
TITLE 345 INDIANA STATE BOARD OF ANIMAL HEALTH

Final Rule

LSA Document #10-123(F)

DIGEST

Amends [345 IAC 8-2-1.1](#), [345 IAC 8-2-1.5](#), and [345 IAC 8-2-1.7](#) and adds [345 IAC 8-2-1.8](#) concerning milk and milk products. Amends [345 IAC 8-2-3](#) to change the bacteria count standard for manufacturing grade raw milk from 1,000,000 bacteria per milliliter to 500,000 per milliliter and to change the somatic cell count standard for manufacturing grade raw milk from 1,000,000 per milliliter to 750,000 per milliliter for all milk other than goat milk, which will be changed to 1,500,000. Amends [345 IAC 8-3-1](#) to update matters incorporated by reference. Partially effective 30 days after filing with the Publisher and partially effective January 1, 2011. *NOTE: [IC 4-22-2-36](#) suspends the effectiveness of a rule document for 30 days after filing with the Publisher. This document was filed December 10, 2010.*

[345 IAC 8-2-1.1](#); [345 IAC 8-2-1.5](#); [345 IAC 8-2-1.7](#); [345 IAC 8-2-1.8](#); [345 IAC 8-2-3](#); [345 IAC 8-3-1](#)

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

[345 IAC 8-2-1.1](#) Definitions**Authority:** [IC 15-17-3-21](#); [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) "Approved grader of raw milk or raw cream" or "approved grader" has the meaning set forth in [IC 15-2.1-2-3-6](#).~~

(2) **(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.

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

- (A) bacterial plate counts;
- (B) direct microscopic counts; and
- (C) plate loop counts;

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

~~(4)~~ **(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.

~~(5)~~ **(4)** "Buttermilk" means a fluid product resulting from the manufacture of butter from milk or cream. Buttermilk contains not less than eight and one-fourth percent (8 1/4%) of milk solids not fat.

~~(6)~~ **(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.

~~(7)~~ **(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\(e\)](#).

~~(8)~~ **(7)** "Clean" means product and contaminants have been thoroughly and effectively removed from direct 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;

~~which,~~ **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;

~~which,~~ **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) "Egg nog" 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.

(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;
- (G) prepared; or
- (H) stored;

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:

- (A) for use in Grade A pasteurized milk products; and
- (B) under the provisions of the "Grade A Pasteurized Milk Ordinance-Current Recommendations of the United States Public Health Service".

(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.

~~(27)~~ **(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;
- (F) prepared; or
- (G) stored;

for distribution.

~~(28) "Industry plant sampler" means an employee of a milk plant, receiving station, or transfer station that is responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station, or transfer station as outlined in the PMO, Appendix N.~~

(29) "Manufacturing grade milk products" means dairy products not considered Grade A **milk and milk products** under this rule, ~~including~~ **such as** the following:

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

(30) "Manufacturing grade producer" means a milk producer that is producing and selling manufacturing grade raw milk.

(31) "Manufacturing grade raw milk" means raw milk produced on a dairy farm that does not have a currently valid permit issued by the board to sell Grade A raw milk for pasteurization.

(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](#))

SECTION 2. [345 IAC 8-2-1.5](#) IS AMENDED TO READ AS FOLLOWS:

[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) Cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, and whipped light cream.
- (2) Sour cream, acidified sour cream, and cultured cream.
- (3) Half and half, sour half and half, acidified sour half and half, and cultured sour half and half.
- (4) Reconstituted or recombined milk and milk products.
- (5) Concentrated (condensed) (1) All milk and concentrated (condensed) milk products with a standard of identity provided for in 21 CFR Part 131, excluding 21 CFR Part 131.120 sweetened condensed milk.
- (6) Nonfat (skim) milk and reduced fat or low fat milk.
- (7) Frozen milk concentrate.
- (8) Eggnog.

- ~~(9) Buttermilk and buttermilk products.~~
- ~~(10) Whey and whey products.~~
- ~~(11) Cultured milk, cultured reduced fat or low fat milk, and cultured nonfat (skim) milk.~~
- ~~(12) Yogurt, low fat yogurt, and nonfat yogurt.~~
- ~~(13) Acidified milk, acidified reduced fat or low fat milk, and acidified nonfat (skim) milk.~~
- ~~(14) Low sodium milk, low sodium reduced fat or low fat milk, and low sodium nonfat (skim) milk.~~
- ~~(15) Lactose reduced milk, lactose reduced reduced fat or low fat milk, and lactose reduced nonfat (skim) milk.~~
- ~~(16) Aseptically processed and packaged milk and milk products.~~
- ~~(17) Milk.~~
- ~~(18) Milk, reduced fat milk, low fat milk, and nonfat (skim) milk that have added microbial organisms.~~
- ~~(19) Any other milk product made by the addition or subtraction of milk fat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification of milk products defined herein.~~
- ~~(20) Dairy foods made by modifying the federally standardized product listed in this section in accordance with 21 CFR 130.10.~~
- ~~(21) Milk and milk products that have been retort processed after packaging or that have been concentrated, condensed, or dried if they are used as an ingredient to produce any milk or milk product defined in this section or are labeled as Grade A.~~
- ~~(22) Manufacturing grade milk products unless the context indicates Grade A milk products.~~
- ~~(23) Dry milk products.~~
- (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](#))

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

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

Authority: [IC 15-17-3-21](#); [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 ~~properly~~ **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 following tables in subsection (b) and held continuously at or above that temperature for at least the time that corresponds with the temperature in the following 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 more, however, 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

~~(b)~~ **(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.

