Document: Final Rule, **Register Page Number:** 28 IR 3557
Source: September 1, 2005, Indiana Register, Volume 28, Number 12
Disclaimer: This document was created from the files used to produce the official CD-ROM Indiana Register.

TITLE 345 INDIANA STATE BOARD OF ANIMAL HEALTH

LSA Document #04-286(F)

DIGEST

Amends 345 IAC 8-2-1.1, 345 IAC 8-2-1.5, 345 IAC 8-2-1.7, and 345 IAC 8-2-1.9 and adds 345 IAC 8-2-1.6 to add and amend definitions and general provisions that coordinate with the 2003 Grade A Pasteurized Milk Ordinance. Amends 345 IAC 8-2-4 to allow goat milk to be collected at least once every seven days. Amends 345 IAC 8-3-1 to update matters incorporated by reference. Amends 345 IAC 8-3-2 and 345 IAC 8-4-1 and adds 345 IAC 8-3-12 to make other changes in the law of milk and milk products sanitation. Effective 30 days after filing with the Secretary of State.

345 IAC 8-2-1.1 **345 IAC 8-2-4**
345 IAC 8-2-1.5 **345 IAC 8-3-1**
345 IAC 8-2-1.6 **345 IAC 8-3-2**
345 IAC 8-2-1.7 **345 IAC 8-3-12**
345 IAC 8-2-1.9 **345 IAC 8-4-1**

SECTION 1. 345 IAC 8-2-1.1 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-2-1.1 Definitions
Authority: IC 15-2.1-3-19; IC 15-2.1-23-6
Affected: IC 15-2.1-2-3.6; IC 15-2.1-4; IC 15-2.1-23; IC 16-42

Sec. 1.1. (a) In the interpretation and enforcement of this article, unless the context otherwise requires, the definitions in IC 15-2.1-2 and the following definitions apply:

(1) "Approved grader of raw milk or raw cream" or "approved grader" has the meaning set forth in IC 15-2.1-2-3.6.

(2) "Automatic milking installation" or "AMI" means the entire installation of one (1) or more automatic milking units, including the hardware and software utilized in the operation of:

(A) individual automatic milking units;

(B) the animal selection system;

(C) the automatic milking machine;

(D) the milk cooling system;

(E) the system for cleaning and sanitizing the automatic milking unit;

(F) the teat cleaning system; and

(G) the alarm systems;

associated with the process of milking, cooling, cleaning, and sanitation.

~~(2)~~ **(3)** "Bacterial counts" means:

(A) bacterial plate counts;

(B) direct microscopic counts; and

(C) plate loop counts;

that, whenever mentioned in dairy product standards of identity, are made according to the methods outlined in the current edition of "Standard Methods for the Examination of Dairy Products", published by the American Public Health Association, and the current edition of Official Methods of Analysis of the Association of Official Analytical Chemists, or such methods that are approved by the board.

~~(3)~~ **(4)** "Butter" means the food product usually known as butter and ~~which~~ **that** is made:

(A) exclusively from milk or cream, or both; **and**

(B) with or without:

(i) common salt; and ~~with or without~~

(ii) additional coloring matter;
and containing not less than eighty percent (80%) by weight of milk fat, all tolerances having been allowed for.
~~(4)~~ **(5)** "Buttermilk" means a fluid product resulting from the manufacture of butter from milk or cream. ~~It~~ **Buttermilk** contains not less than eight and one-fourth percent (8¼%) of milk solids not fat.
~~(5)~~ **(6)** "Buyer of raw milk" means any:
(A) milk producer marketing organization;
(B) milk plant;
(C) receiving station;
(D) transfer station; or
(E) bulk hauler;
that takes delivery of raw milk or raw cream and manages the sale of the raw milk or raw cream.
~~(6)~~ **(7)** "Cheese" means:
(A) natural cheeses;
(B) processed cheeses;
(C) cheese foods;
(D) cheese spreads; and
(E) related foods;
described in the matters incorporated by reference in 345 IAC 8-3-1(e).
(8) "Clean" means product and contaminants have been thoroughly and effectively removed from direct product contact surfaces.
~~(7)~~ **(9)** "Concentrated milk" means **the** fluid product:
(A) that is unsterilized and unsweetened; **and**
(B) resulting from the removal of a considerable portion of the water from the milk;
which, when combined with potable water in accordance with instructions printed on the container, results in a product conforming with the milk fat and the milk solids not fat levels of milk defined in this rule.
~~(8)~~ **(10)** "Concentrated milk products" means:
(A) homogenized concentrated milk;
(B) concentrated nonfat milk;
(C) concentrated reduced fat or low fat milk; and
(D) similar concentrated products made from concentrated milk or concentrate nonfat milk; ~~and~~
which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding milk products in this section.
(11) "Cooling pond" means a manmade structure designed for the purpose of cooling lactating hooved mammals.
~~(9)~~ **(12)** "Cottage cheese" means the product defined in 21 CFR 133.128.
~~(10)~~ **(13)** "Dry curd cottage cheese" means the product defined in 21 CFR 133.129.
(14) "Dry milk products" means products resulting from the:
(A) drying of milk or milk products; or
(B) combination of dry milk products with other wholesome dry ingredients.
~~(11)~~ **(15)** "Eggnog" or "boiled custard" means the product defined in 21 CFR 131.170.
~~(12)~~ **(16)** "Farm bulk tank" or "bulk tank" means the refrigerated tank located on a dairy farm in which raw milk is stored ~~prior to~~ **before** collection by a milk hauler.
~~(13)~~ **(17)** "Food allergens" means proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than ninety percent (90%) of all food allergies:
(A) Peanuts.
(B) Soybeans.
(C) Milk.
(D) Eggs.
(E) Fish.
(F) Crustacea.
(G) Tree nuts.
(H) Wheat.
~~(14)~~ **(18)** "Frozen desserts" means:
(A) ice cream;
(B) frozen custard; ~~ice milk;~~

