

**Proposed Rule**  
LSA Document #16-222

DIGEST

Amends [345 IAC 8-2-1.1](#) to update definitions and align certain definitions with the Grade A Pasteurized Milk Ordinance (PMO). Amends [345 IAC 8-2-1.6](#) to clarify what treatment of an animal makes milk "contaminated milk" unfit for human consumption. Amends [345 IAC 8-2-1.7](#) to clarify the pasteurization requirement for ice cream mix. Amends [345 IAC 8-2-1.9](#) to clarify that manufacturing grade milk products may be sold to final consumers, restaurants, and retail. Amends [345 IAC 8-2-2](#) to phase out the effective date for these standards in accordance with the compliance dates of 21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food. Adds [345 IAC 8-2-2.1](#) to establish the requirements in 21 CFR 117 as the required standards for manufacturing grade milk product plants. Adds [345 IAC 8-2-2.2](#) to exempt a manufacturing grade milk plant that is a qualified facility from certain requirements of 21 CFR 117. Amends [345 IAC 8-2-2.5](#) to phase out the effective date for the plant extended run standards in accordance with the compliance dates of 21 CFR 117. Amends [345 IAC 8-2-4](#) to modify the milk sample container labeling requirements and remove the collection time frame for Grade A milk shipped in cans. Amends [345 IAC 8-2-5](#) to reference the definition of "adulterated" in [IC 15-17](#) and remove sediment standards. Amends [345 IAC 8-3-1](#) to update the incorporation by reference of the Grade A PMO and other Food and Drug Administration (FDA) regulations. Amends [345 IAC 8-3-2](#) to establish a process for a farm to convert a milkhouse bulk tank into a raw milk storage vessel holding commingled milk for pasteurization. Effective 30 days after filing with the Publisher.

[IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses](#)

[345 IAC 8-2-1.1](#); [345 IAC 8-2-1.6](#); [345 IAC 8-2-1.7](#); [345 IAC 8-2-1.9](#); [345 IAC 8-2-2](#); [345 IAC 8-2-2.1](#); [345 IAC 8-2-2.2](#); [345 IAC 8-2-2.5](#); [345 IAC 8-2-4](#); [345 IAC 8-2-5](#); [345 IAC 8-3-1](#); [345 IAC 8-3-2](#)

SECTION 1. [345 IAC 8-2-1.1](#) IS AMENDED TO READ AS FOLLOWS:

**[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) "Drug" means articles intended:**

**(A) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals; or**

**(B) to affect the structure or any function of the body of animals.**

~~(13)~~ **(14)** "Dry curd cottage cheese" means the product defined in 21 CFR 133.129.

~~(14)~~ **(15)** "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)~~ **(16)** "Eggnog" or "boiled custard" means the product defined in 21 CFR 131.170.

~~(16)~~ **(17)** "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)~~ **(18)** "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)~~ **(19)** "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)~~ **(20)** "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)~~ **(21)** "Goat milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats.

~~(21)~~ **(22)** "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)~~ **(23)** "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)~~ **(24)** "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)~~ **(25)** "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 a **Grade A dairy farm permit pursuant to** the provisions of the "~~Grade A Pasteurized Milk Ordinance Current Recommendations of the United States Public Health Service~~". **set forth at [345 IAC 8-3-2](#).**

~~(25)~~ **(26)** "Health authority", "board", or "state board" means the Indiana state board of animal health or its authorized representative.

~~(26)~~ **(27)** "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)~~ **(28)** "Industry plant sampler" means an employee of a milk plant, receiving station, or transfer station that is **certified by the board and** 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)~~ **(29)** "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)~~ **(30)** "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)~~ **(31)** "Manufacturing grade producer" means a milk producer that has a permit from the board to produce and sell manufacturing grade raw milk.
- ~~(31)~~ **(32)** "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)~~ **(33)** "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)~~ **(34)** "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)~~ **(35)** "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)~~ **(36)** "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)~~ **(37)** "Producer" means milk producer **as defined in the PMO.**
- ~~(37)~~ **(38)** "Producer's marketing organization" means a milk producer organization that manages the marketing of a milk producer's raw milk.
- ~~(38)~~ **(39)** "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)~~ **(40)** "Regulatory agency" means the board.
- ~~(40)~~ **(41)** "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)~~ **(42)** "Sheep milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep.
- ~~(42)~~ **(43)** "Standard methods" means the "Standard Methods for the Examination of Dairy Products", published by the American Public Health Association.
- ~~(43)~~ **(44)** "State veterinarian" means the state veterinarian appointed under [IC 15-17-4](#) or an official designee.
- ~~(44)~~ **(45)** "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](#))*

