ARTICLE 8. DAIRY PRODUCTS

Rule 1. Somatic Cell Count Standard–Grade A Raw Milk

345 IAC 8-1-1 Somatic cell tests; violations (Repealed)

Sec. 1. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

Rule 2. Production, Handling, Processing, Packaging, and Distribution of Milk and Milk Products

345 IAC 8-2-1 Definitions (Repealed)

Sec. 1. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

345 IAC 8-2-1.1 Definitions

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-17-2; IC 15-17-4; IC 16-42

Sec. 1.1. (a) In the interpretation and enforcement of this article, unless the context otherwise requires, the definitions in IC 15-17-2 and the following definitions apply:

(1) "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) "Bacterial counts" means:

(A) bacterial plate counts;
and
(B) 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) "Butter" means the food product usually known as butter and that is made:

(A) exclusively from milk or cream, or both; and
(B) with or without:
(i) common salt; and
(ii) additional coloring matter;

and containing not less than eighty percent (80%) by weight of milk fat, all tolerances having been allowed for.

(4) "Buttermilk" means a fluid product which contains not less than eight and one-fourth percent (8 1/4%) of milk solids not fat and is either a:

(A) fluid product resulting from the manufacture of butter from milk or cream; or
(B) Grade A fluid product, also known as "cultured buttermilk", resulting from the pasteurization of milk that is inoculated with an appropriate culture.

Either product may be concentrated (condensed) or dried.

(5) "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) "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).

(7) "Clean" means product and contaminants have been thoroughly and effectively removed from direct and indirect product contact surfaces.

(8) "Clean-in-place (CIP) cleaning" means the removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Components of the equipment that are not designed to be cleaned-in-place are removed from the equipment and cleaned out-of-place (COP) or manually cleaned. Product and solution contact surfaces must be readily accessible for inspection, but, when the cleanability by CIP has been documented and approved by the board, the surfaces do not have to be readily accessible for inspection.

(9) "Concentrated milk" and "condensed 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;

that, 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.

(10) "Concentrated milk products" and "condensed 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;

that, 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 man-made structure designed for the purpose of cooling lactating hooved mammals.

(12) "Cottage cheese" means the product defined in 21 CFR 133.128.

(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.

(15) "Eggnog" or "boiled custard" means the product defined in 21 CFR 131.170.

(16) "Farm bulk tank" or "bulk tank" means the refrigerated tank located on a dairy farm in which raw milk is stored before collection by a milk hauler holding a current hauler/sampler permit issued by the board or a state dairy regulatory agency.

(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.

(18) "Frozen desserts" means:
(A) ice cream;
(B) frozen custard;
(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(f).

(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.

(20) "Goat milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats.

(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 Pasteurized Milk Ordinance" incorporated by reference in 345 IAC 8-3.

(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; or
(G) prepared;

for distribution.

(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.

(24) "Grade A raw milk" means milk that has been produced for use in:
(A) Grade A pasteurized, aseptic, or retorted milk or milk products; or
(B) manufacturing grade milk products;

under the provisions of the "Grade A Pasteurized Milk Ordinance-Current Recommendations of the United States Public Health Service".

(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. Hooved mammals include, but are not limited to, members of the order Cetartiodactyla, such as the following:
(A) The family Bovidae (cattle, water buffalo, sheep, goats, yaks).
(B) The family Camelidae (llamas, alpacas, camels).
(C) The family Cervidae (deer, reindeer, moose).
(D) The family Equidae (horses, donkeys).

(27) "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.

(28) "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; or
(F) prepared;

for distribution.

(29) "Manufacturing grade milk products" means milk and milk products processed and packaged in compliance with the standards of this rule but not considered Grade A, such as the following:

(A) Cheese.
(B) Frozen desserts.
(C) Frozen desserts mixes.
(D) Butter.

(30) "Manufacturing grade producer" means a milk producer that has a permit from the board to produce and sell manufacturing grade raw milk.

(31) "Manufacturing grade raw milk" means raw milk produced on a dairy farm that has a valid permit issued by the board to sell raw milk for manufacturing grade milk and milk products.

(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;
(C) goats;
(D) water buffalo; or
(E) hooved mammals.

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

(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.

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

(36) "Producer" means milk producer.

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

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

(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.

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

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

(43) "State veterinarian" means the state veterinarian appointed under IC 15-17-4 or an official designee.

(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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; filed Dec 10, 2010, 10:42 a.m.: 20110105-IR-345100123FRA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA)*

345 IAC 8-2-1.5 "Grade A milk and milk products" defined

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-17-2; IC 15-18-1

Sec. 1.5. (a) As used in this article, "Grade A milk and milk products" means the following:

(1) All milk and milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR Part 131.120 sweetened condensed milk.

(2) Cottage cheese (21 CFR Part 133.128) and dry curd cottage cheese (21 CFR Part 131.129) when it is produced under the provisions in 345 IAC 8-3-1.

(3) Whey and whey products as defined in 21 CFR 184.1979, 21 CFR 184.1979a, 21 CFR 184.1979b, 21 CFR 184.1979c, and section 1.8 of this rule.

(4) Modified versions of the foods listed in subdivisions (1) through (3) pursuant to 21 CFR Part 130.10.

(5) Milk and milk products as defined in subdivisions (1) through (4) that are packaged in combination with foods not included in this definition that are appropriately labeled with a statement of identity to describe the foods in final packaged form, for example, "cottage cheese with pineapple" and "fat free milk with plant sterols".

(6) Products not included in subdivisions (1) through (5) are milk products if the product has:

(A) a minimum of two percent (2.0%) milk protein (total Kjeldahl nitrogen (TKN) × 6.38); and

(B) a minimum of sixty-five percent (65%) by weight milk, milk products, or a combination of milk products.

(b) Dairy ingredients that are not Grade A dairy ingredients under this article may be utilized in products defined in subsection (a) for a functional or technical effect if they meet all of the following:

(1) The ingredients are safe and suitable as defined in 21 CFR 130.3(d). However, the use of a non-Grade A dairy ingredient to increase weight or volume of a product or to displace grade A dairy ingredients is not a suitable functional or technical effect.

(2) The ingredients and their use are consistent with good manufacturing practices as defined in 21 CFR Part 110.

(3) The ingredients are at least one (1) of the following:

(A) Prior sanctioned under 21 CFR Part 181 or otherwise approved by the United States Food and Drug Administration.

(B) Generally recognized as safe under 21 CFR Part 182 or 21 CFR Part 184.

(C) An approved food additive under 21 CFR Part 172 or 21 CFR Part 173.

(c) Milk and milk products include those milk and milk products that have been aseptically processed and then packaged.

(d) The following are not included in the definition of milk and milk products:

(1) A milk or milk product in which the milkfat of the milk or milk product has been substituted in part or in whole by any other animal or vegetable fat. Provided, however, that other fat sources may be included when they are legally used for purposes currently accepted in other products that are lawfully added to Grade A milk or milk products, such as carriers for vitamins and as an ingredient in emulsifiers and stabilizers.

(2) Coffee based products where coffee or water is the primary ingredient, as indicated in the ingredient statement for the product in compliance with 21 CFR Part 101.

(3) Tea based products where tea or water is the primary ingredient, as indicated in the ingredient statement for the product in compliance with 21 CFR Part 101.

