

901:11-1-01 **Definitions.**

As used in ~~Chapters~~divisions 901:3 and 901:11 of the Administrative Code and the materials incorporated under rule 901:11-1-02 of the Administrative Code:

- (A) "Director" means the director of agriculture or an official, employee, or contractor of the department of agriculture designated by the director of agriculture.
- (B) "Drug" means:
- (1) Articles recognized in the official "United States Pharmacopoeia;" "Official Homeopathic Pharmacopoeia of the United States;" or "Official National Formulary;" or any supplement to any of them;
 - (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
 - (3) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and,
 - (4) Articles intended for use as a component of any articles specified in paragraph (B)(1), (B)(2), or (B)(3) of this rule, but does not include devices or ~~their~~the components, parts, or accessories.
- (C) "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms, thereby maintaining the commercial sterility of ~~its~~the container's contents after processing.
- (D) "Other hooved mammals" means the species of animals as described in section 1, paragraph ~~UX~~X of the PMO.
- (E) "PMO" means the ~~2015~~2019 revision of the "Grade "A" Pasteurized Milk Ordinance" and its appendices, United States department of health and human services, public health service/food and drug administration. A copy of which can be found on the Ohio department of agriculture website www.agri.ohio.gov.
- (F) "Sterilized" when used in reference to piping, equipment, and containers used for milk and milk products, means rendering the piping, equipment, and containers free of viable microorganisms by application of heat, a chemical sterilant or other appropriate treatments.

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Materials incorporated by reference.

(A) Sections 1 to 14 and appendices B to ~~ST~~ of the PMO, except as deleted or amended in this chapter, are adopted as rules of the department of agriculture, state of Ohio, and incorporated into this chapter by reference.

(B) Whenever used in the materials incorporated into this chapter under paragraph (A) of this rule:

- (1) "Appendix B" shall be read as "rules 901:11-4-01 to 901:11-4-13 of the Administrative Code";
- (2) Ellipsis shall refer to the "State of Ohio";
- (3) "Ordinance" shall be read as "rule";
- (4) "Regulatory agency" shall be read as "department of agriculture, State of Ohio";
- (5) "Section 3" shall be read as "rule 901:11-1-04 of the Administrative Code"; and,
- (6) "Permit" or "permits", when used as a noun, shall be read as "license" or "licenses".

(C) Imbedded references in PMO.

- (1) The following federal government publications can be found either at www.fda.gov or www.aphis.usda.gov:
 - (a) Bacteriological analytical manual (BAM), 8th edition, revision A, 1998, online edition, department of health and human services, U.S. food and drug administration, center for food safety and applied nutrition;
 - (b) Evaluation of milk laboratories (EML) ~~2015~~2019 revision, U.S. department of health and human services, public health services, food and drug administration;
 - (c) Methods of making sanitation ratings of milk supplies (MMSR) ~~2015~~2019 revision, U.S. department of health and human services, public health services, food and drug administration;
 - (d) Procedures governing the cooperative state-public health service/food and drug administration program of the national conference on interstate milk shipments (Procedures) 2019 revision, U.S. department of health and human services, public health services, food and drug administration

- (~~d~~)(e) Bovine tuberculosis eradication, uniform methods and rules, effective January 1, 2005 U.S. department of agriculture, animal and plant health inspection services, APHIS 91-45-011;
- (~~e~~)(f) Brucellosis eradication: Uniform methods and rules, effective October 1, 2003, U.S. department of agriculture, animal and plant health inspection service, APHIS 91-45-013;
- (~~f~~)(g) M-a-85, revision number ~~14~~16, beta lactam test methods for use under Appendix N and section 6 of the PMO, ~~March 22, 2012~~December 20, 2018, U.S. department of health and human services, public health services, food and drug administration, center for food safety and applied nutrition;
- (~~g~~)(h) M-a-98, revision number one official grade "A" pasteurized milk ordinance regulatory laboratory tests for grade "A" milk and milk products and grade "A" dairy farm and milk plant water, ~~March 1, 2013~~April 14, 2020, U.S. department of health and human services, public health services, food and drug administration, center for food safety and applied nutrition;
- (~~h~~)(i) M-I-92-11, chloramphenicol screening test methods, November 20, 1992, U.S. department of health and human services, public health services, food and drug administration, center for food safety and applied nutrition;
- (~~i~~)(j) M-I-96-10, revision number ~~8~~10, drug residue test methods for confirmation of presumptive positive results and initial producer traceback, ~~March 22, 2012~~December 20, 2018, U.S. department of health and human services, public health services, food and drug administration, center for food and safety and applied nutrition; and,
- (~~j~~)(k) M-I-06-5, current information addressing item 15r - drug chemical control of the grade "A" PMO, April 19, 2006, U.S. department of health and human services, public health services, food and drug administration, center for food safety and applied nutrition.

