TITLE 345 INDIANA STATE BOARD OF ANIMAL HEALTH

Proposed Rule
LSA Document #17-566

DIGEST

Amends 345 IAC 8-2-2.1 to remove the effective date schedule for manufacturing grade milk plant construction, operation, and sanitation standards and clarify that milk received by a manufacturing grade milk plant must be from a permitted source. Amends 345 IAC 8-3-1 to update the incorporation by reference of the Food and Drug Administration (FDA) Grade A Pasteurized Milk Ordinance (PMO) and other FDA food safety regulations. Amends 345 IAC 8-4-1 to align records retention standards with the PMO and clarify the actions that must be taken by the state veterinarian when milk is found to test as a confirmed positive for drug residues. Repeals 345 IAC 8-2-2 and 345 IAC 8-2-2.5. Effective September 17, 2018.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

345 IAC 8-2-2; 345 IAC 8-2-2.1; 345 IAC 8-2-2.5; 345 IAC 8-3-1; 345 IAC 8-4-1

SECTION 1. 345 IAC 8-2-2.1 IS AMENDED 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.~~

(c) Milk received for pasteurization, processing, or packaging by a manufacturing grade milk plant must be obtained from one (1) of the following sources:
(1) A dairy farm within the state that holds a valid Grade A or manufacturing grade permit issued under this article.
(2) A dairy farm outside the state that holds a valid Grade A or manufacturing grade permit in the state of origin.
(3) Any other source of milk that has been approved by the state veterinarian based upon a finding that the source meets the standards of this article.

(Indiana State Board of Animal Health; 345 IAC 8-2-2.1; filed Dec 7, 2016, 9:26 a.m.:

20170104-IR-345160222FRA)

SECTION 2. 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 ~~(2015~~ **(2017** revision), referred to as the PMO for regulation of the production, transportation, processing, handling, sampling, examination, grading, labeling, and sale of all Grade A milk and milk products in the state. Except where specifically excluded, the board intends to incorporate all parts of the PMO to include all of the administrative procedures and the appendixes. However, the following parts of the PMO are not incorporated by reference as a rule of the board:

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

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

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

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

(c) The board adopts by reference the general provisions relating to food standards set forth by the United States Food and Drug Administration in 21 CFR 130.8, 21 CFR 130.9, 21 CFR 130.10, and 21 CFR 130.11, in effect on April 1, ~~2016.~~ **2017.**

(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, ~~2016.~~ **2017.** 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, ~~2016.~~ **2017.** 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, ~~2016.~~ **2017.** 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, ~~2016.~~ **2017.** 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, ~~2016.~~ **2017.**

(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; filed Dec 7, 2016, 9:26 a.m.: 20170104-IR-345160222FRA) 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 3. 345 IAC 8-4-1 IS AMENDED TO READ AS FOLLOWS:

345 IAC 8-4-1 Drug residues

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

Sec. 1. (a) Milk shall be screened for the presence of drug residues as follows:

(1) Any milk plant that accepts raw milk shall test each bulk milk pickup tanker for beta lactam drug residues. Each bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling of milk using a representative sample from the truck. Samples shall be tested as follows:

(A) Using a test that has been approved by the United States Food and Drug Administration for screening milk for drug residues.

(B) In a laboratory that is certified by the state veterinarian by an analyst that is certified by the state veterinarian.

When a drug residue test is positive, confirmatory testing and testing to determine the farm of origin shall be conducted in accordance with Appendix N of the Grade A Pasteurized Milk Ordinance.

(2) The state veterinarian may implement a testing program to test milk from bulk milk pickup tankers for other drug residues.

(3) The state veterinarian may implement a testing program to test milk from any source for drug residues. The testing programs may include samples from farm bulk tanks, milk plants, or finished products as part of a monthly quality program or other surveillance program. Samples that test positive for drug residues are subject to the provisions of this section.

(4) Milk plants shall keep records of all drug residue tests that are conducted on bulk milk pickup tankers and farm bulk milk tanks and must include the information indicated in Appendix N of the PMO incorporated by reference in 345 IAC 8-3-1. The records shall be kept for not less than ~~six (6) months.~~ **two (2) years.**

(b) All tests completed under this section must meet the following requirements:

(1) The test must be a test approved by the United States Food and Drug Administration for screening milk samples for drug residues.