(4) Dietary supplements that are not otherwise defined or included in the definition in this section.
(5) Infant formula produced under 21 CFR Part 106 and 21 CFR Part 107.
(6) Ice cream and other frozen desserts.
(7) Butter.
(8) Cheese, including standardized cheese but not including cottage cheese (21 CFR Part 133.128) and dry curd cottage cheese (21 CFR Part 131.129) and nonstandardized cheese.
(9) Puddings.

(e) Milk and milk products that have been retort processed after packaging or that have been concentrated, condensed, or dried are only included in definition of Grade A milk and milk products if they are used as an ingredient to produce any milk or milk product defined in subsection (a) or if they are labeled as Grade A. Powdered dairy blends may be labeled Grade A and used as ingredients in Grade A milk and milk products if they meet the requirements of this article, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade A cultured milk and milk products.

(f) Blends of dairy powders that are used as ingredients in Grade A milk and milk products must be blended under conditions that meet all applicable Grade requirements in this article. Grade A powder blends must be made from Grade A powdered milk and milk products. However, small amounts of functional ingredients that are not Grade A may be used in Grade A blends when the:

(1) total use of such ingredients does not exceed ten percent (10%) of the weight of the finished blend; and
(2) finished ingredient is not available in Grade A form (such as sodium caseinate).

(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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Dec 10, 2010, 10:42 a.m.: 20110105-IR-345100123FRA)

345 IAC 8-2-1.6 Abnormalities of milk

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-17-2; IC 15-18-1

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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; readopted filed Aug 7, 2013, 8:32 a.m.: 20130904-IR-345130236RFA)

345 IAC 8-2-1.7 "Pasteurization", "pasteurized", "ultra pasteurization", and "aseptic processing" defined

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-17-2-82; IC 15-18-1

Sec. 1.7. (a) As used in this article, "pasteurization" or "pasteurized" means the process of heating every particle of milk or milk product in a manner that meets all of the following requirements:

(1) The equipment is approved by the board.
(2) The equipment is properly designed and operated. Proper design and operation of the equipment under IC 15-17-2-82 and this article means design and operation according to the requirements in this section and the requirements in Section 7 Items 16p, 16p(A) through 16p(E) and Appendix H in the PMO incorporated by reference in 345 IAC 8-3-1.
(3) Each particle of milk or milk product must be heated to a temperature designated in the tables in subsection (b) and held continuously at or above that temperature for at least the time that corresponds with the temperature in the tables in

subsection (b) using the type of equipment specified in the tables in subsection (b).

(b) Each of the following time and temperature requirement options is subordinate to the operating requirements prescribed in subsection (a)(2). If an operating requirement prescribes a time, temperature, and equipment combination that is different than the following table, the specific operating requirement is required:

(1) Table 1 as follows:

Temperature	Equipment	Time
63 degrees Celsius (145 degrees Fahrenheit)	vat pasteurizer	30 minutes
72 degrees Celsius (161 degrees Fahrenheit)	continuous flow pasteurizer	15 seconds

However, if the fat content of the milk product is ten percent (10%) or greater, the total solids content of the milk product is eighteen percent (18%) or greater, or if the milk product contains added sweeteners, the specified temperature in Table 1 shall be increased by three (3) degrees Celsius (five (5) degrees Fahrenheit).

(2) Table 2 as follows:

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

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

Temperature	Equipment	Time
69 degrees Celsius (155 degrees Fahrenheit)	vat pasteurizer	30 minutes
80 degrees Celsius (175 degrees Fahrenheit)	continuous flow pasteurizer	25 seconds
83 degrees Celsius (180 degrees Fahrenheit)	continuous flow pasteurizer	15 seconds

(c) 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.

(d) 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.

(e) As used in this article, "aseptic processing" and "aseptic processing and packaging" means the heat processing and filling of a milk or milk product into presterilized containers, followed by hermetical sealing with a presterilized closure, in an atmosphere free of microorganisms. Aseptic processing and packaging shall be performed in accordance with the requirements of 21 CFR Parts 108, 110, and 113 to maintain commercial sterility of the product under normal nonrefrigerated conditions.

(f) As used in this article, "aseptic processing and packaging system" and "APPS" means the aseptic processing and packaging system in a milk plant is comprised of the processes and equipment used to process and package aseptic Grade A milk or milk products. The APPS shall be constructed and operated in accordance with the applicable requirements in 21 CFR Parts 108, 110, and 113. The APPS shall begin at the constant level tank and end at the discharge of the packaging machine, provided that the process authority may provide written documentation that clearly defines additional processes or equipment that are considered critical to the commercial sterility of the product.

(g) As used in this article, "low-acid aseptic milk and milk products" means milk or milk products having a water activity (a_w) greater than 0.85 and a finished equilibrium pH greater than 4.6 and are regulated under 21 CFR Parts 108, 110, and 113. Aseptically processed and packaged low-acid milk and milk products are stored under normal nonrefrigerated conditions. This term does not include low-acid milk and milk products that are labeled for storage under refrigerated 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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Dec 10, 2010, 10:42 a.m.: 20110105-IR-345100123FRA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA)*

345 IAC 8-2-1.8 "Whey products" defined

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-17-2; IC 15-18-1

Sec. 1.8. (a) The definitions in this section apply throughout this article.

(b) "Dry whey products" means products resulting from the drying of whey or whey products and any product resulting from the combination of dry whey products with other wholesome dry ingredients.

(c) "Grade A concentrated, condensed, and dry whey and whey products" means concentrated, condensed, and dry whey and whey products that comply with the applicable provisions of this article to be a Grade A product. "Concentrated, condensed, and dry milk products" includes concentrated, condensed, and dry whey and whey products.

(d) "Grade A whey products" means whey products defined in subsection (e) that have been manufactured to meet Grade A standards under this article.

(e) "Whey products" means any of the following products:

(1) Fluid product that is removed from whey.

(2) Product that is made by removing any constituent from whey or by adding any wholesome substance to whey or parts of whey.

(Indiana State Board of Animal Health; 345 IAC 8-2-1.8; filed Dec 10, 2010, 10:42 a.m.: 20110105-IR-345100123FRA)

345 IAC 8-2-1.9 General requirements; permits

Authority: IC 15-17-3-21
Affected: IC 15-18-1-9

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 15-18-1 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 15-18-1 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 15-18-1 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 15-18-1 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 15-18-1 and this article.

(3) A receiving station permit shall be issued for those operations that meet the standards for a receiving station in IC 15-18-1 and this article.

(4) A transfer station permit shall be issued for those operations that meet the standards for a transfer station in IC 15-18-1 and this article.

(e) The state veterinarian shall issue the following permits to persons meeting the appropriate requirements in IC 15-18-1 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 15-18-1 and IC 15-18-1-9. The state veterinarian may take any action with respect to permits the board is authorized to take under IC 15-18-1. *(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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; readopted filed Oct 16, 2014, 9:43 a.m.: 20141112-IR-345140300RFA)*

345 IAC 8-2-2 Manufactured grade milk products plants; construction; operation; sanitation

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1

Sec. 2. (a) A manufacturing grade milk plant shall meet the requirements in this section.