(2) Private and professional standards:

- (a) Standard methods for the examination of dairy products (SMEDP), 17th edition 2004, edited by H. Michael Wehr, PhD and Joseph F. Frank, PhD, American public health association, 800 I Street, NW, Washington, DC 2001. For more information please visit www.apha.org; and,

- (b) Official methods of analysis of the AOAC international (OMA) ~~18th~~21st edition, Dr. ~~William Horwitz~~George W. Latimer, Jr., editor, published by AOAC International, ~~481 North Frederick Ave., Suite 500, Gaithersburg, Maryland 20877-2417~~2275 Research Boulevard, Suite 300, Rockville, Maryland 20850 USA. For more information please visit www.eoma.aoac.org.

(3) Federal regulations:

- (a) Title 21 (~~CFR~~C.F.R.) revised April 1, ~~2013~~2019, published by the national archives and records administration, office of the federal register and the government printing office; and,
- (b) 21 United States Code, Chapter 9, Federal Food Drug and Cosmetic Act (FFD&CA)(2006).

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Materials deleted from the PMO.

(A) The following components of the PMO are deleted:

- (1) In Section 1. Definitions, paragraph ~~FFYY~~, "Regulatory Agency;" is deleted in its entirety;
- (2) In Section 2. "Adulterated or Misbranded Milk or Milk Products," "Administrative Procedures" and its following "Note" is deleted in its entirety~~except for the paragraph titled "Recall Plan" and its following "Note";~~
- (3) Section 3. "Permits;" is deleted in its entirety.
- (4) In Section 5. "Inspection of Dairy Farms and Milk Plants;" "Certified Industry Inspection" is deleted in its entirety;
- (5) In Section 7. "Standards for Grade "A" Milk and/or Milk Products;" the ~~paragraph~~paragraphs titled "Public Health Reasons" contained in items 1r. to 19r. and items 1p. to 22p. are deleted in their entirety;
- (6) In Section 8. "Animal Health;" "Public Health Reason" is deleted in its entirety;
- (7) Appendix B, "Milk Sampling, Hauling and Transportation," is deleted in its entirety except the following sections:
 - (a) Section II, "Requirements for Using an Aseptic Approved In-Line Sampler";
 - (b) Section III, "Requirements for Using an Approved Aseptic Sampler for Milk Tank Trucks";
 - (c) Section IV, "Requirements for Using an Approved Aseptic Sampler for Farm Bulk Milk Tanks and/or Silos"; and,
 - (d) Section V, "Requirements for Using an Approved On-Tanker Farm Bulk Milk Tank Aseptic Sampler for Multiple and/or Single Farm Pickups"; and,
 - (e) Section VI, "Requirements for Sanitizing Sampling Cocks and In-Line Sample Points"; and,
 - ~~(d)~~(f) Section ~~V~~VII, "Requirements for the Sampling of Raw Sheep Milk that has been frozen prior to being tested for Appendix N Drug ~~Residue~~Residues."

(8) In Appendix N. "Drug Residue Testing and Farm Surveillance;" "Enforcement: Penalties for Confirmed Positive Milk" is deleted in its entirety.

(9) The words "(Refer to Appendix A.)" are deleted in their entirety.

(B) The following appendices of the PMO are deleted in their entirety:

(1) Appendix E; and

(2) Appendix P.

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901:11-1-04 **License; registration; license or registration fees; milk inspection fees.**