SECTION 2. [345 IAC 8-2-1.6](#) IS AMENDED TO READ AS FOLLOWS:

**[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 **that have not been met.**

(B) ~~Medicines~~ **Drugs** 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.~~ **human consumption.**

(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](#))

SECTION 3. [345 IAC 8-2-1.7](#) IS AMENDED TO READ AS FOLLOWS:

**[345 IAC 8-2-1.7](#) Pasteurization, ultra pasteurized, and aseptic processing**

**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 **and ice cream mix** 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](#))*

SECTION 4. [345 IAC 8-2-1.9](#) IS AMENDED TO READ AS FOLLOWS:

#### **[345 IAC 8-2-1.9](#) General requirements; permits**

**Authority:** [IC 15-17-3-21](#)

**Affected:** [IC 15-18-1](#)

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~~ **and manufacturing grade milk and milk products from permitted sources may** 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](#))*

SECTION 5. [345 IAC 8-2-2](#) IS AMENDED TO READ AS FOLLOWS:

**[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) **Manufacturing grade** milk plants must meet the following **operational** 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 **and milk products** 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~~ **may not be used.**
- (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; **and**
- (3) supply sufficient hot water to conduct cleaning and sanitizing operations of the facility, equipment, and containers.**

(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 a 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.

**(w) This section applies to the following plants:**

**(1) Manufacturing grade plants that meet the definition of a "small business" set forth at 21 CFR 117.3 must comply with this section until September 17, 2017.**

**(2) Manufacturing grade plants that meet the definition of a "very small business" set forth at 21 CFR 117.3 must comply with this section until September 17, 2018, except for records to support its status as a very small business.**

*(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.*

SECTION 6. [345 IAC 8-2-2.1](#) IS ADDED TO READ AS FOLLOWS:

**[345 IAC 8-2-2.1](#) Manufacturing grade milk plant; construction; operation; sanitation**

**Authority:** [IC 15-17-3-21](#)

**Affected:** [IC 15-18-1-9](#)

**Sec. 2.1. (a) Except as provided in section 2.2 of this rule, a manufacturing grade milk plant shall meet the requirements in this section.**

(b) A manufacturing grade milk plant must follow and the board incorporates by reference the following Subparts of 21 CFR 117 as a rule of the board:

(1) Subpart A – General Provisions. However, the following provisions are not incorporated:

(A) 21 CFR 117.5(b) through 21 CFR 117.5(j).

(B) 21 CFR 117.8.

(2) Subpart B – Good Manufacturing Practices.

(3) Subpart C – Hazard Analysis and Risk Based Preventive Controls.

(4) Subpart D – Modified Requirements, except 21 CFR 117.201 is not incorporated.

(5) Subpart F – Requirements Applying to Records that must be Established and Maintained. However, the following provisions are not incorporated:

(A) 21 CFR 117.320.

(B) 21 CFR 117.325.

(6) Subpart G – Supply Chain Program.

(c) This section takes effect as follows:

(1) Manufacturing grade milk plants that meet the definition of a "small business" set forth at 21 CFR 117.3 must comply with this section on September 18, 2017.

(2) Manufacturing grade milk plants that meet the definition of a "very small business" set forth at 21 CFR 117.3 must comply with this section on September 18, 2018.

(3) All other manufacturing grade plants must comply with this section immediately upon its effective date.

(Indiana State Board of Animal Health; [345 IAC 8-2-2.1](#))

SECTION 7. [345 IAC 8-2-2.2](#) IS ADDED TO READ AS FOLLOWS:

[345 IAC 8-2-2.2](#) Modified requirements that apply to a qualified facility

Authority: [IC 15-17-3-21](#)

Affected: [IC 15-18-1-9](#)

Sec. 2.2. (a) Except as provided in subsection (h), a manufacturing grade milk plant that is a qualified facility as defined in 21 CFR 117.3 is exempt from the requirements set forth in Subpart C and Subpart G of 21 CFR 117, which are incorporated by reference as a rule of the board.

(b) In order to operate under the exemption authorized in subsection (a), a manufacturing grade milk plant must submit attestations to the state veterinarian that meet the requirements set forth at 21 CFR 117.201.

(c) A manufacturing grade milk plant must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(d) The attestations required in subsection (b) must be submitted to the state veterinarian at least every two (2) years during the period beginning on October 1 and ending on December 31. However, when the status of a manufacturing grade milk plant changes from "not a qualified facility" to "qualified facility" based on the annual determination required by subsection (c), the attestations must be submitted by July 31 of the applicable calendar year.