(b) The floors of all rooms in which milk or milk products are handled or processed, or in which milk or milk products utensils are washed or sanitized shall be:

(1) constructed of concrete or other equally impervious and easily cleaned material;

(2) smooth;

(3) properly drained;

(4) provided with trapped drains; and

(5) kept clean;

provided that cold storage rooms and storage rooms for storing dry ingredients or packaging materials need not be provided with drains; however, if no drain is provided, they shall be kept dry at all times. Rooms used for storing only dry ingredients, packaged dry ingredients, packaged dry milk or milk products, or packaging materials may have floors constructed of tightly joined wood.

(c) Walls and ceilings of rooms in which milk or milk products are handled or processed, or in which milk or milk products utensils are washed or sanitized shall:

(1) have smooth, washable, and light-colored surfaces; and

(2) be kept clean.

(d) Unless other effective means are provided to prevent the access of flies and other insects, all openings into the outer air shall be effectively screened and doors shall be self-closing. All screen doors to the outer air, if not of the sliding type, shall open outward. All inner doors opening into processing and packaging areas shall be self-closing. All self-closing doors shall be kept closed.

(e) All rooms shall be provided with natural lighting, artificial lighting, or a combination of both that will furnish at least twenty (20) foot-candles of light in all working areas. Ventilation shall be such that excessive condensation on walls, ceilings, containers, and equipment is prevented. Steam from bottle and can washers, sterilizers, and driers shall be conducted through ducts to the outside of the building.

(f) Milk plants must meet the following requirements:

(1) Operations shall be so located and conducted as to prevent any contamination of clean equipment, milk, or milk products.

(2) All means necessary for the elimination of flies and other insects shall be used, and the plant shall be free from flies and insects.

(3) Pasteurized milk or milk products shall not be permitted to come in contact with unpasteurized milk and equipment with

which unpasteurized milk or milk products have been in contact unless such equipment has first been thoroughly cleaned and subjected to a bactericidal treatment approved by the board.

(4) Rooms in which milk, milk products, cleaned utensils, or containers are handled or stored shall not open directly into living quarters.

(5) A covered and enclosed area complying with this rule relating to floors, walls, ceilings, lighting, and ventilation shall be provided to adequately wash and sanitize milk tank trucks.

(6) The processing rooms of a milk plant shall be used for no other purposes than the processing of milk and milk products and the operations incident thereto. However, the preceding sentence shall not in any way be construed as prohibiting the operation of frozen desserts freezers in any room if the premises otherwise comply with the provisions of this section. Steam boilers shall not be located in the pasteurizing, processing, mixing, freezing, drying, cooling, bottling, packaging, or sterilizing room. Refrigerated rooms shall be free from contaminating odors and be kept clean, sanitary, and in good repair.

(7) Raw milk shall not be strained through woven wire cloth. Pasteurized milk, frozen desserts mix, and frozen desserts shall not be strained or filtered except through a metal strainer constructed of not readily corrodible material other than woven wire.

(8) There shall be no raw milk or raw milk product bypass around the pasteurization holding tube or vat.

(9) Receiving tanks, dump vats, and weigh tanks shall be constructed so as to prevent the entrance of dust, dirt, or other contamination. All openings into tanks, vats, and mix reservoirs shall be protected by raised edges or otherwise protected to prevent drainage into the opening from the surface of the tank, vat, or mix reservoir. A milk plant must provide condensation-diverting aprons that are as close to the tank, vat, or mix reservoir as possible on all pipes, thermometers, and other equipment extending into the tank unless a watertight joint with the tank is provided.

(g) All vehicles, conveyances, and containers transporting raw milk and those that are clean and empty intended for raw milk shall be tightly enclosed. Milk products or empty containers used for milk products shall not be hauled in any unclean vehicle and shall not be hauled in vehicles that are also used for hauling livestock, manure, garbage, or coal.

(h) Every milk plant shall provide toilet facilities for employees. Toilet rooms shall not open directly into any room in which milk, frozen desserts mix, frozen desserts, milk products, equipment, or containers are handled or stored. The doors of all toilet rooms shall be self-closing. Toilet rooms shall be kept in a clean condition, kept in good repair, and be well ventilated. In case privies are used, they shall be:

(1) separate from the building;

(2) sanitary; and

(3) located and properly constructed and maintained so that the waste:

(A) is inaccessible to flies; and

(B) does not pollute the surface soil or contaminate any water supply.

(i) The water supply for a milk plant shall:

(1) be adequate, accessible, and under pressure; and

(2) meet the standards of quality for drinking purposes of the Indiana department of environmental management.

(j) A milk plant shall provide convenient handwashing facilities for employees, including warm running water, soap, and sanitary towels. The use of a common towel is prohibited.

(k) All milk and liquid milk products shall be moved from one (1) piece of equipment to another through sanitary milk piping of a type that can be easily cleaned with a brush, through approved clean-in-place sanitary milk piping, or by other means approved by the state veterinarian.

(l) Multi-use containers and equipment that come into contact with milk or milk products shall be:

(1) constructed to be smooth and easily cleanable; and

(2) kept in good repair.

All surfaces with which milk or milk products come in contact shall be noncorrodible metal or an unbroken vitreous material free from broken seams, breaks, corrosion, and threaded surfaces. Equipment shall be self-draining, easily accessible, and easily disassembled for cleaning.

(m) Wastes from sinks, drains, toilets, or equipment shall be connected with a disposal system or otherwise disposed of in a manner that complies with the rules of the board, the Indiana state department of health, the local health department, and the Indiana department of environmental management. Covered receptacles shall be provided for waste materials, and such waste

materials shall be removed and emptied daily from the work rooms.

(n) Requirements for cleaning and bactericidal treatment of containers and equipment shall be as follows:

(1) Every milk plant shall be equipped with equipment that is capable of producing sufficient hot water or steam for cleaning and sanitizing.

(2) Except as provided in section 2.5 of this rule, all milk or milk products equipment shall be disassembled and the parts thoroughly cleaned after it is used, but at least once every twenty-four (24) hours. Storage tanks must be cleaned when emptied, but at least once every seventy-two (72) hours. The equipment must be cleaned using clean hot water containing a dairy cleanser that is safe for use on dairy equipment according to the manufacturer's recommendation. Soap may not be used. Multi-use containers shall be cleaned before each use.

(3) This section does not prohibit the cleaning of dairy equipment by a clean-in-place method, provided the individual clean-in-place system and method used and the results obtained comply with the 3-A Sanitary Standards and are approved by the board. Cleaned-in-place systems that are welded or otherwise constructed so as to make daily visual inspection impractical shall be equipped with a temperature recording device installed in the return solution line to record the temperature and time during which the line or equipment is exposed to cleaning and sanitizing. Recording devices and charts shall comply and conform with 3-A Sanitary Standards and be approved by the board prior to installation and operation.

(o) All multi-use milk and milk products containers and equipment shall be sanitized with an effective bactericidal process before they are used. After bactericidal treatment, all bottles, cans, and other multi-use milk and milk products containers and equipment shall be stored, while not in use, in such manner as to be protected from contamination. Between bactericidal treatment and usage, and during usage, containers and equipment shall not be handled, used, or operated in such manner as to permit contamination of the milk or milk products.