- (A) No person located in Ohio shall act as or hold the person's self out as a producer; processor; milk dealer; or raw milk retailer; unless the person holds a valid license or registration issued by the director under section 917.09 of the Revised Code and this rule.
- (B) A person whose religion prohibits the person from obtaining a license under this rule, in place of a license, shall register with the director as a producer; processor; milk dealer; raw milk retailer; milk hauler; or weigher, sampler, or tester. The registrant shall submit a religious exemption certificate with the application for each desired registration type. A registrant is subject to all provisions governing licensees such as provisions concerning testing, sampling and inspection of dairy products. A registrant is subject to provisions governing issuance of a temporary weigher, sampler, or tester license. A registration shall be suspended, revoked and canceled under the same terms as a license.
- (C) The director shall issue a license or registration for each application upon a determination that the applicant is in compliance with sections 917.01 to 917.23 of the Revised Code and rules adopted thereunder of the Administrative Code.
- (D) The director has determined the following categories for each license or registration type to be as follows:
- (1) Producer
- (a) Grade A bulk milk producer (milking cows)
 - (b) Grade A can milk producer (milking cows)
 - (c) Grade A bulk milk producer (milking goats)
 - (d) Grade A can milk producer (milking goats)
 - (e) Grade A bulk milk producer (milking sheep)
 - (f) Grade A can milk producer (milking sheep)
 - (g) Manufacture bulk milk producer (milking cows)
 - (h) Manufacture can milk producer (milking cows)
 - (i) Manufacture bulk milk producer (milking goats)

- (j) Manufacture can milk producer (milking goats)
- (k) Manufacture bulk milk producer (milking sheep)
- (l) Manufacture can milk producer (milking sheep)
- (m) Grade A bulk milk producer (other hooved animals)
- (n) Grade A can milk producer (other hooved animals)
- (o) Manufacture bulk milk producer (other hooved animals)
- (p) Manufacture can milk producer (other hooved animals)

(2) Processor

- (a) Grade A fluid milk processor
- (b) Grade A cultured milk processor
- (c) Grade A milk receiving station
- (d) Grade A milk transfer station
- (e) Grade A condensed milk products processor
- (f) Grade A dry milk products processor
- (g) Manufacture milk receiving station
- (h) Manufacture milk transfer station
- (i) Butter manufacturer
- (j) Frozen desserts manufacturer
- (k) Natural cheese manufacturer
- (l) Processed cheese manufacturer
- (m) Cottage cheese manufacturer
- (n) Condensed milk products manufacturer
- (o) Dry milk products manufacturer

- (p) Dairy product blender
 - (q) ~~Nonstandardized~~Non-standardized dairy product manufacturer
 - (r) Milk transport cleaning facility
- (3) Milk dealer
- (4) Raw milk retailer
- (E) An application shall be submitted for each license type as follows: milk producer; milk processor; milk dealer; and raw milk retailer. A license fee of fifteen dollars shall accompany each license or registration application. After the initial issuance of a license or registration, an application and license fee as set forth in this paragraph shall be submitted when an additional category within the license type is desired. A license or registration shall remain valid unless suspended, revoked or canceled.
- (F) An application for a milk dealer license or registration shall be accompanied by evidence of financial responsibility. Upon filing thereof and payment of the prescribed license fee, the director shall issue to the applicant a license or registration.
- (G) Licenses or registrations are not transferable with respect to persons or locations.
- (H) Licenses or registrations may be canceled by the director if the licensee or registrant:
- (1) Makes such a request of the director;
 - (2) Transfers the licensed or registered activity to another location;
 - (3) Transfers the licensed or registered activity to another person;
 - (4) Does not perform the licensed category activity or registered category activity for six months; or,
 - (5) Expired.
- Cancellation of license, registration or category thereunder shall be at no cost to the licensee or registrant.
- (I) Milk producers, and milk processors located in Ohio shall pay the milk inspection fees prescribed by the milk sanitation board in accordance with section 917.031 of the Revised Code, in addition to the license or registration fee prescribed by section 917.09 of the Revised Code and this rule. Inspection fees shall be paid to the treasurer, state of Ohio, within fifteen days after the receipt of the invoice. Failure to pay inspection fees shall be cause for license or registration revocation.