~~(e)~~ **(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.

~~(d)~~ **(e)** As used in this article, "aseptic processing" means the filling of a commercially sterilized cooled product into presterilized containers, followed by hermetical sealing with a presterilized closure, in an atmosphere free of microorganisms. Aseptic processing shall be performed in accordance with the requirements of 21 CFR 113 and ~~the applicable provisions of Section 7, Items 16p and 16p(C) and Appendix H in the Pasteurized Milk Ordinance incorporated by reference in~~ [345 IAC 8-3](#) to maintain commercial sterility of the product under normal **nonrefrigerated** 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](#))

SECTION 4. [345 IAC 8-2-1.8](#) IS ADDED TO READ AS FOLLOWS:

[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](#))

SECTION 5. [345 IAC 8-2-3](#) IS AMENDED TO READ AS FOLLOWS:

[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 ~~which~~ **that**:

(A) are capable of being secreted in the milk; and ~~which~~,

(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) A separate milking area of adequate size shall be provided.

(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 milkhous 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 milkhous must be protected from contamination.

(d) A milkhous 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 milkhous 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 ~~shall be~~

(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 dairy farms that do not have a valid permit from the board to sell Grade A raw milk for pasteurization 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, a commingled sample of each producer's milk shall be tested for drug residues. ~~When a producer's milk shows a Positive test he or she shall be excluded from all markets immediately and shall not be reinstated until a subsequent test of the producer's milk is negative for drug residues.~~ **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 classification shall be "acceptable".**

~~(ii) the bacteria count using the standard plate count, direct microscopic count, or plate loop count, or other official approved methods shall be indicates the presence of not more than one million (1,000,000) five hundred thousand (500,000) bacteria per milliliter.~~

~~(iii) (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 (1,000,000) five hundred thousand (1,500,000) cells per milliliter.~~

~~(iv) (iii) The milk shall not contain drug residues.~~

(B) Milk not meeting the standards in clause (A) shall be designated as undergrade. ~~Undergrade milk may not be sold for human consumption or processing into products for human consumption.~~

~~(C) After the board designates a producer's milk sample is designated undergrade, the following shall apply:~~

~~(i) The board will notify the buyer and the buyer will notify the producer of milk designated undergrade. shall be notified immediately by the buyer.~~

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

~~(iii) A buyer may continue to accept milk from a producer whose milk has been designated undergrade as long as the testing requirements set forth in this clause are complied with, and all undergrade milk is excluded from market.~~

(3) Plants receiving manufacturing grade milk shall run a ~~direct microscopic somatic cell count, or other an official approved test for the detection of abnormal milk~~ **somatic cell count and bacteria count** four (4) times in any six (6) month period. Confirmatory tests by means of the ~~direct microscopic cell count or the electronic~~ **using an approved method** shall be performed as necessary. ~~Warning letters of excessive somatic cell counts shall be sent to a producer when a test shows somatic cell counts in excess of the legal limit.~~

~~(4) After running a screening test outlined in subdivision (3), a method utilized requires confirmatory test must be conducted on any sample with a count exceeding one million (1,000,000) per milliliter. tests.~~

~~Whenever the somatic cell count or bacteria test indicates the presence of more than one million (1,000,000) per milliliter, undergrade milk, the following 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 ~~excessive somatic cell count.~~ **violation.**

(B) Whenever two (2) of the last four (4) consecutive ~~somatic cell counts~~ **tests** exceed ~~one million (1,000,000) per milliliter, 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 ~~one million (1,000,000) per milliliter. In addition to the written notice, an inspection shall be made of the farm facility by a representative of the buyer. the limit.~~ A check sample shall be taken after a lapse of three (3) days and within fourteen (14) days of the ~~inspection.~~ **warning notice.** If this sample also indicates a ~~high somatic cell count,~~ **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". 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 ~~which~~ **that** has been excluded due to failure to meet quality standards shall not be

accepted by another plant until quality standards are met. ~~The buyer of raw milk shall report to the board, by telephone, the producer(s) excluded or reinstated.~~

(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.]) 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.

SECTION 6. [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, ~~Publication No. 229 (2007~~ **(2009** revision), referred to as the PMO ~~including all footnoted language regarding cottage cheese and the appendixes, is hereby incorporated by reference as a rule of the board for~~ regulation of the production, transportation, processing, handling, sampling, examination, grading, labeling, and sale of all Grade A milk and milk products in the state. ~~provided,~~ **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 K.
- (4) 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.

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

(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, ~~2007.~~ **2009.**

(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, ~~2007.~~ **2009.** 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, ~~2007.~~ **2009.** 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, 2007: **2009**. 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, 2007: **2009**. 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 June 1, 2007: **2009**.

(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.

(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](#)) 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 7. SECTION 5 of this document takes effect January 1, 2011. NOTE: [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 December 10, 2010.

LSA Document #10-123(F)

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Documents Incorporated by Reference: Grade A Pasteurized Milk Ordinance, 2009 revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration; 21 CFR

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