(C) goat's milk ice cream;
(D) sherbets;
(E) mellorine; and
(F) related foods;
described in the matters incorporated by reference in ~~345 IAC 8-3-1(g).~~ **345 IAC 8-3-1(f).**
~~(15)~~ **(19)** "Frozen milk concentrate" means a frozen milk product with a composition of milk fat and milk solids that are not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milk fat and the milk solids not fat requirements of whole milk.
~~(16)~~ **(20)** "Goat milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats.
~~(17)~~ **(21)** "Grade A dry milk and whey products" means products that have been:
(A) produced for use in Grade A pasteurized or aseptically processed milk products; and
(B) manufactured under the provisions of the ~~"Grade A Condensed and Dry Milk Products and Condensed and Dry Whey Supplement I to the~~ **"**Grade A Pasteurized Milk Ordinance" incorporated by reference in 345 IAC 8-3.
~~(18)~~ **(22)** "Grade A milk plant" means any place, premises, or establishment where Grade A milk products are:
(A) collected;
(B) handled;
(C) processed;
(D) stored;
(E) pasteurized;
(F) bottled;
(G) prepared; or
(H) stored for distribution.
~~(19)~~ **(23)** "Grade A producer" means a milk producer that is producing and selling Grade A raw milk under a Grade A permit issued by the board.
~~(20)~~ **(24)** "Grade A raw milk" means milk that has been produced:
(A) for use in Grade A pasteurized milk products; and
(B) under the provisions of the "Grade A Pasteurized Milk Ordinance–Current Recommendations of the United States Public Health Service".
~~(21)~~ **(25)** "Health authority", "board", or "state board" means the Indiana state board of animal health or its authorized representative.
(26) "Hooved mammals milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy hooved mammals.
~~(22)~~ **(27)** "Manufacturing grade milk plant" means any place, premises, or establishment where manufacturing grade milk products are:
(A) collected;
(B) handled;
(C) processed;
(D) stored;
(E) pasteurized;
(F) prepared; or
(G) stored for distribution.
(28) "Industry plant sampler" means an employee of a milk plant, receiving station, or transfer station that is responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in the PMO, Appendix N.
~~(23)~~ **(29)** "Manufacturing grade milk products" means dairy products not considered Grade A under this rule including **the following:**
(A) Cheese.
(B) Frozen desserts. ~~and~~
(C) Frozen desserts mixes. ~~and~~
(D) Butter.
~~(24)~~ **(30)** "Manufacturing grade producer" means a milk producer that is producing and selling manufacturing grade raw milk.
~~(25)~~ **(31)** "Manufacturing grade raw milk" means raw milk produced on a dairy farm ~~which~~ **that** does not have a currently valid permit issued by the board to sell Grade A raw milk for pasteurization.

~~(26)~~ **(32)** "Milk" means the normal lacteal secretion, practically free from colostrum, obtained by the complete milking of one (1) or more healthy:

(A) cows;

(B) sheep; ~~or~~

(C) goats;

(D) water buffalo; or

(E) hooved mammals.

~~(27)~~ **(33)** "Milk plant" means a Grade A milk plant or a manufacturing grade milk plant. ~~But,~~ For the purposes of the matters incorporated by reference at 345 IAC 8-3-1(a), ~~and 345 IAC 8-3-1(b),~~ **however,** "milk plant" means a Grade A milk plant only.

~~(28)~~ **(34)** "Milk tank truck driver" means a person who transports raw or pasteurized milk products to or from a:

(A) milk plant;

(B) receiving station; or

(C) transfer station.

~~(29)~~ **(35)** "New producer" means any milk producer who has not sold raw milk within a period of ninety (90) days ~~prior to~~ **before** the delivery in question.

~~(30)~~ **(36)** "Producer" means milk producer.

~~(31)~~ **(37)** "Producer's marketing organization" means a milk producer organization ~~which~~ **that** manages the marketing of a milk producer's raw milk.

~~(32)~~ **(38)** "Reconstituted or recombined milk and milk products" means milk or milk products defined in this rule that result from **the** reconstituting or recombining ~~or~~ **of** milk constituents with potable water when appropriate.

~~(33)~~ **(39)** "Regulatory agency" means the board.

(40) "Sanitization" means the application of any effective method or substance to surfaces that are clean to destroy pathogens and other microorganisms as far as is practical without adversely affecting the following:

(A) Equipment.

(B) Milk products.

(C) The health of consumers.

~~(34)~~ **(41)** "Sheep milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep.

~~(35)~~ **(42)** "Standard methods" means the "Standard Methods for the Examination of Dairy Products", published by the American Public Health Association.

~~(36)~~ **(43)** "State veterinarian" means the state veterinarian appointed under IC 15-2.1-4 or an official designee.

~~(37)~~ **(44)** "Uniform Indiana Food, Drug, and Cosmetic Act" means the Uniform Food, Drug, and Cosmetic Act at IC 16-42-1 through IC 16-42-4.

(b) Where a definition in a matter incorporated by reference conflicts with a definition in this section, the express provisions of this section shall control. *(Indiana State Board of Animal Health; 345 IAC 8-2-1.1; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3343; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 125; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 329; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3557)*

SECTION 2. 345 IAC 8-2-1.5 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-2-1.5 "Milk products" defined

Authority: IC 15-2.1-3-19; IC 15-2.1-23-6

Affected: IC 15-2.1-2; IC 15-2.1-23

Sec. 1.5. As used in this article, "milk products" means the following:

(1) Cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, and whipped light cream.

(2) Sour cream, acidified sour cream, and cultured cream.

(3) Half-and-half, sour half-and-half, acidified sour half-and-half, and cultured sour half-and-half.

(4) Reconstituted or recombined milk and milk products.

(5) Concentrated **(condensed)** milk and concentrated **(condensed)** milk products.

(6) Nonfat (skim) milk and reduced fat or low fat milk.

(7) Frozen milk concentrate.

(8) Eggnog.

(9) Buttermilk **and buttermilk products.**
(10) Whey and whey products.
~~(10)~~ **(11)** Cultured milk, cultured reduced fat or low fat milk, and cultured nonfat (skim) milk.
~~(11)~~ **(12)** Yogurt, low fat yogurt, and nonfat yogurt.
~~(12)~~ **(13)** Acidified milk, acidified reduced fat or low fat milk, and acidified nonfat (skim) milk.
~~(13)~~ **(14)** Low-sodium milk, low-sodium reduced fat or low fat milk, and low-sodium nonfat (skim) milk.
~~(14)~~ **(15)** Lactose-reduced milk, lactose-reduced reduced fat or low fat milk, and lactose-reduced nonfat (skim) milk.
~~(15)~~ **(16)** Aseptically processed and packaged milk and milk products.
~~(16)~~ **(17)** Milk.
~~(17)~~ **(18)** Milk, reduced fat milk, low fat milk, and nonfat (skim) milk that have added microbial organisms.
~~(18)~~ **(19)** Any other milk product made by the addition or subtraction of milk fat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification of milk products defined herein.
~~(19)~~ **(20)** Dairy foods made by modifying the federally standardized product listed in this section in accordance with 21 CFR 130.10.
~~(20)~~ **(21)** Milk and milk products that have been retort processed after packaging or that have been concentrated, condensed, or dried if they are used as an ingredient to produce any milk or milk product defined in this section or are labeled as Grade A.
~~(21)~~ **(22)** Manufacturing grade milk products unless the context indicates Grade A milk products.
(23) Dry milk products.
(Indiana State Board of Animal Health; 345 IAC 8-2-1.5; filed Sep 27, 2002, 2:40 p.m.: 26 IR 331; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3560)

