permit.

(a) *General.* The Department may take action to suspend or revoke a raw milk permit if a permitholder does not comply with the act or this chapter.

(b) *Procedure.*

(1) The act requires that the Department provide a raw milk permitholder with at least 5 days' advance written notice of a raw milk permit revocation or suspension. This written notice will be sent by certified mail.

(2) If the basis for a proposed raw milk permit suspension or revocation is that pathogenic bacteria have been detected in the raw milk, or foreign substances are present in the raw milk, or any condition exists where consumption of raw milk produced and sold prior to revocation or suspension of the raw milk permit may pose a threat to the health or safety of those persons who consume it, the Department will immediately notify the raw milk permit holder and request that it voluntarily cease all sales of raw milk--without regard to whether the raw milk permit holder has received the 5 days' advance written notice required under the act.

(i) If a raw milk permit holder complies with a request that it voluntarily cease raw milk sales, the Department will consider this cooperation a mitigating factor as it determines any penalty or sanction relating to the violation.

(ii) If a raw milk permit holder does not choose to comply with a request that it voluntarily cease raw milk sales, the Department will do the following:

(A) Apprise the Department of Health and any local health department having jurisdiction with notice of the situation, and recommend these entities take lawful action to ensure that sales of raw milk cease.

(B) Consult with the Office of Attorney General regarding whether it should institute legal action to obtain an injunction to prohibit the raw milk sales.

(C) Arrange for an administrative hearing before a hearing examiner, if the raw milk permit holder requests a hearing on the proposed permit suspension or revocation.

(D) Issue a final adjudication, ordering the suspension or revocation, if the raw milk permit holder does not request a hearing on the proposed permit suspension or revocation.

(c) *Ownership of raw milk permit.* A raw milk permit is and remains the property of the Department--even when it is in the physical custody of the permit holder. If a raw milk permit is suspended or revoked, the person in possession of the raw milk permit shall immediately return or surrender that raw milk permit to the Department. In the case of a permit suspension, the Department will promptly return the raw milk permit to the permit- holder at the end of the suspension period.

§ 59a.414. Enforcement: Summary criminal prosecution.

If a raw milk permit holder violates any provision of the act or this chapter, the Department may file a summary prosecution against a raw milk permit holder for the violation. The violation is graded as a summary offense.

§ 59a.415. Enforcement: Injunctions.

The Department may ask the Attorney General to initiate legal action to enjoin a person from selling raw milk without the required raw milk permit or from violating the act or this chapter. Violations of an injunction can result in fines or imprisonment, or both.

§ 59a.416. Enforcement: Seizure, condemnation, denaturing or destruction of raw milk; exclusion from sale.

(a) *Seizure, condemnation, denaturing or destruction of raw milk.* Whenever, in the opinion of the Secretary, a given supply of raw milk or illegally-produced raw milk products is considered unsafe or a menace to public health, the Secretary may seize, condemn, denature or destroy the milk or milk products, without compensation to the owner of the milk or milk products.

(b) *Excluding milk from sale.* The Department may exclude raw milk or illegally-produced raw milk products from sale in either of the following circumstances:

- (1) The Secretary considers the raw milk or illegally-produced milk products to be unsafe.
- (2) If a raw milk permitholder violates a provision of the act or this chapter.