(p) Single-service containers shall be:

(1) purchased and stored only in sanitary tubes and cartons; and

(2) kept therein in a clean, dry place.

Single-service articles shall be stored in a sanitary manner between the time that they are removed from the original container and used.

(q) All milk and milk products received for pasteurization or processing shall immediately be cooled in approved equipment to forty-five (45) degrees Fahrenheit or less and maintained at that temperature until pasteurized unless they are to be pasteurized within two (2) hours after receipt. All pasteurized milk and milk products shall be immediately cooled in approved equipment to an average temperature of forty-five (45) degrees Fahrenheit or less, except when recognized standard processing practices dictate higher temperatures for cultured products and related byproducts.

(r) A milk plant must use approved mechanical equipment for packaging. No multi-use container shall be filled or refilled until it is empty and has been cleaned and sanitized.

(s) All persons coming in contact with milk, milk products, containers, or equipment shall:

(1) wear clean outer garments;

(2) wear hair nets, facial hair restraints, caps, or other effective hair restraints; and

(3) keep their hands clean;

at all times they are engaged in activity where they come into contact with milk, milk products, containers, or equipment.

(t) Miscellaneous provisions shall be as follows:

(1) Overflow milk or milk products that have become machine contaminated shall not be sold for human food.

(2) Milk products shall not be returned to the manufacturer for resale after the original package has been opened. Milk products that have been returned to the manufacturer after the original package has been opened must be destroyed.

(u) Frozen desserts in the manufacturer's unbroken package shall have a bacterial plate count of not more than thirty thousand (30,000) per gram and a coliform count of not more than ten (10) per gram. The bacterial plate count shall be considered satisfactory when the results of not more than two (2) of the last four (4) consecutive samples taken on separate days exceed thirty thousand (30,000) per gram. The coliform count shall be considered satisfactory when the results of not more than one (1) of four (4) consecutive samples taken upon separate days exceed ten (10) per gram.

(v) Before milk plants, including transfer stations and receiving stations regulated under this rule are constructed, reconstructed, or extensively altered, construction plans shall be submitted to the board for written approval before work is begun. *(Indiana State Board of Animal Health; HDP 86 Rule 13, Sec 2; filed Apr 26, 1979, 12:00 p.m.: 2 IR 690, eff one hundred twenty*

(120) days after filing with secretary of state; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3344; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; filed Mar 23, 2000, 4:49 p.m.: 23 IR 1914; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 333; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; readopted filed Aug 7, 2013, 8:32 a.m.: 20130904-IR-345130236RFA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-13-2) to the Indiana State Board of Animal Health (345 IAC 8-2-2) by P.L.138-1996, SECTION 76, effective July 1, 1996.

345 IAC 8-2-2.5 Milk products plants cleaning frequency

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1

Sec. 2.5. (a) As used in this section, "extended operation" means using equipment for longer than twenty-four (24) hours between cleaning.

(b) A manufacturing grade milk plant may use equipment in extended operation up to seventy-two (72) hours if the plant qualifies its processes and equipment under this section.

(c) A manufacturing grade milk plant that wants to qualify a process and the equipment used in that process for extended operation must submit a written request for approval to the state veterinarian. The request for approval must contain the following:

(1) The applicant's identity and the location of the plant.

(2) A brief description of the applicant's manufacturing process.

(3) A description of a proposed qualification plan that will demonstrate that producing products with the relevant equipment in extended operations will not create a public health hazard.

(d) The state veterinarian shall review the proposed qualification plan and may approve it if the following requirements are satisfied:

(1) The request for approval meets the requirements in subsection (c).

(2) The qualification plan contains a qualification study designed to evaluate if the extended operation in the processes studied creates a public health hazard.

The state veterinarian and the applicant may agree to changes in the proposed qualification plan. The state veterinarian may approve changes in an approved qualification plan at any time if the amended plan meets the requirements in subdivision (2).

(e) After the state veterinarian approves a qualification plan under subsection (d), the applicant may conduct the qualification studies in the plan. During the operation of a qualification study, the applicant must allow board personnel access to data collected pursuant to the qualification plan upon request.

(f) After the qualification study is completed, the applicant may submit the study data to the state veterinarian for review. The state veterinarian may approve a manufacturing grade milk plant's extended operation if the following requirements are met:

(1) The qualification study was conducted according to the approved qualification plan.

(2) Data from the qualification study establish that extended operation in the processes that were studied does not create a public health hazard.

(g) A plant that is utilizing extended operation must do the following:

(1) Make, keep, and allow board personnel access to the following records:

(A) An operational unit run time chart. The operational unit run time chart's content must be approved as part of the qualification plan.

(B) Cleaning charts.

(C) Pasteurization records.

(D) A summary that clearly shows:

(i) when an operational unit was placed in use;

(ii) when the equipment was cleaned; and

(iii) how long the equipment was in use.

(2) Provide finished product produced under the qualified process to board personnel for official testing upon request.

(h) The state veterinarian may require that a process be requalified or revoke approval for an extended operation if any of the following occur:

(1) The equipment is operated outside the parameters of the approval.
(2) A plant fails to meet the requirements in subsection (g).
(3) There are significant changes in the qualified process.
(4) The extended run creates or appears to create a hazard to the public health.

(i) The state veterinarian, in coordination with an industry representative organization, shall prepare and maintain a guidance document that contains a description of the qualification process and guidelines for qualification plans and qualification studies. *(Indiana State Board of Animal Health; 345 IAC 8-2-2.5; filed Mar 23, 2000, 4:49 p.m.: 23 IR 1917; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; readopted filed Aug 7, 2013, 8:32 a.m.: 20130904-IR-345130236RFA)*

345 IAC 8-2-3 Manufacturing grade dairy farms; construction; operation; sanitation

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1-18

Sec. 3. (a) Manufacturing grade dairy farms must meet the following requirements:

(1) All dairy cattle and goats must comply with IC 15-18-1-18 and current board laws relating to the control and eradication of tuberculosis and brucellosis.

(2) Cows, sheep, or goats that show evidence of the secretion of abnormal milk in any quarter shall be milked last or in separate equipment and the milk shall be discarded. Cows, sheep, or goats that have been treated with or that have consumed chemical, medicinal, or radioactive agents that:

(A) are capable of being secreted in the milk; and
(B) in the judgment of the state veterinarian may be deleterious to human health;

shall be milked last or with separate equipment and the milk disposed of as the state veterinarian may direct.

(b) The area where milking is conducted must meet the following requirements:

(1) The milking area shall be separate from horses, calves, bulls, or maternity pens or stalls, and feed rooms or silos. The milking area shall be of adequate size.

(2) The milking area shall be provided with the following:

(A) Natural lighting or artificial lighting, or a combination of both, to furnish at least ten (10) foot-candles of light in work areas.
(B) Ventilation.
(C) Impervious floors and floor gutters.

(3) Floors, walls, and ceilings shall be constructed of a smooth, easily cleanable material that is light-colored or painted a light color and kept clean and in good repair. The outside of any milking equipment located in the milking area shall be kept clean. Surcingles, antikickers, and milk stools shall be kept clean and stored above the floor.

(4) No swine or fowl shall be allowed in the milking area.