SECTION 3. 345 IAC 8-2-1.6 IS ADDED TO READ AS FOLLOWS:

345 IAC 8-2-1.6 Abnormalities of milk
Authority: IC 15-2.1-3-19; IC 15-2.1-23-6
Affected: IC 15-2.1-2; IC 15-2.1-23

Sec. 1.6. The following definitions apply throughout this article:
(1) "Abnormal milk" means milk that is visibly changed in color, odor, or texture.
(2) "Contaminated milk" means milk that is unsaleable or unfit for human consumption following treatment of the animal with either of the following:
(A) Veterinary products that have withhold requirements.
(B) Medicines or insecticides not approved for use on dairy animals by the United States Food and Drug Administration (FDA) and Environmental Protection Agency (EPA).
(3) "Undesirable milk" means milk that, before milking the animal, is known to be unsuitable for sale, such as colostrum.
(Indiana State Board of Animal Health; 345 IAC 8-2-1.6; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3560)

SECTION 4. 345 IAC 8-2-1.7 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-2-1.7 "Pasteurization", "pasteurized", "ultra pasteurization", and "aseptic processing" defined
Authority: IC 15-2.1-3-19; IC 15-2.1-23-6
Affected: IC 15-2.1-2; IC 15-2.1-23

Sec. 1.7. (a) As used in this article, "pasteurization" ~~and~~ **or** "pasteurized" means the process of heating every particle of milk or milk product, in properly designed and operated equipment, to a temperature designated in the following tables, and held continuously at or above that temperature for at least the time that corresponds with the temperature in the following tables:
(1) Table 1 as follows:

Temperature	Time
63 degrees Celsius (145 degrees Fahrenheit)	30 minutes
72 degrees Celsius (161 degrees Fahrenheit)	15 seconds

~~But,~~ If the fat content of the milk product is ten percent (10%) or more, **however,** or if it contains added sweeteners, the specified temperature in ~~the preceding~~ Table **1** shall be increased by three (3) degrees Celsius (five (5) degrees Fahrenheit).
(2) Table 2 as follows:

Temperature	Time
89 degrees Celsius (191 degrees Fahrenheit)	1 second
90 degrees Celsius (194 degrees Fahrenheit)	0.5 second
94 degrees Celsius (201 degrees Fahrenheit)	.1 second
96 degrees Celsius (204 degrees Fahrenheit)	.05 second
100 degrees Celsius (212 degrees Fahrenheit)	.01 second

(3) Notwithstanding ~~the preceding~~ Tables **1 and 2,** eggnog shall be heated to at least the following temperature and time specifications:

Temperature	Time
69 degrees Celsius (155 degrees Fahrenheit)	30 minutes
80 degrees Celsius (175 degrees Fahrenheit)	25 seconds
83 degrees Celsius (180 degrees Fahrenheit)	15 seconds

(b) A pasteurization process that is different than those described in subsection (a) may be used if the following requirements are met:

(1) The process has been officially recognized by the United States Food and Drug Administration to be equally effective.

(2) The state veterinarian approves the procedure as being equally effective.

(c) As used in this article, "ultra pasteurized" means dairy products that have been thermally processed at or above two hundred eighty (280) degrees Fahrenheit **(one hundred thirty-eight (138) degrees Celsius)** for at least two (2) seconds, either before or after packaging, so as to extend **the** shelf life **of the product** under refrigerated conditions.

(d) As used in this article, "aseptic processing" means the filling of a commercially sterilized cooled product into presterilized containers, followed by hermetical sealing with a presterilized closure, in an atmosphere free of microorganisms. Aseptic processing shall be performed in accordance with the requirements **of** 21 CFR 113 and the applicable provisions of the Pasteurized Milk Ordinance incorporated by reference in 345 IAC 8-3 **to maintain commercial sterility of the product under normal conditions.** *(Indiana State Board of Animal Health; 345 IAC 8-2-1.7; filed Sep 27, 2002, 2:40 p.m.: 26 IR 331; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3560)*

SECTION 5. 345 IAC 8-2-1.9 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-2-1.9 General requirements; permits

Authority: IC 15-2.1-3-19; IC 15-2.1-23-2

Affected: IC 15-2.1-23-3

Sec. 1.9. (a) Milk and milk products, **including hooved mammals milk,** must be:

(1) produced;

(2) transported;

(3) processed;

(4) handled;

(5) sampled;

(6) examined;

(7) graded;

(8) labeled; and

(9) sold;

in accordance with IC 15-2.1-23 and this article.

(b) Only Grade A pasteurized, ultra pasteurized, or aseptically processed milk and milk products shall be sold to final consumers, restaurants, or retail establishments. A person may not sell pasteurized milk or milk products that have not been maintained at the temperature set forth in Section 7 of the Pasteurized Milk Ordinance adopted by reference in 345 IAC 8-3.

(c) A person shall obtain a permit from the state veterinarian before operating a dairy farm in Indiana. The state veterinarian shall issue the following dairy farm permits:

(1) A Grade A farm permit shall be issued for farms that meet the standards for a Grade A farm in IC 15-2.1-23 and this article.
(2) A manufacturing grade farm permit shall be issued for farms that do not meet the standards for a Grade A farm but do meet the standards for a manufacturing grade farm in IC 15-2.1-23 and this article.

A person may not hold a Grade A farm permit and a manufacturing grade farm permit for the same operation.

(d) A person shall obtain a permit from the state veterinarian before operating a milk plant in Indiana. The state veterinarian shall issue the following milk plant permits:
(1) A Grade A milk plant permit shall be issued for those operations that meet the standards for a Grade A milk plant in IC 15-2.1-23 and this article.
(2) A manufacturing grade milk plant permit shall be issued for those operations that meet the standards for a manufacturing grade milk plant in IC 15-2.1-23 and this article.
(3) A receiving station permit shall be issued for those operations that meet the standards for a receiving station in IC 15-2.1-23 and this article.
(4) A transfer station permit shall be issued for those operations that meet the standards for a transfer station in IC 15-2.1-23 and this article.

(e) The state veterinarian shall issue the following permits to persons meeting the appropriate requirements in IC 15-2.1-23 and this article:
(1) A milk distributor permit for persons acting as a milk distributor.
(2) A bulk milk hauler/sampler permit to persons acting as a bulk milk hauler/sampler.
(3) Milk tank truck operator for persons operating milk tank trucks.
(4) A permit to operate a milk tank truck cleaning facility.
(5) A permit to manufacture containers for milk or milk products.

