

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: Grade A Pasteurized Milk and Milk Products
- 2) Code Citation: 77 Ill. Adm. Code 775
- 3) Section Numbers: Proposed Action:

775.10 Amendment
775.20 Amendment
775.30 Amendment
775.120 Amendment
775.130 Amendment
- 4) Statutory Authority: Authorized by and implementing the Grade A Pasteurized Milk and Milk Products Act [410 ILCS 635].
- 5) A Complete Description of the Subjects and Issues Involved:

This rulemaking will update references to several documents that are incorporated by reference in the Grade A Pasteurized Milk and Milk Products rules. Documents that are being updated include the Grade A Pasteurized Milk Ordinance (PMO), the Methods of Making Sanitation Ratings of Milk Shippers (MMSR), the Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration (FDA) Program of the National Conference on Interstate Milk Shipments, Evaluation of Milk Laboratories, and the incorporated sections of the Code of Federal Regulations, all published by the FDA, and the Standard Methods for the Examination of Dairy Products as well as one reference to State of Illinois rules and statutes, the Veterinary Medicine and Surgery Act.

Key changes to the 2005 revision of the PMO include allowing for the determination of time/temperature control for the safety of milk and milk products. Also, many inspection and rating forms were updated. In addition, the cooling requirements for some cultured products have been changed. The revision also eliminates repetitive and outdated language. A major change in Appendix N allows for the exemption of quarterly sample collection provided the sites involved participate in the biennial on-site evaluation and annual split sample comparisons.

A key change in the MMSR combines the PMO with the Grade A Dry Milk Ordinance into one document.

A key change in the Procedures document has spelled out the certification procedure for State Rating Officers (SROs) who will conduct HACCP listing audits.

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

Key changes to the Evaluation of Milk Laboratories include updating some 2400 series forms as well as allowing for drug residue test kits to be evaluated and approved for raw milk analysis up to 45 degrees.

Modifications in the 17th edition of the Standard Methods for the Examination of Dairy Products update the document to keep pace with the rapidly changing technology used by dairy laboratories, including the Department.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking:

The Grade A Pasteurized Milk Ordinance (PMO), and Appendices A through R (except Sections 16 and 17) Recommendations of the United States Public Health Service/Food and Drug Administration, 2005 Revision (Publication 229).

Evaluation of Milk Laboratories (2005 Revision), U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration.

Methods of Making Sanitation Ratings of Milk Supplies (2005 Revision), U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration.

Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers (2005 Revision), U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration.

The Standard Methods for the Examination of Dairy Products (17th Edition, 2004, American Public Health Association, 1015 – 18th Street, N.W., Washington, D.C. 20036). (See Section 775.70(b).)

Official Methods of Analysis of the Association of Official Analytical Chemists (16th Edition, 1996, Association of Official Analytical Chemists, P.O. Box 540, Ben Franklin Station, Washington, D.C. 20044).

- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? Yes

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

10) Are there any other proposed rulemakings pending on this Part? No

11) Statement of Statewide Policy Objectives:

This rulemaking does not create or expand any state mandates on units of local government.

12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor
Springfield, Illinois 62761
217/782-2043
e-mail: rules@idph.state.il.us

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not for profit corporations affected:

Bulk milk hauler/samplers, milk tank truck owners, dairy producers and processors.

B) Reporting, bookkeeping or other procedures required for compliance:

There will be no change in the reporting, bookkeeping or other procedures required for compliance.

C) Types of professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized:

July 2006

The full text of the Proposed Amendments begins on the next page:

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER m: FOOD, DRUGS AND COSMETICS

PART 775
GRADE A PASTEURIZED MILK AND MILK PRODUCTS

Section

775.1	Minimum Regulations (Renumbered)
775.10	Definitions
775.20	Incorporated <u>and Referenced</u> Materials
775.30	Minimum Requirements
775.40	Local Government Implementation
775.50	Permits
775.60	Suspension of Permits
775.70	Inspections and Investigations
775.80	Approval of Construction Plans
775.90	Administrative Hearings
775.100	Milk Hauler-Samplers Examination
775.110	Milk Tank Trucks
775.120	Cleaning and Sanitizing Procedures
775.130	Action Levels -for Added Water in Milk
775.140	Pesticide, Herbicide and Mycotoxin Residue Control Program
775.150	Drug Residue Control Program

AUTHORITY: Authorized by and implementing the Grade A Pasteurized Milk and Milk Products Act [410 ILCS 635].