(c) Any person who is milking shall have clean hands and clothing. Cows' flanks, udders, and tails shall be clean at time of milking. Udders shall be washed clean, sanitized, and dried immediately prior to milking. All milk shall be strained in the milkhouse unless a straining receptacle:

(1) protected from splash;
(2) raised above the floor; and
(3) provided with a self-closing lid;

is provided. Milk being strained or carried to the milkhouse must be protected from contamination.

(d) A milkhouse of adequate size and conveniently located shall be provided for the handling, straining, and cooling of milk, and for the washing, handling, and storing of utensils and equipment. The milkhouse must meet the following requirements:

(1) A minimum of twenty (20) foot-candles of light from natural or artificial lighting, or a combination of both, shall be provided at all work areas.

(2) Ventilation shall be provided to minimize odors and condensation.

(3) Floors shall be impervious and graded to drain.

(4) Walls and ceilings shall be constructed of a smooth, easily cleanable material that is light-colored or painted a light color.

(5) Vats shall be provided for washing and rinsing of utensils and equipment. Hot water shall be available, and water must be readily accessible.

(6) The construction of the milkhouse shall be sufficiently tight to prevent the entrance of rodents and flies. Flies shall be kept out of the milkhouse. Outer doors shall be self-closing.

(7) Liquid milkhouse wastes shall be disposed of in a manner that will preclude insect breeding or contamination of surface or underground water.

(8) The milk product contact surfaces of all multi-use containers, equipment, and utensils shall be:

(A) cleaned after each usage; and

(B) sanitized before each usage.

(9) Equipment and utensils shall be stored and drained completely so as to prevent contamination.

(10) Strainer pads, sock filters, and similar single-service articles are stored in a clean, tight cabinet or container.

(11) Multi-use milk contact equipment:

(A) must be made of smooth, nonabsorbent, and nontoxic materials; and

(B) shall be so constructed and maintained so as to be easily cleaned.

Single-service articles shall not be reused.

(e) Only pesticides approved by the board are to be used in the milkhouse. Pesticides not approved for use in the milkhouse shall not be stored in the milkhouse.

(f) Medicinals, antibiotics, and approved pesticides may be kept in the milkhouse only in separate tight cabinets or containers provided exclusively for their use. Pesticides must be stored in separate cabinets from animal drugs. Animal drugs must be properly labeled, and lactating drugs must be segregated from nonlactating drugs. Drugs not approved for use in dairy animals must not be used except in compliance with state and federal law.

(g) The floors, walls, ceilings, and surfaces of all milkhouse equipment and appurtenances shall be clean. The milkhouse shall be used for milking operations only, and only those articles directly related to milkhouse activities shall be permitted in the milkhouse. Trash, animals, and fowl shall be kept out of the milkhouse.

(h) Farms with bulk milk coolers shall provide a suitable hose port opening with a tight self-closing cover. The area under the outside of the hose port shall be surfaced with a material that will prevent soiling of the milk transfer hose.

(i) Manure shall be handled in a manner that controls insect breeding. Manure piles or storage areas shall be inaccessible to cows. Cowyards, free stalls, and loafing areas shall be kept clean. Surroundings shall be neat, clean, and free of conditions that could result in rodent harborages or insect attractants and breeding areas. Dead livestock shall be properly disposed of promptly in accordance with requirements of the board.

(j) The water supply for the milkhouse and for washing and sanitizing of utensils shall be:

(1) properly located, constructed, and operated;

(2) adequate;

(3) easily accessible; and

(4) of a safe, sanitary quality.

(k) Every dairy farm shall be provided with a sanitary toilet conveniently located and accessible to those persons performing the milking operation. The toilet shall be constructed and maintained so that the waste:

(1) is inaccessible to flies; and

(2) does not pollute the surface soil or contaminate any water supply.

(l) Raw milk from manufacturing grade dairy farms shall not be stored on such dairy farms in cans for more than forty-eight (48) hours or in a farm bulk tank for more than seventy-two (72) hours. The milk must be cooled to sixty (60) degrees Fahrenheit and maintained at that temperature at the point of origin unless delivered to a milk plant, receiving station, or transfer station within two (2) hours after milking. Auxiliary can milk storage shall not be permitted on dairy farms equipped for bulk milk cooling and storage.

(m) Manufacturing grade raw milk must undergo the following tests and meet the following requirements, and official test results for bacteria and somatic cell count tests must be reported to the board within ten (10) business days of the sample being taken:

(1) In addition to drug residue screening of manufacturing grade milk delivered for processing as required under 345 IAC 8-4-1, at least four (4) times in any six (6) month period at irregular intervals, plants receiving manufacturing grade raw

milk shall test a commingled sample of each producer's milk for drug residues. Positive test results must be reported to the board immediately. The procedures and penalties in 345 IAC 8-4-1 apply when drug residues are found in a producer's milk.

(2) Bacteriological, somatic cell, and drug residue standards shall be as follows:

(A) Manufacturing grade milk shall meet the following standards:

(i) The milk will be classified as "acceptable" if a laboratory examination to determine the bacterial estimate using the standard plate count, direct microscopic count, plate loop count, or other official approved methods indicates the presence of not more than five hundred thousand (500,000) bacteria per milliliter.

(ii) The somatic cell count, using the direct microscopic somatic cell count or other official laboratory test, shall be not more than seven hundred fifty thousand (750,000) per milliliter. However, the somatic cell count for goat's milk may not be more than one million five hundred thousand (1,500,000) cells per milliliter.

(iii) The milk shall not test positive for drug residues.

(B) Milk not meeting the standards in clause (A)(i) or (A)(ii) shall be designated as undergrade.

(C) Milk that does not meet the standard in clause (A)(iii) shall not be used for human food. It may be used for animal food if it is diverted in accordance with rules of the board.

(D) After the board designates a producer's milk sample undergrade, the following shall apply:

(i) The board will notify the buyer and the buyer will notify the producer of milk designated undergrade.

(ii) Additional samples of the producer's milk shall be tested and classified by the buyer at least monthly with the buyer immediately notifying the producer of the results.

(3) Plants receiving manufacturing grade milk shall run an official approved test on a commingled sample of each producer's milk for somatic cell count and bacteria count four (4) times in any six (6) month period. Confirmatory tests using an approved method shall be performed when the test method utilized requires confirmatory tests. Whenever the somatic cell count or bacteria test indicates undergrade milk, the procedure in subdivision (4) shall be applied.

(4) The following apply when milk is determined to be undergrade because of a somatic cell count or bacteria count in excess of the limits set forth in this section:

(A) A notice shall be sent to the producer notifying him or her of the violation.

(B) Whenever two (2) of the last four (4) consecutive tests exceed the limit for somatic cells or bacteria as the case may be, a warning notice shall be sent to the producer. The notice shall remain in effect as long as two (2) of the last four (4) consecutive samples exceed the limit. A check sample shall be taken after a lapse of three (3) days and within fourteen (14) days of the warning notice. If this sample also indicates a violation, that milk shall be excluded from the market.

(C) Whenever three (3) out of the last (5) consecutive tests exceed the limit for somatic cells or bacteria as the case may be, the farm permit will be suspended until an official sample tests below the limit and the farm passes an inspection by the board.

