18 AAC 32.060 is amended to read:

18 AAC 32.060. Raw milk and raw milk products. Except as provided in 18 AAC

32.010(c), a milk producer may not allow raw milk or a raw milk product, including cream from raw milk, to be removed from the dairy farm unless

(1) the product is being transported directly to a milk processing plant with a

permit issued under 18 AAC 32.030 or by another state; [OR]

(2) the product has been decharacterized with an approved denaturant and labeled

"FOR ANIMAL FOOD NOT FOR HUMAN CONSUMPTION" in letters at least three inches

high on each container; for purposes of this paragraph, "approved denaturant" means

(A) finely powdered charcoal;

(B) FD & C Blue No. 1, FD & C Blue No. 2, Ultramarine Blue; or

(C) FD & C Green No. 3, FD & C Red No. 3, or FD & C Red No. 40; or

(3) the producer is selling raw milk or raw milk products under

<u>18 AAC 32.070.</u> (Eff. 5/23/98, Register 146; am _/_/_, Register_)

Authority:	AS 03.05.020	AS 17.20.020	AS 17.20.290
	AS 03.05.090	AS 17.20.030	AS 17.20.340
	AS 17.20.010	AS 17.20.040	AS 44.46.020

18 AAC 32 is amended by adding a new section to read:

18 AAC 32.070. Raw milk and raw milk products production and sales. (a) Raw sheep, goat, or cow milk and milk product producers are not subject to other provisions of this chapter, except as otherwise indicated in this section, if

(1) the producer owns the milk producing animal;

(2) the producer has a valid veterinarian-client-patient relationship with a

licensed veterinarian who oversees the milk producing herd's care, including routine physical examinations;

(3) the producer has detailed knowledge about the milk-producing animal care, husbandry, and general health; and the facility, raw milk handling procedures and packaging process; and the producer provides this information upon request to the department and consumers;

(4) raw milk and raw milk products sold under this section are not distributed interstate;

(5) sold off-farm, the product is transported in packaging described in18 AAC 32.070(c) and kept below 40° Fahrenheit until accepted by end-consumer or permitted retail market;

(6) the producer registers their activity with the department and confirms that they have read and understand this section; when registering, the producer must complete the form developed by the department and include an example of the label intended for use on the container to be sold to consumer, as described in (c)(4) of this section; once registered, the producer will receive from the department a unique registration number, which is required to sell products under this section; (7) the producer or permitted retail market displays conspicuously to consumers on a card, placard, or sign that is posted at the point of sale, the statement "THIS PRODUCT IS NOT SUBJECT TO ROUTINE STATE INSPECTION"; and

(8) raw milk or raw milk products are not sold, donated, or served in an institution, as defined under 18 AAC 31.990(71) or a childcare facility as described under 7 AAC 57.010.

(b) The farm where raw milk and raw milk products are produced must include

(1) a facility for animal housing that

(A) is separated from the rest of the farm by, at a minimum, floor to ceiling walls;

(2) a facility for milking that

(A) is separated from the rest of the farm by, at a minimum, floor to ceiling walls, has overhead protection, and is constructed of materials conducive to cleaning;

(B) has a handwashing sink that meet the requirements set out in 18 AAC31.525(a);

(C) has a sink that is used exclusively for washing, rinsing, and sanitizing equipment, utensils, and other items that contact raw whole milk during the milking process; and

(D) uses potable water, or water from an approved public water system;

(3) a facility for raw milk processing that

(A) is separated from the rest of the farm by, at a minimum, floor to ceiling walls, is fully enclosed with solid doors and windows, and has overhead

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protection;

(B) has walls, ceiling, and floors that are made of materials conducive to cleaning;

(C) has a sink that is used exclusively for washing, rinsing, and sanitizing equipment, utensils, and other items that contact milk during the bottling process;

(D) has a handwashing sink that meets the requirements set out in 18 AAC 31.525(a);

(E) has food-contact surfaces that are constructed of materials that do not allow the migration of deleterious substances or impart colors, odors, or tastes to raw whole milk that meets the requirements set out in 18 AAC 31.400(a)(1);

(F) has a utility sink or other approved fixture used exclusively for cleaning the processing facility; and

(G) uses potable water, or water from an approved public water system;

(4) at least one toilet facility, that meets requirements set out in 18 AAC 31.520;

and

(5) a wastewater system that disposes of wastewater in an approved manner

under 18 AAC 72;

(c) The producer shall provide containers for the raw milk and raw milk products and ensure that each container

(1) is filled in a sanitary manner on farm, in the processing facility;

(2) is either made of

(A) glass that is cleaned and sanitized on farm in the processing facility;

or

(B) single-use plastic that is of food-grade material;