SOURCE: Adopted and codified at 8 Ill. Reg. 4190, effective March 16, 1984; amended at 11 Ill. Reg. 1464, effective February 1, 1987; amended at 12 Ill. Reg. 17925, effective December 1, 1988; amended at 17 Ill. Reg. 14015, effective August 15, 1993; amended at 19 Ill. Reg. 12271, effective August 10, 1995; amended at 22 Ill. Reg. 20633, effective November 10, 1998; amended at 25 Ill. Reg. 11904, effective September 1, 2001; amended at 25 Ill. Reg. 12629, effective September 25, 2001; amended at 27 Ill. Reg. 15979, effective October 1, 2003; amended at 31 Ill. Reg. _____, effective _____.

Section 775.10 Definitions

In addition to the definitions contained in Section 1 of the Grade A Pasteurized Milk Ordinance and Grade A Condensed and Dry Milk Products and Dry Whey Supplement, the following

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

definitions shall apply:

"Act" means the Grade A Pasteurized Milk and Milk Products Act [410 ILCS 635].

"Bulk milk pickup tank" means the tank, and those *appurtenances necessary for its use, used by a milk hauler-sampler to transport bulk raw milk for pasteurization from a dairy farm to a milk plant, receiving station, or transfer station.* (Section 3(b)(16) of the Act)

"Clarification" means an operational procedure that removes sediment from milk.

"*Cleaning and sanitizing facility*" means any place, premise or establishment where milk tank trucks are cleaned and sanitized. (Section 3(b)(15) of the Act)

"Cultured dairy products" means milk and milk products that have been soured after pasteurization using harmless lactic-acid producing bacteria, food grade phosphoric acid, lactic acid, citric acid or hydrochloric acid, with or without rennet and/or other safe, suitable milk-clotting enzymes.

"*Dairy farm*" means any place or premise where one or more cows, goats or sheep are kept, and from which a part or all of the milk or milk products are provided, sold or offered for sale to a milk plant, transfer station, or receiving station. (Section 3(b)(1) of the Act)

"Department" means the Illinois Department of Public Health. (Section 3(b)(7) of the Act)

"Director" means the Director of the Illinois Department of Public Health. (Section 3(b)(8) of the Act)

"Downstream ~~Down-stream~~" means after the automatic milk flow safety device.

"*Embargo or hold for investigation*" means a detention or seizure designed to deny the use of milk or milk products which may be unwholesome or to prohibit the use of equipment which may result in contaminated or unwholesome milk or dairy products. (Section 3(b)(9) of the Act)

"Enforcing agency" means the Illinois Department of Public Health or a unit of local government electing to administer and enforce the Act as provided for in the

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

Act. (Section 3(b)(12) of the Act)

"Field representative" means a person qualified and trained in the sanitary methods of production and handling of milk as set forth in this Part, and generally employed by a processing or manufacturing plant for the purpose of doing quality control work.

"Grade A" means that milk and milk products are produced and processed in accordance with the latest United States Public Health Service – Food and Drug Administration Grade A Pasturized Milk Ordinance as may be amended. The term Grade A is applicable to "dairy farm", "milk hauler-sampler", "milk plant", "milk product", "receiving station", "transfer station", "bulk milk pickup tank", and "certified pasteurizer sealer" whenever used in the Act. (Section 3(a) of the Act)

"High temperature short time flow-diversion device" or "H.T.S.T." means an automatic milk-flow safety device that controls the flow of milk in relation to the temperature of the milk or heating medium and/or pressure, vacuum, or other auxiliary equipment.

"Imminent hazard to the public health" means any hazard to the public health when the evidence is sufficient to show that a product or practice, posing or contributing to a significant threat of danger to health, creates or may create a public health situation that should be corrected immediately to prevent injury and that should not be permitted to continue while a hearing or other formal proceeding is being held. (Section 3(b)(10) of the Act)

"Milk" means the milk of cows, goats or sheep and includes skim milk and cream. (Section 3(b)(2) of the Act)

"Milkfat and Nonfat Solid Content Standards" means the standards set forth in 21 CFR 131.110 (~~2005 2001~~). (See Section 775.20.)

"Milk hauler-sampler" means a person who is qualified and trained for the grading and sampling of raw milk in accordance with federal and State quality standards and procedures (Section 3(b)(14) of the Act) and transports bulk raw milk for pasteurization from a dairy farm to a receiving station, transfer station, or milk plant. (Section 3(b)(16)(A) of the Act)

"Milk product" means any product including cream, light cream, light whipping

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured half-and-half, reconstituted or recombined milk and milk products, concentrated milk, concentrated milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, cultured milk, cultured reduced fat or lowfat milk or nonfat (skim) milk, cottage cheese (including dry curd, reduced fat, lowfat, and nonfat), yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, or nonfat (skim) milk, low-sodium milk, low-sodium reduced fat lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products, and milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined in this Section. (Section 3(b)(4) of the Act)

"Milk tank truck" is the term used to describe both a bulk or milk pickup tanker and a milk transport tank.