All milk quality tests shall be made in accordance with methods described in the latest edition of Standard Methods for the Examination of Dairy Products or the Official Methods of Analyses of the Association of Analytical Chemists. Samples shall be analyzed at a laboratory approved by the state veterinarian.

(5) An examination shall be made on the first shipment of milk from producers shipping milk to a plant for the first time, or from a producer who has not shipped milk for a period of ninety (90) days. The milk shall meet all quality standards defined by this rule. Thereafter, the milk shall be tested in accordance with the procedure established for regular shippers.

(6) The milk of a producer that has been excluded due to failure to meet quality standards shall not be accepted by another plant until quality standards are met.

(n) Before milkhouses, milking barns, stables, or parlors regulated under this rule are constructed or extensively altered, construction plans shall be submitted to the board for written approval before work is begun. *(Indiana State Board of Animal Health; HDP 86 Rule 13, Sec 3; filed Apr 26, 1979, 12:00 p.m.: 2 IR 693, eff one hundred twenty (120) days after filing with secretary of state; filed Jan 29, 1986, 3:10 p.m.: 9 IR 1315; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3347; 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 335; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; filed Dec 10, 2010, 10:42 a.m.: 20110105-IR-345100123FRA, eff Jan 1, 2011 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #10-123*

was filed Dec 10, 2010.]; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-13-3) to the Indiana State Board of Animal Health (345 IAC 8-2-3) by P.L.138-1996, SECTION 76, effective July 1, 1996.

345 IAC 8-2-3.5 Milk transportation

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1

Sec. 3.5. (a) Raw milk that is picked up from a farm for delivery to a milk plant shall be collected at the farm only by a person holding a valid bulk milk hauler/sampler permit issued by the state veterinarian. Bulk milk hauler/samplers shall collect milk at dairy farms using the procedures set forth in IC 15-18-1, this rule, and the Pasteurized Milk Ordinance (PMO) incorporated by reference 345 IAC 8-3. The state veterinarian may evaluate the equipment and procedures used by a bulk milk hauler/sampler to determine compliance.

(b) Bulk milk hauler/samplers shall attend a training session approved by the state veterinarian as a condition of obtaining a bulk milk hauler/sampler permit. The state veterinarian may issue a conditional bulk milk hauler/sampler permit to an applicant that meets all of the other requirements for obtaining a permit but has not attended an approved training session. The conditional permit may be conditioned on the applicant attending the next available approved training session. The state veterinarian may require additional training to renew a license or to keep a license if a licensee violates the provisions of IC 15-18-1 or this article.

(c) Milk plants may accept raw milk from dairy farms only if it is collected by a permitted bulk milk hauler/sampler. After collection from a dairy farm, milk may be transported by a person holding a valid milk tank truck operator permit or a bulk milk hauler/sampler permit issued by the state veterinarian.

(d) Bulk shipments of milk shall be in milk tank trucks that have been inspected by board personnel and meet the standards for design, construction, maintenance, and operation of milk tank trucks in IC 15-18-1 and this article, including Appendix B of the PMO incorporated by reference in 345 IAC 8-3. Milk tank trucks that have been inspected as a part of another state's milk inspection program and hold a current valid permit from that state do not need an Indiana permit. An inspection of a milk tank truck by the dairy regulatory agency of another state may be used to issue an Indiana permit for the truck. *(Indiana State Board of Animal Health; 345 IAC 8-2-3.5; filed Sep 27, 2002, 2:40 p.m.: 26 IR 337; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; readopted filed Oct 16, 2014, 9:43 a.m.: 20141112-IR-345140300RFA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA)*

345 IAC 8-2-4 Bulk milk collection; pickup tankers; samples

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1-12

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 cleaning and sanitizing the truck and equipment regularly 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 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 (1 1/2) 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 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) 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 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:

(A) date and time of milk collection;

(B) temperature of the raw milk;

(C) volume of milk collected;

(D) grade of milk collected (Grade A or manufacturing grade);

(E) milk hauler's signature; and

(F) hauler's 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 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. The milk hauler shall collect one (1) of the following:

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

(B) A portion of the volume of milk stored in the farm bulk tank at the time of collection may be collected only if an automatic recording chart is utilized with the tank.

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 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 and silo after the milk has been thoroughly agitated and before opening the outlet valve. Samples may be collected from a properly installed and operated in-line-sampler or aseptic sampler that is approved by the board to collect representative samples. The sample shall be collected in the following manner:

(1) If a sample dipper is used, the following apply:

(A) The dipper 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.

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

(C) The sample dipper shall then be:

(i) rinsed twice in the milk in the farm bulk tank; and

(ii) drained.

(D) Samples must be taken through the port opening in the cover of the bulk tank.

(2) A sample of not less than four (4) fluid ounces in volume or other sample sizes approved by the board shall be collected and placed in a sterile container.

(3) The sample container shall be closed immediately after collection 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. A sample carrying case may only be used to store samples of producer raw milk. 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. The samples shall not be frozen.

(4) 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.

(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.

(5) 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. 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.

(6) Sampling equipment shall be rinsed in clean water immediately after each usage.

(7) 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 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 (1/2) pint capacity, which shall be cleaned and sanitized before the collection of each sample, shall be used. 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) 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.

(2) Manufacturing grade raw milk shipped in cans shall be collected at least one (1) time every forty-eight (48) hours.

(3) Grade A bulk tank raw milk shall be collected at least one (1) time every forty-eight (48) hours.

(4) Grade A milk shipped in cans shall be collected at least one (1) time every twenty-four (24) hours.

(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 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;

(2) ascertain and record the temperature of the temperature sample;

(3) see that the samples are properly identified and stored before delivery to the laboratory; 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 sixty (60) hours after the time of sample collection. Results of 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 15-18-1-12. 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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA) 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.*

345 IAC 8-2-5 Grading raw milk and cream; testing; records

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1

Sec. 5. (a) The following milk and cream that is unfit for human consumption shall not be allowed to enter into commerce and shall be destroyed:

(1) Milk is unfit for human consumption if it meets any of the following criteria:

(A) The milk contains or shows evidence of:

(i) blood;

(ii) mastitis;

(iii) ropiness;

(iv) filth;

(v) insects;

(vi) insect parts; or

(vii) visible foreign matter.

(B) The milk is adulterated as defined in this article and the Uniform Indiana Food, Drug, and Cosmetic Act.

(C) The milk contains two and fifty-hundredths (2.50) or more milligrams weight of sediment when sediment tested in accordance with subsection (f).

(2) Cream is unfit for human consumption if it meets any of the following criteria:

(A) The cream contains:

(i) filth;

(ii) insects;

(iii) insect parts; or

(iv) visible foreign matter.

(B) The cream has a definite wrinkled layer of white mold or significant patches of colored mold.

(C) The cream is in an active state of yeast fermentation, as evidenced by a pronounced gas or yeasty odor.

(D) The cream is:

(i) putrid;

(ii) rancid;

(iii) cheesy; or

(iv) otherwise similarly decomposed.

(E) The cream contains three (3) or more milligrams of sediment in a one (1) pint sample from cream that has been stirred.

(F) The cream is adulterated as defined in this article and the Uniform Indiana Food, Drug, and Cosmetic Act.

(b) Laboratories performing quality testing in accordance with Section 6 of the Grade A Pasteurized Milk Ordinance will perform those tests pursuant to the requirements of the board.