(f) All permits issued under this article are subject to the provisions in IC 15-2.1-23-2 and IC 15-2.1-23-3. The state veterinarian may take any action with respect to permits the board is authorized to take under IC 15-2.1-23. *(Indiana State Board of Animal Health; 345 IAC 8-2-1.9; filed Sep 27, 2002, 2:40 p.m.: 26 IR 332; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3561)*

SECTION 6. 345 IAC 8-2-4 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-2-4 Bulk milk collection; pickup tankers; samples
Authority: IC 15-2.1-3-19; IC 15-2.1-23-6
Affected: IC 15-2.1-23-4

Sec. 4. (a) Every bulk milk pickup tanker used to collect raw milk on a bulk milk route shall be of sanitary design and construction. The owner of a tank truck shall be responsible for maintaining it and its milk contact equipment in good repair. The bulk milk pickup tanker owner is responsible for making certain the truck and equipment have been cleaned and sanitized at least once every twenty-four (24) hours in a manner and at a location approved by the board. A cleaning and sanitizing tag approved by the board shall be completed and affixed in the rear compartment of the bulk milk pickup tanker each day after cleaning and sanitizing. The bulk milk pickup tanker and its milk contact equipment shall be protected from contamination after being cleaned and sanitized.

(b) Milk in a bulk milk pickup tanker shall be maintained at a temperature of forty-five (45) degrees Fahrenheit or less from the time of collection until delivered to a milk plant, receiving station, or transfer station. If the milk being delivered is manufacturing grade raw milk, the raw milk shall be maintained at a temperature of sixty (60) degrees Fahrenheit or less from the time of collection until delivered to a manufacturing grade milk plant, receiving station, or transfer station.

(c) Tank trucks used to transport milk shall not be used to transport other products unless they have been thoroughly washed and sanitized after having been used to transport such other products. Only products fit for human consumption are authorized to be stored or transported in tank trucks used to transport milk or milk products.

(d) The name and address of the owner of a bulk milk pickup tanker shall be legibly marked on both sides or on the rear of the vehicle. The name of the owner shall be in letters not less than three (3) inches in height provided that markings in use ~~prior to~~ **before** March 1, 1998, may be the same height as the address, and the address shall be in letters not less than one and one-half (1½) inches in height.

(e) Every bulk milk pickup tanker used to collect raw milk on a bulk milk route shall be equipped with the following:

(1) A sample dipper or other sampling device of sanitary construction approved by the board.

(2) Sampling devices protected from contamination.

(3) A sample carrying case constructed of such material and in such a way as to maintain producer raw milk samples at a temperature of thirty-two (32) to forty (40) degrees Fahrenheit from the time such samples are collected until they are delivered to the milk plant, receiving station, or transfer station.

(4) A sample rack approved by the board and of sufficient size to hold at least one (1) sample of raw milk in an upright position from each bulk milk tank of each milk producer represented on the load of raw milk being transported to a milk plant, receiving station, or transfer station, plus one (1) sample to be used for temperature determination.

(f) Each milk hauler shall be equipped with an accurate pocket-type thermometer with an unbreakable stem when collecting milk from dairy farms and shall observe the following sanitary practices in collecting milk:

(1) The hauler's hands and outer clothing shall be clean during all pickup operations.

(2) The milk shall be smelled through the port opening in the cover of the bulk tank for off-odors ~~prior to~~ **before** raising the lid for a visual examination of the raw milk.

(3) The hauler must visually examine the raw milk in the bulk tank. Milk that is visibly unfit for human consumption in accordance with the provisions of the Uniform Indiana Food, Drug, and Cosmetic Act shall be rejected and not collected. The lid shall be closed immediately after making the visual examination whenever possible.

(4) The milk transfer hose used to withdraw raw milk from the farm bulk tank shall enter the milkhouse only through the port hole provided for that purpose.

(5) ~~Prior to~~ **Before** connecting the transfer hose to the outlet port of the farm bulk tank, the outlet port shall be sanitized. If milk has leaked past the core of the outlet valve of the farm bulk tank, the outlet port of the valve shall be washed and sanitized ~~prior to~~ **before** withdrawing the milk.

(6) When the cap from the end of the transfer hose is being removed, it shall be handled in a sanitary manner and stored so as to prevent it from being contaminated while milk is being pumped from the farm bulk tank into the bulk milk pickup tanker.

(7) After the milk has been removed from the farm bulk tank, the bottom of the tank shall be observed for sediment and milk abnormalities.

(8) Conditions of abnormality or sediment shall be noted on the producer's copy of the weight ticket.

(9) The date and time of milk collection, the temperature of the raw milk, and the milk hauler's signature and permit number shall be legibly entered on the weight ticket.

(10) After the milk has been removed from the farm bulk tank, the transfer hose shall be removed and recapped before the farm bulk tank is rinsed with water. After recapping, the transfer hose shall be rinsed free of exterior soil.

(11) A milk hauler shall not collect milk from any dairy farm for delivery to a milk plant, receiving station, or transfer station for use in Grade A milk or milk products unless the farm holds a valid permit from the board authorizing the sale of Grade A raw milk for pasteurization.

(12) At the time of collection of milk from each dairy farm, the milk hauler shall collect:

(A) only that raw milk that has been stored continuously in the farm bulk tank from the time of milking until the time of milk collection; and ~~shall collect~~

(B) the entire volume of milk being stored in the farm bulk tank at the time of collection.

All precautions shall be taken to prevent the entrance of flies into the milkhouse.

(13) At least once each month, the milk hauler shall check the accuracy of the thermometer on each of his **or her** milk producer's bulk milk ~~tank~~ **tanks** against his **or her** pocket-type thermometer. The temperature obtained from both thermometers shall be entered on the weight ticket. If there is a difference between the readings on the two (2) thermometers, the reading of the bulk milk hauler's thermometer shall be reported as the official temperature on that day and on each succeeding day until the thermometer on the bulk milk tank is adjusted or repaired to be accurate.

(g) Every time a milk hauler collects milk from a dairy farm, he or she shall collect a sample of milk from each farm bulk tank after the milk has been thoroughly agitated and before opening the outlet valve. ~~Such~~ **The** sample shall be collected in the following manner:

(1) If a sample dipper is used, it shall be clean and transported between farms on the bulk milk route in a sanitizing solution equivalent to one hundred (100) parts per million chlorine. Other sampling devices shall be kept free of contamination.

(2) After removal from the sanitizing solution, all of the sanitizing solution shall be drained from the sample dipper.