(2) The test must be conducted as follows:

(A) By an analyst approved by the state veterinarian under the standards in Appendix N of the PMO incorporated by reference in 345 IAC 8-3-1.

(B) In a laboratory approved by the state veterinarian under the standards in Appendix N of the PMO incorporated by reference in 345 IAC 8-3-1.

(3) A test that is being run to confirm a positive drug residue test result must be the same test that was used to obtain the initial positive drug residue result. A person may use a different confirmatory test, however, if the state veterinarian approves the use of that confirmatory test. The state veterinarian may approve the use of a confirmatory test that is different from a prior test after:

(A) evaluating the circumstances surrounding the request; and

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

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

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

(1) The milk that tests positive for drug residues is adulterated under IC 15-17-2-2 and must be disposed of in a manner that:

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

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

(2) The state veterinarian shall determine the origin of the contaminated milk. Milk from the farm of origin creates an imminent hazard to the public health. The state veterinarian shall:

(A) suspend the Grade A farm permit or manufacturing grade farm permit; ~~as the case may be, and no milk may be removed from~~ **or**

(B) take other equally effective measures to prevent the ~~farm until the permit is reinstated.~~ **sale of milk containing drug residues.**

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

(A) reinstate the farm permit; **or**

(B) take other action to allow the sale of milk for human food.

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

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

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

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

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

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

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

(i) complete an approved protocol to prevent future drug residue violations; and

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

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

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

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

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

(i) complete an approved protocol to prevent future drug residue violations; and

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

Failure to complete the protocol and provide proof of completion will result in action to suspend the

producer's permit.

(C) The producer must attend a meeting called by the state veterinarian to discuss the violations and demonstrate that appropriate practices have been implemented to mitigate the risk of further residue violations.

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

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

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

(C) If a producer requests reinstatement of the producer's permit, the producer must submit to the state veterinarian a set of written procedures that he or she will follow to prevent future drug residue violations. The procedures must be specific, practical, and reasonably likely to lessen the possibility of a drug residue violation when followed by the producer.

(g) The following definitions apply throughout this section:

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

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

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

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

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

(2) All monetary penalties must be:

(A) paid by the producer; and

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

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

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

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

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

(5) No penalty may exceed one thousand dollars ($1,000) for a first offense or two thousand dollars ($2,000) for a subsequent offense. Civil penalties collected under this section must be deposited in the dairy drug residue abatement fund established under IC 15-18-1-31.

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

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

(1) A fine is calculated as follows for a first or subsequent offense:

(A) Total positive truck load CWT: 500

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

(C) Producer's daily production CWT: 50

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

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

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

(2) A fine is calculated as follows for a first or subsequent offense:
(A) Total positive truck load CWT: 500
(B) Positive producer's CWT on positive tanker (two (2) days' production): 400
(C) Producer's daily production CWT: 200
(D) Co-op requires producer to pay for other producers' milk that is contaminated at fifteen dollars ($15) per CWT.

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

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

(3) A fine is calculated as follows for a first or subsequent offense:
(A) Positive bulk tank on monthly quality check or otherwise.
(B) Producer's daily production (CWT): 50

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

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

(Indiana State Board of Animal Health; 345 IAC 8-4-1; filed Apr 17, 1998, 9:00 a.m.: 21 IR 3355; errata filed Aug 13, 1998, 1:16 p.m.: 22 IR 126; readopted filed May 2, 2001, 1:45 p.m.: 24 IR 2895; filed Sep 27, 2002, 2:40 p.m.: 26 IR 342; filed Jul 18, 2005, 1:00 p.m.: 28 IR 3566; readopted filed May 9, 2007, 3:16 p.m.: 20070516-IR-345070037RFA; errata filed Oct 3, 2008, 3:30 p.m.: 20081022-IR-345080767ACA; readopted filed Oct 16, 2014, 9:43 a.m.: 20141112-IR-345140300RFA; filed Dec 4, 2014, 1:59 p.m.: 20141224-IR-345140199FRA)

SECTION 4. THE FOLLOWING ARE REPEALED: 345 IAC 8-2-2; 345 IAC 8-2-2.5.

SECTION 5. SECTIONS 1 through 4 of this document take effect September 17, 2018.

Notice of Public Hearing

Posted: 03/07/2018 by Legislative Services Agency
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