(e) When the status of a manufacturing grade milk plant changes from "qualified facility" to "not a qualified facility" based on the annual determination required by subsection (c), the facility must:

(1) notify the state veterinarian of the change in status by July 31 of the applicable calendar year; and

(2) comply with 21 CFR 117 Subparts C and G, which are incorporated by reference as a rule of the board, no later than December 31 of the applicable calendar year unless otherwise agreed to by the state veterinarian and the facility.

(f) A qualified facility that does not submit an attestation under subsection (b) must provide notification to consumers in accordance with 21 CFR 117.201.

**(g) A qualified facility must maintain the records relied upon to support the attestations that are required by subsection (b). The records that a qualified facility must maintain are subject to the requirements of 21 CFR 117 Subpart F, which is incorporated by reference as a rule of the board.**

**(h) The state veterinarian may withdraw the exemption granted to a qualified facility under 21 CFR 117.5, which is incorporated by reference as a rule of the board, upon the following conditions:**

- (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or**
- (2) Upon a determination that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.**

*(Indiana State Board of Animal Health; [345 IAC 8-2-2.2](#))*

SECTION 8. [345 IAC 8-2-2.5](#) IS AMENDED TO READ AS FOLLOWS:

**[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.

**(j) This section applies to the following plants:**

**(1) Manufacturing grade plants that meet the definition of a "small business" set forth at 21 CFR 117.3 must comply with this section until September 17, 2017.**

**(2) Manufacturing grade plants that meet the definition of a "very small business" set forth at 21 CFR 117.3 must comply with this section until September 17, 2018, except for records to support its status as a very small business.**

*(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](#))*

SECTION 9. [345 IAC 8-2-4](#) IS AMENDED TO READ AS FOLLOWS:

**[345 IAC 8-2-4](#) Bulk milk collection; pickup tankers; samples**

**Authority:** [IC 15-17-3-21](#); [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.

**(E) The permit number of the bulk milk hauler.**

(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) (4)~~ Grade A and manufacturing grade goat milk shall be collected at least one (1) time every seven (7) days.

~~(6) (5)~~ 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.*

SECTION 10. [345 IAC 8-2-5](#) IS AMENDED TO READ AS FOLLOWS:

#### **[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 15-17-2-2](#); [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. [IC 15-17-2-2](#).
  - (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. [IC 15-17-2-2](#).

(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, **somatic cell, and inhibitory substance** 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) (f)~~ 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) (g)~~ 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 **human** food and the vessel has been properly cleaned and sanitized.

~~(i) (h)~~ 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) (i)~~ 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.*

SECTION 11. [345 IAC 8-3-1](#) IS AMENDED TO READ AS FOLLOWS:

**[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~~ (2015 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 appendices. 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~~. **2016**.

(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~~. **2016**. 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~~. **2016**. 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~~. **2016**. 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~~. **2016**. 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~~. **2016**.

(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.*

SECTION 12. [345 IAC 8-3-2](#) IS AMENDED TO READ AS FOLLOWS:

### **[345 IAC 8-3-2](#) Grade A milk production and storage**

**Authority:** [IC 15-17-3-21](#); [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.

**(8) A farm's milkhouse bulk tank may only be used for collection and storage of raw milk for pasteurization. A farm's milkhouse bulk tank may be converted to a raw milk storage vessel holding commingled raw milk for pasteurization as follows:**

- (A) Once the final milking has been completed and before processing, a bulk tank sample of the farm's milk supply must be collected by a permitted hauler/sampler for quality and drug residue testing.**
- (B) The collected sample must be tested and meet the Grade A quality and drug residue standards.**
- (C) Raw milk from other bulk tank units (BTU) may only be commingled after milk quality and drug residue samples have been collected and the milk from each BTU meets Grade A standards.**
- (D) Before untested milk may be added to the milkhouse bulk tank, the bulk tank must be emptied, cleaned, and sanitized in accordance with the PMO. Untested milk shall not be added or commingled with tested milk in the farm milkhouse bulk tank.**

**(9) A farm producing raw milk for pasteurization must protect the milk in the bulk tank from cross contamination when that milk is being used for purposes in addition to sales as Grade A milk. When milk is being removed from the bulk tank, it shall be removed in the following order:**

- (A) Grade A milk for pasteurization.**
- (B) Milk for manufacturing.**
- (C) Milk for animal feed.**
- (D) Milk for personal consumption.**

Once all of the milk has been removed, the bulk tank shall be cleaned and sanitized prior to the next milking.

*(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.*

## [Notice of Public Hearing](#)

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