(3) The sample dipper shall then:

(A) be rinsed twice in the milk in the farm bulk tank; and ~~then~~

(B) drained.

(4) A sample of not less than four (4) fluid ounces in volume or other sample sizes approved by the state board shall then be collected through the port opening in the cover of the bulk tank and placed in a sterile container.
(5) The sample container shall then be closed and immediately placed in melting ice water in the sample carrying case on the bulk milk pickup tanker in such a way that the top of the sample container is not submerged in the refrigerant. Producer raw milk samples shall be maintained at a temperature of thirty-two (32) to forty (40) degrees Fahrenheit until delivered to the milk plant, receiving station, or transfer station. ~~Such~~ **The** samples shall not be frozen.
(6) Each sample container shall be legibly marked with **the following:**
(A) The date the sample was collected.
(B) The temperature of the milk in the farm bulk tank.
(C) The route and patron number of the milk producer. ~~and,~~
(D) In the case of Grade A milk producers, the Indiana Grade A permit number of the dairy farm from which the sample was collected.
(7) ~~Prior to~~ **Before** or at the time of collecting raw milk from the first milk producer on the bulk milk route, the milk hauler shall collect a sample of milk for temperature determination. ~~Such~~ **The** sample shall be refrigerated in the sample carrying case on the bulk milk pickup tanker until it arrives at the milk plant, receiving station, or transfer station.
(8) Sampling equipment shall be rinsed in clean water immediately after each usage.
(9) If one (1) pint samples are used to conduct sediment tests of each milk producer's raw milk, the milk hauler shall collect and legibly identify ~~such~~ **the** full one (1) pint samples as requested by the milk plant, receiving station, transfer station, or board. A sample dipper of not less than one-half (½) pint capacity, which shall be cleaned and sanitized ~~prior to~~ **before** the collection of each sample, shall be used. ~~Such~~ **The** one (1) pint samples shall be collected and transported in such a manner as to not interfere with the proper conduct of sediment tests.

(h) ~~All~~ **Bulk milk tank raw milk shall be collected within the following time frames:**
(1) Manufacturing grade milk bulk tank raw milk shall be collected at least **one (1) time** every seventy-two (72) hours. ~~and all~~
(2) Manufacturing grade raw milk shipped in cans shall be collected at least **one (1) time** every forty-eight (48) hours. ~~These milk collection frequencies may be waived in the case of emergencies. all~~
(3) Grade A bulk tank raw milk shall be collected at least **one (1) time** every forty-eight (48) hours. ~~and all~~
(4) Grade A milk shipped in cans shall be collected **at least one (1) time** every twenty-four (24) hours. ~~except~~
(5) Grade A and manufacturing grade goat milk shall be collected at least one (1) time every seven (7) days.
(6) In the case of ~~emergencies.~~ **an emergency, the state veterinarian or the state veterinarian's designee may permit milk to be collected after the time frames otherwise specified in this subsection.**
Bulk milk tank raw milk that is not collected within these time frames may not be collected and used for Grade A or manufacturing grade milk or milk products.

(i) It shall be the responsibility of the milk plant, receiving station, or transfer station to:
(1) provide competent personnel to receive producer raw milk samples from each bulk milk pickup tanker; ~~to~~
(2) ascertain and record the temperature of the temperature sample; ~~and to~~
(3) see that the samples are properly identified and stored ~~prior to~~ **before** delivery to the laboratory; ~~The milk plant, receiving station, or transfer station shall also be responsible for providing~~ **and**
(4) provide facilities for the storage of producer raw milk samples at a temperature of thirty-two (32) to forty (40) degrees Fahrenheit at which temperature they shall be maintained until they are received by an official or officially designated laboratory for analysis.
Producer raw milk samples shall not be frozen, and samples to be used for bacteriological determinations shall not be transferred to another sample container after they have been collected by the milk hauler except under conditions and by personnel approved by the board. Required laboratory analysis should begin within forty-eight (48) hours after the time of sample collection. Results of ~~such~~ **the** analysis on the milk of Grade A producers shall be submitted to the board on forms and in a manner approved by the board. Milk producers and milk haulers shall not receive notice of which samples are to be used for bacteriological analysis.

(j) Any truck transporting raw, heat-treated, or pasteurized milk and milk products to a milk plant from another milk plant, receiving station, or transfer station must meet the identification and shipping requirements in IC 15-2.1-23-4(c). A shipping manifest must also indicate the bulk tank **unit or** units or plant identification number. *(Indiana State Board of Animal Health; HDP 86 Rule 13, Sec 4; filed Apr 26, 1979, 12:00 p.m.: 2 IR 696, eff one hundred twenty (120) days after filing with secretary of state; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3349; errata filed Aug 13, 1998, 1:13 p.m.: 22 IR 125; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 338; filed Jul 18, 2005, 1:00 p.m.: 28 IR*

3562) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-13-4) to the Indiana State Board of Animal Health (345 IAC 8-2-4) by P.L.138-1996, SECTION 76, effective July 1, 1996.

SECTION 7. 345 IAC 8-3-1 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-3-1 Incorporation by reference; standards
Authority: IC 15-2.1-3-18; IC 15-2.1-3-19; IC 15-2.1-23-6
Affected: IC 15-2.1-2; IC 15-2.1-23

Sec. 1. (a) The Grade A Pasteurized Milk Ordinance, United States Department of Health and Human Services, Public Health Service, Food and Drug Administration, Publication No. 229 ~~(2001~~ **(2003** revision), referred to as the PMO, including all footnoted language regarding cottage cheese and the appendixes, is hereby incorporated by reference as a rule of the board for regulation of the production, transportation, processing, handling, sampling, examination, grading, labeling, and sale of all Grade A milk and milk products in the state provided, however, the following parts of the PMO are not incorporated:

(1) Section (16) on penalties.

(2) Section (17) on repeal and date of effect.

(3) Appendix K.

~~(b) Part II of the Grade A Condensed and Dry Milk Products and Condensed and Dry Whey–Supplement I to the Grade A Pasteurized Milk Ordinance (1995 version), known as the dry milk ordinance or DMO, including the appendixes, is hereby incorporated by reference as a rule of the board for the regulation of the production, manufacture, packaging, labeling, and sale of all Grade A condensed milk and Grade A dry milk products and Grade A condensed whey and Grade A dry whey for use in the preparation of Grade A milk products, provided, however, the following parts of the DMO are not incorporated:~~

~~(1) Section (13) on penalties.~~

~~(2) Section (14) on repeal and date of effect.~~

~~(3) Appendix P, "Performance-Based Dairy Farm Inspection System".~~

~~(c)~~ **(b)** References in the PMO ~~and the DMO~~ to the regulatory agency shall mean and refer to the board.