"Milk transport tank" means a vehicle, including the truck and tank used to transport bulk shipments of milk from a transfer station, receiving station or milk plant to another transfer station, receiving station or milk plant.

"PMO" means the Grade A Pasteurized Milk Ordinance incorporated by reference. (See Section 775.20.)

"Permit" means a document awarded to a person for compliance with the provisions of and under conditions set forth in the Act and this Part. (Section 3(b)(13) of the Act)

"Person" means any individual, group of individuals, association, trust, partnership, corporation, person doing business under an assumed name, the State of Illinois, or any political subdivision or Department thereof, or any other entity. (Section 3(b)(11) of the Act)

"Quality assurance program" means the Milk and Dairy Beef Quality Assurance Program, Boeckman, Steve and Carlson, Keith R., Agri-Education Inc., Stratford, Iowa 50249 or equivalent program as determined by the Department.

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

"Receiving station" means any place, premise, or establishment where raw milk is received, collected, handled, stored or cooled and prepared for further transporting. (Section 3(b)(5) of the Act)

"Separation" means an operational procedure that removes butterfat from milk.

"Transfer station" means any place, premise, or establishment where milk or milk products are transferred directly from one milk tank to another. (Section 3(b)(6) of the Act)

"Violative drug residue" means a drug residue at or above the tolerance and/or safe levels as set forth in 21 CFR 556 (~~20052001~~) and Appendix N of the PMO.

(Source: Amended at 31 Ill. Reg. _____, effective _____)

Section 775.20 Incorporated and Referenced Materials

a) The following regulations, guidelines, standards, rules, and statutes are incorporated or referenced in this Part:

1) Federal government publications:

A) The Grade A Pasteurized Milk Ordinance (PMO), and Appendices A through ~~R P~~ (except Sections 16 and 17) Recommendations of the United States Public Health Service/Food and Drug Administration, ~~2005 2001~~ Revision (Publication 229). In addition, the jurisdiction name, left blank in Sections 1, 2, 3, 5, and 11 of the PMO, for the purposes of this Part, shall mean the State of Illinois; and the regulatory agency referred to in Section 1 shall mean the Illinois Department of Public Health. (See Section 775.30(a).)

~~B) The Grade A Condensed and Dry Milk Ordinance, 1995 Revision, Part II and Appendices A through N (Grade A Condensed and Dry Milk Products and Condensed and Dry Whey— Supplement I to the Grade A Pasteurized Milk Ordinance, 1995 Recommendations). (See Section 775.30(b).)~~

~~B)C~~ Evaluation of Milk Laboratories (~~20051995~~ Revision), U.S. Department of Health and Human Services, Public Health

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

Service/Food and Drug Administration.

~~C)D)~~ Methods of Making Sanitation Ratings of Milk Supplies (~~20052004~~ Revision), U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration.

~~D)E)~~ Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers (~~20052004~~ Revision), U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration.

2) Private and professional standards:

A) The Standard Methods for the Examination of Dairy Products (~~17th16th~~ Edition, ~~20041992~~, American Public Health Association, 1015 – 18th Street, N.W., Washington, D.C. 20036). (See Section 775.70(b).)

B) Official Methods of Analysis of the Association of Official Analytical Chemists (16th Edition, 1996, Association of Official Analytical Chemists, P.O. Box 540, Ben Franklin Station, Washington, D.C. 20044). (See Section 775.70(b).)

3) Federal regulations:

A) 21 CFR 131.110, Milk (~~20052004~~). (See Section 775.10, the definition of "milkfat and nonfat solid content standards".)

B) 21 CFR 556, Tolerances for Residues or New Animal Drugs in Food (~~20052004~~). (See Section 775.10, the definition of "violative drug residue".)

C) 40 CFR 180, Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food (~~20052004~~). (See Section 775.140(a)(1).)

4) State of Illinois rules and statutes:

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- A) Illinois Plumbing Code – 77 Ill. Adm. Code 890, Illinois Department of Public Health. (See Section 775.30(c)(4).)
- B) Rules of Practice and Procedure in Administrative Hearings – 77 Ill. Adm. Code 100, Illinois Department of Public Health. (See Section 775.90.)
- C) The Veterinary Medicine and Surgery Practice Act of ~~1994~~ 2004 [225 ILCS 115].