- (J) Any license or registration issued under this rule may be denied, suspended, or revoked by the director for violation of sections 917.01 to 917.23 of the Revised Code or rules adopted thereunder of the Administrative Code. Except as provided by section 917.22 of the Revised Code and by this rule, the denial, suspension, or revocation of a license or registration is not effective until notice in writing of the violation has been delivered to the licensee or registrant and a reasonable opportunity for the correction of the violation has been given and a hearing afforded before the director. Upon determination by the director that a dairy product exceeds bacterial or chemical standards established by Chapter 917. of the Revised Code or rules of the Administrative Code adopted thereunder, that a dairy product is adulterated as described in section 3715.59 of the Revised Code, or that an emergency exists that presents a clear and present danger to the public health, the director, in addition to taking any other appropriate legal actions, may order a denial, suspension, or revocation of any license or registration, effective immediately without a hearing, provided that thereafter an opportunity for a hearing shall be afforded without delay.
- (K) All proceedings under sections 917.01 to 917.23 of the Revised Code and this chapter are subject to Chapter 119. and section 917.22 of the Revised Code.
- (L) When the director determines that a grade A milk producer sold or offered for sale raw milk containing drug residues in excess of levels specified, the grade A milk producer license shall be:
- (1) Immediately suspended for a minimum of two days on the first occurrence in a ~~twelve-month~~twelve-month period;
 - (2) Immediately suspended for a minimum of four days on the second occurrence in a ~~twelve-month~~twelve-month period; and,
 - (3) Immediately suspended for a minimum of four days on the third and subsequent occurrences in a ~~twelve-month~~twelve-month period, and the director shall initiate administrative procedures to revoke the grade A milk producer license.
 - (4) Whenever a grade A milk producer license is suspended or revoked for drug residues found in raw milk, in no event shall that grade A milk producer license be reinstated by the director until:
 - (a) A sample taken from the grade A milk producer's milk is no longer positive for drug residues;
 - (b) The grade A milk producer has on display in the milkhouse a validation form signed by the grade A milk producer and a licensed veterinarian stating that the "Milk and Dairy Beef Residue Prevention" manual has been

reviewed and a valid "Veterinarian Client/Patient Relationship" (VCPR) exists; and,

- (c) A copy of the validation form, signed by both the producer and a licensed veterinarian, shall be provided to the director.

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901:11-1-05 **Amendments to the PMO.**

(A) Section 5. "Inspection of Dairy Farms and Milk Plants" is amended as follows:

- (1) The words "the Regulatory Agency shall" wherever used in the section shall be amended to read "the Regulatory Agency may."
- (2) The words "Appendix B" wherever used in the section shall be amended to read "rule 901:11-4-01 to 901:11-4-13 of the Ohio Administrative Code."

(B) Section 6. "The Examination of Milk and/or Milk Products" is amended as follows:

- (1) In the ~~fifth~~sixth paragraph of Section 6. the word "shall" is amended to read "may".
- (2) In the ~~sixth~~seventh paragraph of Section 6. the word "shall" is amended to read "may".
- (3) In the ~~seventh~~eighth paragraph of Section 6. the words "shall be collected by the Regulatory Agency" shall be amended to read "may be collected by the Regulatory Agency".

(C) Section 7. "Standards for Grade "A" Milk and/or Milk Products" is amended as follows:

- (1) In Item 10r. "Utensils and Equipment - Cleaning," insert numbered paragraph "4" which shall read: Regardless of whether a milk storage/holding tank has had a partial removal of milk, the milk storage/holding tank shall be cleaned and sanitized when emptied and shall be emptied at least every seventy-two hours. Milk storage/holding tanks used in the production of goat milk shall be clean and sanitized when empty and shall be emptied at least every seven days. In the event of an emergency situation, such as inclement weather, natural disaster, etc., a variance may be permitted at the discretion of the Regulatory Agency."
- (2) In Item 7p. "Water Supply," under "Administrative Procedures", numbered paragraph "8," the words, "samples shall be taken" shall be amended to read "samples may be taken".
- (3) In Item 12p. "Cleaning and Sanitizing of Containers and Equipment," under "Administrative Procedures," numbered paragraph "(2)(d)" the word "shall" is amended to read "may".
- (4) In Item 12p. "Cleaning and Sanitizing of Containers and Equipment," under "Administrative Procedures," in the "Note" immediately following "Table 2" the word "shall" is amended to read "may".

(5) In Item 12p. "Cleaning and Sanitizing of Containers and Equipment," under "Administrative Procedures," numbered paragraph "(6)(c)" the word "shall" is amended to read "may".

(6) In Item 17p. "Cooling of Milk and/or Milk Products," under "Administrative Procedures," numbered paragraph "11" the words "shall be taken" are amended to read "may be taken".

(D) Appendix M. "Reports and Records" is amended as follows:

(1) Ohio department of agriculture, dairy division, form 3505 may be accepted where "Form FDA 2359" is.

(2) Ohio department of agriculture, dairy division, form 0502 may be accepted where "Form FDA 2359a" is.

(3) Ohio department of agriculture, dairy division, forms 3507 and 3508 may be accepted where "Form FDA 2359b" is.

(4) Ohio department of agriculture, dairy division, form 3509 may be accepted where "Form FDA 2399a" is.

(5) Ohio department of agriculture, dairy division, form 3510 may be accepted where "Form FDA 2399b" is.

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