~~(d)~~ **(c)** The board adopts by reference the general provisions relating to food standards set forth by the United States Food and Drug Administration in 21 CFR 130.8, 21 CFR 130.9, 21 CFR 130.10, and 21 CFR 130.11, in effect on April 1, ~~2001.~~ **2004.**

~~(e)~~ **(d)** The board adopts by reference the definitions and standards of identity for milk and milk products set forth by the United States Food and Drug Administration in 21 CFR 131.3 et seq., titled "Part 131–Milk and Cream", in effect on April 1, ~~2001.~~ **2004.** Milk and milk products must conform to these standards.

~~(f)~~ **(e)** The board adopts by reference the definitions and standards of identity for cheeses and related cheese products set forth by the United States Food and Drug Administration in 21 CFR 133.3 et seq., titled "Part 133–Cheeses and Related Cheese Products", in effect on April 1, ~~2001.~~ **2004.** Cheese and cheese products must conform to these standards.

~~(g)~~ **(f)** The board adopts by reference the definitions and standards of identity for frozen desserts set forth by the United States Food and Drug Administration in 21 CFR 135.3 et seq., titled "Part 135–Frozen Desserts", in effect on April 1, ~~2001.~~ **2004.** Frozen desserts must conform to these standards.

~~(h)~~ **(g)** The board adopts by reference the current good manufacturing practices for manufacturing, packing, or holding human food set forth by the United States Food and Drug Administration in 21 CFR 110 and 21 CFR 113, in effect on April 1, ~~2001.~~ **2004.** The criteria and definitions in 21 CFR 110, 21 CFR 113, and this rule shall apply in determining whether a food is adulterated under IC 15-2.1-23 in that the food has been manufactured under such conditions that it is unfit for human food or the food has been prepared, packed, or held under ~~insanitary~~ **unsanitary** conditions under which the product may:

(1) become contaminated with filth; or ~~under which the product may~~

(2) have been made injurious to health.

~~(i)~~ **(h)** The board adopts by reference as a rule of the board the food labeling requirements set forth by the United States Food and Drug Administration in 21 CFR 101, but not including Subpart C, in effect on June 1, ~~2001.~~ **2004.**

~~(j)~~ **(i)** The board incorporates by reference into this rule the definitions set forth in IC 15-2.1-2 and the matters set forth in IC 15-2.1-23.

~~(k)~~ **(j)** Where the matters incorporated by reference in this section conflict with provisions of this article, IC 15-2.1-2, or IC 15-2.1-23, the express provisions of this article and the Indiana Code shall control.

~~(l)~~ **(k)** Incorporated documents are available for public inspection at the board. *(Indiana State Board of Animal Health; 345 IAC 8-3-1; emergency rule filed Jan 27, 1994, 5:00 p.m.: 17 IR 1223, eff Feb 1, 1994; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3354; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 340; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3564) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-8.1) to the Indiana State Board of Animal Health (345 IAC 8-3-1) by P.L.138-1996, SECTION 76, effective July 1, 1996.*

SECTION 8. 345 IAC 8-3-2 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-3-2 Grade A milk production and storage
Authority: IC 15-2.1-3-19; IC 15-2.1-23-6
Affected: IC 15-2.1-23-7

Sec. 2. The following are required to hold a Grade A dairy farm permit:
(1) Milk that is produced or processed must meet the chemical, bacteriological, and temperature standards in Section 7 and Table 1 of the PMO adopted by reference in section 1 of this rule.
(2) The farm must meet the sanitation, construction, operation, and other standards in the provisions of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule, including the following:
(A) Section 7, "Standards for Grade "A" Raw Milk For Pasteurization, Ultra-Pasteurization, or Aseptic Processing", Items 1r through 19r.
(B) Appendix C, "Dairy Farm Construction Standards; Milk Production".
(C) Appendix D, "Standards for Water Sources".
(D) Appendix F, "Sanitization".
(E) A farm utilizing an automatic milking installation (AMI) must comply with Appendix Q.
(3) The animals on the farm must meet the animal health requirements in IC 15-2.1-23-7 and Section 8 of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule.
(4) The "administrative procedures" set forth in the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule shall be followed in implementing the standards required in this section.
(5) Before:
(A) milkhouses;
(B) milking barns;
(C) stables; or
(D) parlors;
regulated under this rule are constructed or extensively altered, construction plans shall be submitted to the state veterinarian for written approval before work is begun.
(6) Raw milk for pasteurization shall not be stored:
(A) on a dairy farm for more than forty-eight (48) hours; and
(B) outside a farm bulk milk tank.
(7) Agitation and refrigeration of all farm bulk milk cooling and holding tanks shall be automatically controlled with automatic controls that will maintain mixed milk temperature between thirty-two (32) degrees Fahrenheit and forty-five (45) degrees Fahrenheit and an interval timer that will activate agitation of the milk for a minimum period of two (2) minutes in every sixty (60) minute interval. Persons holding Grade A permits issued under this article on January 1, 2003, must meet the automatic refrigeration and interval timer requirements in this subsection not later than January 1, 2005. ~~But,~~ All plans for new construction or extensive alteration that are submitted for approval under this section, **however,** shall meet the refrigeration and interval timer requirements in this subsection. All applicants for a new Grade A permit shall meet the refrigeration and interval timer requirements of this subsection as a condition of receiving the permit.

(Indiana State Board of Animal Health; 345 IAC 8-3-2; emergency rule filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3355; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 341; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3565) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-8.2) to the Indiana State Board of Animal Health (345 IAC 8-3-2) by P.L.138-1996, SECTION 76, effective July 1, 1996.

SECTION 9. 345 IAC 8-3-12 IS ADDED TO READ AS FOLLOWS:

345 IAC 8-3-12 Components of Grade A dairy products
Authority: IC 15-2.1-3-19; IC 15-2.1-23-6
Affected: IC 15-2.1-23-10

Sec. 12. (a) Powdered dairy blends may be labeled Grade A and used as ingredients in Grade A dairy products only if they meet the requirements of this rule. If a powdered blend is to be used as an ingredient in the production of a Grade A product, the following apply:
(1) The blend must be labeled Grade A.
(2) The plant where the Grade A powders are manufactured must meet the requirements in 345 IAC 8-2-1.9 or IC 15-2.1-23-10.
(3) The plant where the powders are blended must meet the requirements in 345 IAC 8-2-1.9 or IC 15-2.1-23-10.

(b) Blends of dairy powders that are used as an ingredient in Grade A milk products must be blended under conditions that meet all of the requirements for production of Grade A milk products in this rule.