(3) is fitted with a lid intended to be used with the container and is of food-grade material; lids must be clean and affixed in a sanitary manner in the processing facility at the time of packaging; lids may not be reused;

(4) is clearly labeled with a label that does not contain marks or words that are misleading and that include

(A) the words "RAW MILK" or "RAW MILK PRODUCT" in letters at least one-quarter inch tall;

(B) the statement "ATTENTION: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness, or even death. Infants, children, the elderly, women who are pregnant, and persons with weakened immune systems are at highest risk"; the word "ATTENTION" must be in letters at least one-quarter inch tall and the remainder of the warning statement must be legible;

(C) the statement "KEEP REFRIGERATED TO 40°F OR BELOW";

(D) the net volume of contents;

(E) the production date and the statement "CONSUME WITHIN FOUR DAYS OF PRODUCTION DATE";

(F) the facility registration number assigned by the department;

(G) the name and physical address of the farm where the product was

produced;

(H) the common name of the species of animal from which the raw milk or raw milk product was obtained;

(I) for raw milk products, a list of ingredients in descending order of

predominance; and

(J) the words "ALLERGEN WARNING: Milk" and any other known allergen ingredient including shellfish, wheat, soy, sesame, fish, peanuts, tree nuts, and eggs.

(d) The producer shall ensure

(1) raw milk is cooled to 40° Fahrenheit within two hours after the start of milking;

(2) the raw milk or raw milk product's temperature is maintained at 40°Fahrenheit or lower once it is cooled as specified in (d)(1) of this section;

(3) the holding temperature of the refrigeration unit where raw milk and raw milk products are stored is capable of holding at 40° Fahrenheit, is equipped with a working and calibrated thermometer, and temperature is kept at 40° Fahrenheit or lower. Temperatures are checked at least weekly and documented as further described under (k)(4) of this section;

(4) raw milk is packaged the same day it is obtained from the animal;

(5) a four-to-six-ounce sample of every milking, labeled with the date collected, is kept and refrigerated at 40° Fahrenheit for 14 days to allow for traceback in the event of a public complaint, foodborne illness or animal health outbreak;

(6) that food is protected from contamination, including by use of gloves, as specified in 18 AAC 31.220;

(7) protection against the transmission of foodborne disease, as specified in18 AAC 31.300 – 18 AAC 31.320;

(8) utensils, equipment, and other product contact surfaces are washed, rinsed and sanitized in accordance with provisions specified in, as specified in 18 AAC 31.422 – 18 AAC

31.424;

(9) equipment used for milking is cleaned in accordance with the equipment manufacturer's recommendation and equipment is used according to intended purpose;

(10) bottles, lids, and other packaging are stored in a manner that prevents damage and contamination; and

(11) persons that purchase raw milk or raw milk product are offered the opportunity to voluntarily share their contact information, with the expressed purpose of that information being used to notify consumers in the event of suspected or confirmed foodborne illness outbreak or product recall.

(e) Raw milk or raw milk product may not contain any drug residue. The producer must follow veterinarian prescriptions and withdrawal times for any drug or chemical compound that is administered to the milk producing animal.

(f) Raw milk and raw milk products may not be sold to a consumer after four days from the production date.

(g) Raw milk or raw milk product that is adulterated may not be sold or provided to consumers.

(h) The producer shall conduct routine screening for mastitis and disease, as recommended by the veterinarian overseeing the animal care of the herd.

(i) Raw whole milk must be collected only from healthy animals showing no sign of mastitis or disease.

(j) Testing may be conducted at the discretion of the department in response to suspected foodborne illness or animal health outbreak. A producer may also test raw milk or raw milk product at their discretion. If any testing is conducted:

(1) a producer shall immediately report to the department results of any product testing showing antibiotic residue or pathogens that impact the health of the milk producing animal, or that which may negatively impact the quality of the product to be offered to the public under this section;

(2) a producer shall destroy a product in a way the department recommends or repurpose the product for a use other than human consumption after consultation with their veterinarian, if the product is negatively affected by any items for which it was tested. The producer shall, record this information in the production records as described in (k)(3) of this section;

(3) a producer may not sell or offer to consumers, a product that is outside the following standards

- (A) aerobic bacteria exceeding 20,000 per milliliter (20,000/ml);
- (B) somatic cell counts exceeding
 - (i) cow and sheep: 500,000/ml; or
 - (ii) goat: 1,000,000/ml;
- (C) any detection of the following pathogenic bacteria:
 - (i) Listeria monocytogenes;
 - (ii) Salmonella spp.;
 - (iii) Campylobacter spp.; or
 - (vi) Shiga-toxin producing Escherichia coli (STEC), including

E coli O157:H7.