(c) Every milk plant, receiving station, or transfer station that receives raw milk or raw cream from a producer shall inspect the raw milk or raw cream to prevent the receiving entity from accepting raw milk or raw cream that is unfit for human consumption. The milk plant, receiving station, or transfer station shall inspect and test all raw milk and raw cream as provided for in this rule.

(d) Every milk plant, receiving station, or transfer station receiving milk from any producer shall cause a bacterial test to be conducted on a representative sample of each such producer's raw milk at least once each month. A milk hauler of producer's milk shall collect a mixed sample of milk for bacteriological testing from each refrigerated farm tank and transport all the samples to the milk plant, receiving station, or transfer station. The kind of bacterial test employed shall be approved by the board, and the testing procedures shall be approved by the Association of Analytical Chemists, Food and Drug Administration or the National Conference on Interstate Milk Shipments. Each milk producer shall be notified promptly of the results of tests on his or her milk on forms and in a manner approved by the board. Records of the results of the tests shall be kept on file for not less than two (2) years.

(e) Every milk plant, receiving station, and transfer station shall make visual and olfactory inspections of all milk and cream received. The inspections shall be made of all milk or cream immediately upon opening the original containers in which the milk or cream is received. All milk or cream found unfit for human consumption shall be rejected.

(f) Milk and cream shall be classified for sediment content by comparing the sediment tests with the official sediment standard found in the standard methods. Milk plants, receiving stations, and transfer stations shall reject all milk and cream that:

(1) does not meet the minimum standards; or

(2) is unfit for human consumption.

(g) Unfit milk or cream in cans shall be treated by the addition of a harmless red food coloring that has been certified by the U.S. Food and Drug Administration. Sufficient red coloring shall be added to such rejected products to produce a distinct red color in the milk or cream to prevent its being processed or manufactured for food. The milk plant, receiving station, and transfer station shall affix a tag of uniform type approved by the board to all containers of rejected milk or cream indicating on the tag the reason for the rejection. Under no circumstances shall such tags of rejected milk or cream be removed from a container holding rejected milk or cream except by the producer of the rejected milk or cream.

(h) Qualified milk plant personnel shall identify rejected milk in farm bulk tanks or in bulk milk transportation tank trucks by affixing a tag of uniform type approved by the board to the tank in which the milk is located. The reason for the rejection of the milk shall be stated on the tag. Rejected milk shall not be transported by anyone to a location for manufacture or processing into food. The rejection tag shall remain on the bulk farm tank or bulk milk transportation tank truck until the unfit product has been dumped to waste or removed for salvage for use other than for food and the vessel has been properly cleaned and sanitized.

(i) On the next shipment following a rejection of a producer's milk, a milk plant, receiving station, or transfer station shall not receive more milk (reasonable variations in milk volume being permitted) from that producer than the producer normally ships per delivery.

(j) Every milk plant, receiving station, and transfer station shall keep or cause to be kept a complete system of records, including monthly records of quality tests, all other tests, pickups, and deliveries. Records relating to milk and cream shall be kept by the:

(1) route, name, number, or other identification of the producer;

(2) date of the test;

(3) nature of the test;
(4) classification of the test;
(5) total producers tested; and
(6) number of producers of milk or cream rejected.

A summary of results of all tests made during the current month shall be mailed to the board not later than the fifteenth day of the following month on forms prescribed and furnished by the board. *(Indiana State Board of Animal Health; HDP 86 Rule 13, Sec 5; filed Apr 26, 1979, 12:00 p.m.: 2 IR 698, eff one hundred twenty (120) days after filing with secretary of state; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3352; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA) NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-13-5) to the Indiana State Board of Animal Health (345 IAC 8-2-5) by P.L.138-1996, SECTION 76, effective July 1, 1996.*

345 IAC 8-2-6 References for standard examination methods (Repealed)

Sec. 6. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

Rule 3. Standards for Milk and Milk Products and Grade A Standards

345 IAC 8-3-1 Incorporation by reference; standards

Authority: IC 15-17-3-19; IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-17-2; IC 15-18-1

Sec. 1. (a) The board incorporates by reference as a rule of the board the Grade A Pasteurized Milk Ordinance, United States Department of Health and Human Services, Public Health Service, Food and Drug Administration (2013 revision), referred to as the PMO 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. Except where specifically excluded, the board intends to incorporate all parts of the PMO to include all of the administrative procedures and the appendixes. However, the following parts of the PMO are not incorporated by reference as a rule of the board:

(1) Section 16 on penalties.
(2) Section 17 on repeal and date of effect.
(3) Appendix P.

The board intends to incorporate the footnoted language in the PMO regarding cottage cheese that will apply to any person producing Grade A cottage cheese and Grade A dry curd cottage cheese. However, a person may produce cottage cheese and dry curd cottage cheese as a manufacturing grade milk product (not Grade A) by complying with the manufacturing grade milk products requirements under this article. References in the PMO to the regulatory agency shall mean and refer to the board.

(b) The board will utilize the latest edition of the following documents when interpreting and implementing the provisions of the PMO, this article, and IC 15-18:

(1) The following National Conference on Interstate Milk Shipments model documents:
    (A) Procedures Governing the Cooperative State-Public Health Service / Food and Drug Administration Program of the National Conference on Interstate Shipments.
    (B) Methods of Making Sanitation Ratings of Milk Shippers.
    (C) Evaluation of Milk Laboratories.
(2) The following sets of documents issued by the United States Food and Drug Administration, Milk Safety Branch:
    (A) Memoranda of Interpretation (M-a series documents).
    (B) Memoranda of Milk Ordinance Equipment Compliance (M-b series documents).
    (C) Memoranda of Information (M-I series documents).

(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, 2014.

(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, 2014. Milk and milk products must conform to these standards.

(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, 2014. Cheese and cheese products must conform to these standards.

(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, 2014. Frozen desserts must conform to these standards.

(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, 2014. 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 15-18-1 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 unsanitary conditions under which the product may:

(1) become contaminated with filth; or

(2) have been made injurious to health.

(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 April 1, 2014.

(i) The board incorporates by reference into this rule the definitions set forth in IC 15-17-2 and the matters set forth in IC 15-18-1.

(j) Where the matters incorporated by reference in this section conflict with provisions of this article, IC 15-17-2, or IC 15-18-1, the express provisions of this article and the Indiana Code shall control.

(k) Incorporated documents are available for public inspection at the board. Copies of incorporated documents and interpreting and implementing documents may be obtained from the Food and Drug Administration, Milk Safety Branch website, the U.S. Government Printing Office website, or by sending a written request to 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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Dec 18, 2007, 3:45 p.m.: 20080116-IR-345070296FRA; filed Aug 11, 2008, 3:37 p.m.: 20080910-IR-345080125FRA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; filed Dec 10, 2010, 10:42 a.m.: 20110105-IR-345100123FRA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA) 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.*

345 IAC 8-3-2 Grade A milk production and storage

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1-18

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 and Packaging", 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 15-18-1-18 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; however, sheep and goat milk may be stored on a dairy farm for up to seven (7) days in accordance with the procedures in the Grade A Pasteurized Milk Ordinance; 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.

(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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA) 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.