(c) Grade A powder blends must be made from Grade A powdered dairy products. Small amounts of functional ingredients that are not Grade A, however, are allowed in Grade A blends when the finished ingredient is not available in Grade A form, for example, sodium caseinate. For the purpose of this subsection, "small amounts" means the total amount of the ingredient may not exceed five percent (5%) by weight of the finished blend. *(Indiana State Board of Animal Health; 345 IAC 8-3-12; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3565)*

SECTION 10. 345 IAC 8-4-1 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-4-1 Drug residues
Authority: IC 15-2.1-3-19; IC 15-2.1-23-6
Affected: IC 15-2.1-2-2.3; IC 15-2.1-23-6.5; IC 15-2.1-23-17

Sec. 1. (a) Milk shall be screened for the presence of drug residues as follows:
(1) Any milk plant that accepts raw milk shall test each bulk milk pickup tanker for beta lactam drug residues. Each bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling of milk using a representative sample from the truck. Samples shall be tested **as follows:**
(A) Using a test that has been approved by the United States Food and Drug Administration for screening milk for drug residues. ~~Samples shall be tested~~
(B) In a laboratory that is certified by the state veterinarian by an analyst that is certified by the state veterinarian.
When a drug residue test is positive, another test shall be run to confirm the positive. When a drug residue test is confirmed positive, samples collected from each producer on the load shall be tested to determine the farm of origin.
(2) The state veterinarian may implement a testing program to test milk from bulk milk pickup tankers for other drug residues.
(3) The state veterinarian may implement a testing program to test milk from any source for drug residues. ~~Such~~ **The** testing programs may include samples from farm bulk tanks, milk plants, or finished products as part of a monthly quality program or other surveillance program. Samples that test positive for drug residues are subject to the provisions of this section.
(4) Milk plants shall keep records of all drug residue tests that are conducted on bulk milk pickup tankers and farm bulk milk tanks and ~~their results.~~ **must include the information indicated in Appendix N of the PMO incorporated by reference in 345 IAC 8-3-1.** The records shall be kept for not less than six (6) months.

(b) All tests completed under this section must meet the following requirements:
(1) The test must be a test approved by the United States Food and Drug Administration for screening milk samples for drug residues.
(2) The test must be conducted **as follows:**
(A) By an analyst approved by the state veterinarian **under the standards in Appendix N of the PMO incorporated by reference in 345 IAC 8-3-1.**
~~(3) The test must be conducted~~ **(B)** In a laboratory approved by the state veterinarian **under the standards in Appendix N of the PMO incorporated by reference in 345 IAC 8-3-1.**
~~(4)~~ **(3)** A test that is being run to confirm a positive drug residue test result must be the same test that was used to obtain the initial

positive drug residue result. ~~But,~~ A person may use a different confirmatory test, **however,** if the state veterinarian approves the use of that confirmatory test. The state veterinarian may approve the use of a confirmatory test that is different from a prior test after:

(A) evaluating the circumstances surrounding the request; and

(B) determining that the use of the proposed confirmatory test is consistent with the purposes of this section.

(c) Milk tests positive for drug residues if a test meeting the requirements in subsection (b) indicates the presence of drug residues in the milk at any level.

(d) Whenever milk tests positive for drug residues and is confirmed, the following apply:

(1) The milk that tests positive for drug residues is adulterated under IC 15-2.1-2-2.3 and must be disposed of in a manner that:

(A) removes it from the human and animal food chain; or ~~that~~

(B) acceptably reconditions the milk under United States Health and Human Services–Food and Drug Administration compliance policy guidelines.

(2) The state veterinarian shall determine the origin of the contaminated milk. Milk from the farm of origin creates an imminent hazard to the public health. The state veterinarian shall suspend the Grade A farm permit or manufacturing grade farm permit, as the case may be, and no milk may be removed from the farm until the permit is reinstated.

(3) When a drug test shows the producer's milk is negative for drug residues, the state veterinarian may reinstate the farm permit.

(e) All positive drug residue test results must be called into the office of the state veterinarian immediately, and a written report of the test results must be faxed or delivered to the office of the state veterinarian within twenty-four (24) hours of the test. The producer whose milk tested positive must be notified of the positive drug residue test immediately. The company that conducted the test is responsible for the reporting requirements in this subsection.

(f) A producer whose milk tests positive for drug residues shall pay a fine and participate in drug residue education activities as follows:

(1) The following is imposed on a producer for the first positive test for drug residues within a twelve (12) month period:

(A) The positive producer must pay a fine to the board equal to the result of the following equation:

(DP) (2 days) ($3) - (PR)

However, if the result is less than five dollars ($5), then the fine is five dollars ($5).

(B) The positive producer must, in conjunction with his or her veterinarian and an official of the board:

(i) complete the "Milk and Dairy Beef Residue Prevention Protocol"; and

(ii) provide proof of completion to the board, office of the state veterinarian within thirty (30) days of the drug residue violation.

Failure to complete the protocol and submit proof of completion within thirty (30) days will result in action to suspend the producer's permit.

(2) The following is imposed for a second positive test for drug residues within a twelve (12) month period:

(A) The positive producer must pay a fine to the board equal to the result of the following equation:

(DP) (4 days) ($3)

However, if the result is less than five dollars ($5), then the fine is five dollars ($5).

(B) The positive producer must, in conjunction with his or her veterinarian and an official of the board:

(i) complete the "Milk and Dairy Beef Residue Prevention Protocol"; and

(ii) provide proof of completion to the board, office of the state veterinarian within thirty (30) days of the drug residue violation.

Failure to complete the protocol and provide proof of completion will result in action to suspend the producer's permit.

(C) The producer must attend a producer education program or meeting designated by the state veterinarian. The producer is responsible for paying registration and material fees and other costs associated with attending the education program or meeting. The producer must provide proof of attendance to the state veterinarian within ten (10) days of completion of the program or meeting.

(3) The third positive test result for drug residues within a twelve (12) month period shall result in the following:

(A) The board revoking a producer's Grade A permit if the producer has one.

(B) The sanctions for a second offense set forth in subdivision (2) are imposed.

(C) The producer must submit to the state veterinarian a set of written procedures that he or she will follow to prevent future drug residue violations. The procedures must be:

(i) submitted with the proof of completion required in subdivision (2)(B); and ~~must be~~

(ii) specific, practical, and reasonably likely to lessen the possibility of a drug residue violation when followed by the producer.

(D) After a producer's Grade A permit is revoked for a third offense violation under this rule, he or she shall not receive a new Grade A permit for a revocation period of thirty (30) days from the date of the revocation. After the revocation period, the state veterinarian must issue a conditional Grade A permit to a producer that has applied for a permit if the following requirements are met:

(i) The producer has met all of the requirements of this rule at the time of application.