(k) Except as specified in (5) of this paragraph, the producer shall maintain the following records at the production farm for at least two years and shall make the records available to the

department and may provide these records to the consumers upon request:

(1) routine and non-routine physical examinations, including examinations for mastitis, other disease, and other care, as overseen by a licensed veterinarian; records must include the reason for examination and the outcome, and any medication given;

(2) product quality tests as described in (j) of this section;

(3) test results for bacterial counts or adulteration in raw whole milk, as described in (j) of this section, and what was done with the adulterated product;

(4) temperature of raw whole milk during processing and storage, as required under (d)(1) and (d)(2), and temperature of refrigeration unit under (d)(3) of this section;

(5) a consumer contact list of persons that purchased product, as described in (d)(11) of this section, which includes consumer contact information and the date product was purchased. These records must be kept at the production farm for one month following the date of purchase and provided to the department upon request, in the event of a suspected foodborne illness outbreak.

(1) If a consumer complaint is filed, or a foodborne illness or animal health outbreak is suspected, the department may conduct inspections of the farm where product is produced for sale or conduct audits, with or without prior notice, to assess compliance with this section, including:

(1) inspecting the farm, or other facility where raw milk or raw milk products are sold;

(2) examining and making copies of labels and records;

(3) observing procedures;

(4) obtaining samples;

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- (5) collecting samples and conducting tests;
- (6) interviewing employees; and
- (7) taking photographs.

(m) The department may require that a producer detain raw milk or raw milk product if the department finds, or has cause to believe, that it is adulterated, misbranded, or processed in violation of this section; detention under this section is subject to the following procedures:

(1) the department will

(A) issue a notice of detention and inform the producer of the conditions under which the detention can be terminated; and

(B) affix, or instruct the producer to affix to the product container a "detained" tag or other appropriate marking that gives notice that the milk has been detained;

(2) if, after issuing a notice of detention, the department finds that the product is not adulterated, misbranded, or in violation of this section, the department will terminate detention and notify the producer;

(3) if the department finds that the product is adulterated, misbranded, or in violation of this section, the department will

(A) notify the producer of the corrective action necessary; corrective

action may include destruction of the product; and

(B) comply with the procedures set out in AS 17.20.240;

(4) a producer may not take, without department approval, an action with respect to an item detained under this section;

(5) the department may require a producer to destroy product if it violates

standards or tolerances set out in (j) of this section, or if it was handled under the same conditions as other products found to violate those standards or tolerances;

(6) if the department determines that an imminent health hazard exists, the department, in addition to requiring detention or destruction under this section, may take any other actions authorized under AS 03.05, AS 17.20, and AS 44.46.020, including revoking a producer's authorization under (a)(6) of this section, ordering product recall, and issuing an order to stop sale;

(7) a person subject to this section may seek an informal review under 18 AAC 15.185 of a department decision or an adjudicatory hearing under AS 44.62 (Administrative Procedure Act); an adjudicatory hearing may be requested by submitting a request to the commissioner not later than 30 days after the notice of the department decision; upon receipt of a timely request for adjudicatory hearing, the commissioner may refer the matter to the office of administrative hearings (AS 44.64.010) for a hearing and recommended decision under 2 AAC 64.100 – 2 AAC 64.990 to the commissioner or the commissioner's designee if the designee is a person other than the person who issued the contested decision.

(n) An exemption under this section does not relieve the operator from complying with other applicable statutes and regulations, including AS 17.20 (Food, Drug, and Cosmetic Act), AS 18.60.705 (State Plumbing Code), 18 AAC 30, 18 AAC 32, 18 AAC 36, or 18 AAC 50.

(o) In this section

(1) "destroy" or "destruction" means to dispose of product in a manner that precludes human or animal consumption;

(2) "farm" includes all facilities listed in 18 AAC 32.070 (b) and other areas that the milk producing herd has regular access;

(3) "permitted retail market" means a food establishment that has a permit and a variance for the requested activity under 18 AAC 31;

(4) "producer" means a person who owns milk producing animals, and produces and sells raw milk and raw milk products from the milk producing animal; and

(5) "raw milk and raw milk products" is milk or a dairy product made from raw milk that has not been pasteurized and is not regulated under Grade "A" milk regulations under 18 AAC 32.020; raw milk products are limited to yogurt, kefir, cheese, ice cream, cream, and butter.

(Eff.___, Register____)

Authority:	AS 03.05.011	AS 17.20.070	AS 17.20.250
	AS 03.05.030	AS 17.20.072	AS 17.20.260
	AS 03.05.050	AS 17.20.180	AS 17.20.270
	AS 17.20.005	AS 17.20.190	AS 17.20.280
	AS 17.20.020	AS 17.20.220	AS 44.46.020
	AS 17.20.040	AS 17.20.230	
	AS 17.20.050	AS 17.20.240	