345 IAC 8-3-3 Grade A milk transfer (Repealed)

Sec. 3. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

345 IAC 8-3-4 Milk, milk products, and condensed or dry milk products; health and sanitation standards (Repealed)

Sec. 4. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

345 IAC 8-3-5 Water reclaimed from milk, milk products, and whey (Repealed)

Sec. 5. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

345 IAC 8-3-6 Air supply equipment (Repealed)

Sec. 6. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

345 IAC 8-3-7 Culinary steam (Repealed)

Sec. 7. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

345 IAC 8-3-8 Thermometer specifications (Repealed)

Sec. 8. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

345 IAC 8-3-9 Pasteurization equipment and controls; test standards (Repealed)

Sec. 9. *(Repealed by Indiana State Board of Animal Health; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358)*

345 IAC 8-3-10 Grade A milk plants standards

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1

Sec. 10. A person operating a Grade A milk plant shall meet the following requirements:

(1) Milk that is processed must meet the chemical, bacteriological, and temperature standards in Section 7 and Table 1 of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule. Milk from manufacturing grade dairy farms may not be used.

(2) The milk plant must meet the sanitation, construction, operation, and other standards set forth in the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule, including the following:

(A) Section 6, "The Examination of Milk and Milk Products".

(B) Section 7, "Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed and Packaged Milk and Milk Products", Items 1p through 22p.

(C) The personnel health standards and procedures set forth in Sections 13 and 14.

(D) Appendix D, "Standards for Water Sources".

(E) Appendix F, "Sanitization".

(F) Appendix G, "Chemical and Bacteriological Tests".

(G) Appendix H, "Pasteurization Equipment and Procedures".

(H) Appendix I, "Pasteurization Equipment and Controls–Tests".

(I) If a plant fabricates containers, Appendix J, "Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products".

(J) Appendix N, "Drug Residue Testing and Farm Surveillance".

(K) Appendix O, "Vitamin Fortification of Fluid Milk Products".

(L) A milk plant that enters into an agreement with the board to participate in a voluntary HACCP Program under Appendix K shall comply with the requirements of the agreement and Appendix K.

(3) Milk for pasteurization, ultra-pasteurization, or aseptic processing and packaging may be obtained only from dairy farms that hold a valid Grade A dairy farm permit issued under this article or, in the case of milk from outside the state, is a source that is listed on the National Conference of Interstate Milk Shipments interstate milk shippers list as meeting standards equal to or greater than the Grade A standards in the Pasteurized Milk Ordinance incorporated 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 used in implementing the standards required in this section.

(Indiana State Board of Animal Health; 345 IAC 8-3-10; filed Sep 27, 2002, 2:40 p.m.: 26 IR 341; errata, 26 IR 793; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; filed Sep 11, 2012, 2:35 p.m.: 20121010-IR-345120107FRA) NOTE: Agency cited as 345 IAC 8-3-3, which was renumbered by the publisher as 345 IAC 8-3-10.

345 IAC 8-3-11 Labeling

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1

Sec. 11. (a) All packages and containers enclosing milk or milk products shall be labeled in accordance with the applicable requirements of the following:

(1) IC 15-18-1 and this article.

(2) The federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(3) 21 CFR, Chapter I, Subchapter B.

(b) The following shall be marked as set forth in Section 4 of the Pasteurized Milk Ordinance adopted by reference in section 1 of this rule:

(1) Bottles, containers, and packages enclosing milk or milk products.

(2) Milk tank trucks.

(3) Storage tanks.

(4) Cans of raw milk from individual dairy farms.

(c) Labels shall not contain any misleading marks, words, or endorsements. Super grade designations are misleading and are prohibited. Super grade designations are words or symbols that give the consumer the impression that such a grade is significantly safer than "Grade A". Super grade designations include, without limitation, the following terms:

(1) Grade AA Pasteurized.

(2) Selected Grade A Pasteurized.

(3) Special Grade A Pasteurized.

Descriptive labeling terms must not be used in conjunction with the Grade A designation or name of the milk or milk product and must not be false or misleading. *(Indiana State Board of Animal Health; 345 IAC 8-3-11; filed Sep 27, 2002, 2:40 p.m.: 26 IR 342; errata, 26 IR 793; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; readopted filed Oct 16, 2014, 9:43 a.m.: 20141112-IR-345140300RFA) NOTE: Agency cited as 345 IAC 8-3-4, which was renumbered by the publisher as 345 IAC 8-3-11.*

345 IAC 8-3-12 Components of Grade A dairy products

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1-24

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 15-18-1-24.

(3) The plant where the powders are blended must meet the requirements in 345 IAC 8-2-1.9 or IC 15-18-1-24.

(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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; readopted filed Oct 16, 2014, 9:43 a.m.: 20141112-IR-345140300RFA)*

Rule 4. Drug Residues and Other Adulterants

345 IAC 8-4-1 Drug residues

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-17-2-2; IC 15-18-1-31

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.

(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, confirmatory testing and testing to determine the farm of origin shall be conducted in accordance with Appendix N of the Grade A Pasteurized Milk Ordinance.

(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. 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 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.

(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.

(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. 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 15-17-2-2 and must be disposed of in a manner that:

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

(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 an approved protocol to prevent future drug residue violations; 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 fine set forth in subdivision (1) is imposed.

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

(i) complete an approved protocol to prevent future drug residue violations; 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 meeting called by the state veterinarian to discuss the violations and demonstrate that appropriate practices have been implemented to mitigate the risk of further residue violations.

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

(A) The board shall initiate action under IC 15-18 to suspend or revoke a producer's Grade A permit if the producer has a permit.

(B) The fine set forth in subdivision (1) is imposed.

(C) If a producer requests reinstatement of the producer's permit, 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 specific, practical, and reasonably likely to lessen the possibility of a drug residue violation when followed by the producer.

(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 Appendix N of the Pasteurized Milk Ordinance.

(2) All monetary penalties must be:

(A) paid by the producer; and

(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

(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 15-18-1-31.

(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) A fine is calculated as follows for a first or subsequent 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) A fine is calculated as follows for a first or subsequent 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) A fine is calculated as follows for a first or subsequent 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.

(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; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; readopted filed Oct 16, 2014, 9:43 a.m.: 20141112-IR-345140300RFA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA)

Rule 5. References

345 IAC 8-5-1 References for Article 8

Authority: IC 15-17-3-21; IC 15-18-1-14
Affected: IC 15-18-1

Sec. 1. (a) Grade A Pasteurized Milk Ordinance and Dry Milk Products and Condensed and Dry Whey supplement to the Pasteurized Milk Ordinance are available from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

(b) Standard Methods for the Examination of Dairy Products is available from:

American Public Health Association
1015-18th Street, NW

Washington, D.C. 20036
(c) Official Methods of Analysis of the Association of Official Analytical Chemists is available from:
Association of Official Analytical Chemists
P.O. Box 540
Benjamin Franklin Station
Washington, D.C. 20044
(d) Code of Federal Regulations is available from:
U.S. Government Printing Office
Superintendent of Documents
Mail Stop: SSOP
Washington, D.C. 20402-9328

(Indiana State Board of Animal Health; 345 IAC 8-5-1; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3358; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; readopted filed Aug 7, 2013, 8:32 a.m.: 20130904-IR-345130236RFA)

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