(ii) The producer meets all other requirements of the board for obtaining a Grade A permit.

The permit will be issued on the condition that all of the requirements of this rule must be completed within the time frames set forth in this rule. A permit issued under this subdivision automatically becomes unconditional after the producer fully complies with all of the provisions of this rule.

(4) For each drug residue violation in a twelve (12) month period in excess of three (3), the producer is subject to the penalties for a third offense in subdivision (3), but for Grade A producers the revocation period will:

(A) begin on the date his or her permit is revoked; and

(B) run for a period equal to the length of the revocation period imposed after the producer's last drug residue violation times two (2).

For example, the revocation period for a fourth offense in a twelve (12) month period is sixty (60) days, and, for a fifth offense, the revocation period is one hundred twenty (120) days.

(g) The following definitions apply throughout this section:

(1) "DP" or "daily production" means the amount of milk, measured by hundredweight, produced by the positive producer in one (1) day, measured on the day in which the drug residue violation occurred.

(2) "PR" or "producer reimbursement" means an amount assessed against the positive producer to reimburse others for milk contaminated by the positive producer's contaminated milk, not including the value of the positive producer's contaminated milk for which he or she was not paid.

(3) "Revocation period" means the period after a Grade A producer's permit is revoked under this rule that he or she may not apply for a Grade A permit.

(h) The following shall apply to penalties imposed by this section:

(1) In cases where the positive producer holds a Grade A permit from the board, the provisions in this section shall operate in place of and as an equivalent to the penalties in Part II(B) of Appendix N of the Pasteurized Milk Ordinance.

(2) All monetary penalties must be:

(A) paid by the producer; and ~~must be~~

(B) received by the office of the state veterinarian within sixty (60) days of notice of the drug residue violation.

(3) The state veterinarian may, by special permit, allow a producer that objects to the imposition of a fine to dump two (2) days of milk production on a first offense and four (4) days of milk production on the second or third offense instead of paying a monetary fine where payment of a fine would impose undue hardship on a producer. The state veterinarian may:

(A) set the conditions under which the milk is to be dumped; and ~~may~~

(B) require documentation from the producer showing the circumstances under which the milk was dumped.

(4) Proof that a producer reimbursement was in fact assessed must be submitted to the office of the state veterinarian within sixty (60) days of notice of the drug residue violation along with any monetary penalty due.

(5) No penalty may exceed one thousand dollars ($1,000) for a first offense or two thousand dollars ($2,000) for a subsequent offense. Civil penalties collected under this section must be deposited in the dairy drug residue abatement fund established under IC 15-2.1-23-17.

(i) The state veterinarian may suspend the permit of a producer that does not comply with the requirements of this rule within the designated time periods allowed under this rule until such time as the violation is remedied.

(j) The following are examples that illustrate the calculation of the fine imposed by this rule:

(1) First offense:

(A) total positive truck load CWT: 500

(B) positive producer's CWT on positive tanker (two (2) days' production): 100

(C) producer's daily production CWT: 50

(D) co-op requires producer to pay for other producers' milk that is contaminated at fifteen dollars ($15) per CWT.

Penalty = (DP) (2 days) ($3) - (PR).
= [50 (2) ($3)] - [(500 - 100) ($15)].
= [$300 fine] - [$6,000 reimbursement paid to other producers].

Because the reimbursement to other producers exceeded the fine, no money is payable to the state as long as proof of the reimbursement assessment is provided to the board.

(2) First offense:

(A) total positive truck load CWT: 500

(B) positive producer's CWT on positive tanker (two (2) days' production): 400

(C) producer's daily production CWT: 200

(D) co-op requires producer to pay for other producers' milk that is contaminated at fifteen dollars ($15) per CWT.

Penalty = (DP) (2 days) ($3) - (PR).
= [200 (2) ($3)] - [(500 - 400) ($15)].
= [$1,200 fine] - [$1,500 reimbursement paid to other producers].

Because the reimbursement to other producers exceeded the fine, no money is payable to the state as long as proof of the reimbursement assessment is provided to the board.

(3) First offense:

(A) total positive truck load CWT: 500

(B) positive producer's CWT on positive tanker (two (2) days' production): 500

(C) producer's daily production CWT: 250

(D) co-op requires producer to pay for other producers' milk that is contaminated at fifteen dollars ($15) per CWT.

Penalty = (DP) (2 days) ($3) - (PR).
= [250 (2) ($3)] - [(500 - 500) ($15)].
= [$1,500 fine] - [$0 reimbursement paid to other producers].

Because there was no reimbursement to other producers, all of the fine is payable to the state, but the fine is limited by this section to one thousand dollars ($1,000).

(4) First offense:

(A) Positive bulk tank on monthly quality check or otherwise.

(B) Producer's daily production (CWT): 50

Penalty = (DP) (2 days) ($3) - (PR).
= [50 (2) ($3)] - 0.

Because there was no reimbursement to other producers, all of the three hundred dollar ($300) fine is payable to the state.

(5) Second offense:

(A) total positive truck load CWT: 500

(B) positive producer's CWT on positive tanker (two (2) days' production): 100

(C) producer's daily production (CWT): 50

(D) co-op requires producer to pay for other producers' milk that is contaminated at fifteen dollars ($15) per CWT.

Penalty = (DP) (4 days) ($3).
= 50 (4) ($3).

Because this is a second offense, no reimbursement is recognized, and all of the six hundred dollar ($600) fine is paid to the state.

(6) Fourth offense:

(A) total positive truck load CWT: 500

(B) positive producer's CWT on positive tanker (two (2) days' production): 100

(C) producer's daily production (CWT): 50

(D) co-op requires producer to pay for other producers' milk that is contaminated at fifteen dollars ($15) per CWT.

Penalty = (DP) (4 days) ($3).
= 50 (4) ($3).

Because this is a fourth offense, no reimbursement is recognized, and all of the six hundred dollar ($600) fine is paid to the state. A Grade A producer's permit will be revoked for a period of one hundred twenty (120) days after which time he or she may reapply for a Grade A permit.

(Indiana State Board of Animal Health; 345 IAC 8-4-1; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3355; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 342; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3566)

LSA Document #04-286(F)
Notice of Intent Published: December 1, 2004; 28 IR 983
Proposed Rule Published: March 1, 2005; 28 IR 1821
Hearing Held: April 21, 2005
Approved by Attorney General: June 27, 2005
Approved by Governor: July 15, 2005
Filed with Secretary of State: July 18, 2005, 1:00 p.m.
IC 4-22-7-5(c) Notice from Secretary of State Regarding Documents Incorporated by Reference: None Received by Publisher