- b) All incorporations by reference of federal guidelines and regulations and the standards of professional organizations refer to the materials on the date specified and do not include any amendments or editions ~~additions or deletions~~ subsequent to the date specified.
- c) All citations to federal regulations in this Part concern the specified regulation in the 2005 ~~2001~~ Code of Federal Regulations, unless another date is specified.
- d) Copies of all incorporated materials are available for inspection and copying by the public at the Department's Central Office, Division of Food, Drugs, and Dairies, 525 West Jefferson Street, Springfield, Illinois 62761.

(Source: Amended at 31 Ill. Reg. _____, effective _____)

Section 775.30 Minimum Requirements

- a) The production, transportation, processing, handling, sampling, examination, grading, labeling and sale of all milk and milk products; the inspection of dairy herds, dairy farms and milk plants, receiving and transferring stations, and cleaning and sanitizing facilities; the suspension of permits to milk producers and haulers, shall be regulated in accordance with the provisions of the Grade A Pasteurized Milk Ordinance (PMO) and Appendices A through ~~R P~~ (with the exception of Sections 16 and 17) of the PMO. (See Section 775.20.)
- b) The production, manufacture, packaging, labeling and sale of all Grade A condensed milk, Grade A dry milk products, Grade A condensed whey and Grade A dry whey, for use in the commercial preparation of Grade A pasteurized milk products; the inspection of condensing plants and/or drying plants; and the suspension of permits to condensing plants and/or drying plants, shall be

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

regulated in accordance with the provisions of the Grade A Pasteurized Milk Ordinance (PMO) and Apendices A through R (with the exception of Section 16 and 17 or the PMO. (See Section 775.20). Part II and Appendixes A through N of the Grade A Condensed and Dry Milk Ordinance, 1995 Revision (Grade A Condensed and Dry Milk Products and Condensed and Dry Whey Supplement I to the Grade A Pasteurized Milk Ordinance).

- c) In addition to ~~the provisions contained in~~ Section 775.30(a) and (b), the following provisions shall apply:
- 1) In addition to ~~the provisions of~~ Section 7, item 15p of the PMO:
 - A) All raw milk piping and equipment must be completely separated from pasteurized milk and milk product piping and equipment during processing. No raw milk piping or fittings shall be interchanged with pasteurized milk piping and fittings unless they have been washed and sanitized before use.
 - B) Heat-treated and pasteurized milk or milk products that are not produced at the packaging plant, but, that are to be used within a plant for processing pasteurized milk or milk products, shall be repasteurized.
 - C) No separation or clarification may occur downstream ~~down stream~~ from any high temperature short time (H.T.S.T.) flow-diversion device.
 - D) Blending of pasteurized milk or milk products may ~~only~~ occur downstream ~~down stream~~ from the high temperature short time (H.T.S.T.) flow-diversion device only when approved by the Department in accordance with the following specific requirements:
 - i) All pasteurized milk product lines, raw product lines and cleaning lines within the milk plant shall be labeled so in ~~such a manner~~ that the lines can be differentiated by visual inspection. The specific configuration of the lines must be verified by a Department on-site inspection prior to the issuance or renewal of a permit. In addition, any segments

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

of lines that are or can be removed for cleaning must be individually labeled.

- ii) All products subject to blending ~~downstream~~ ~~down stream~~ of the high temperature short time flow diversion device shall be required to undergo daily testing for standard plate count, coliform, phosphatase and salmonella. These analyses shall be conducted by a state-certified laboratory, and the results shall be maintained for one year.
- iii) Cultured dairy products are exempt from this requirement.

2) In addition to ~~complying with~~ the provisions of Section 6 of the PMO, ~~it shall be the responsibility of~~ each approved milk plant shall ~~to~~ retain from each processing day at least one time and date stamped sample from each continuous processing of a specific pasteurized fluid milk product as defined in the Grade A Pasteurized Milk Ordinance (see Section 1 of the PMO). These samples shall be of the pasteurized milk product itself and not of each type of container in which the milk product is packaged. In addition, the samples shall be retained until two days after the guaranteed sale date in accordance with the refrigeration requirements of the PMO (see Section 7 of the PMO).

3) In addition to the provisions of Section 7, items 8r and 7p₂ of the PMO, the Illinois Plumbing Code (77 Ill. Adm. Code 890) shall apply.

(Source: Amended at 31 Ill. Reg. _____, effective _____)

Section 775.120 Cleaning and Sanitizing Procedures

Milk tank trucks used to haul Grade A milk and milk products must be cleaned and sanitized in accordance with ~~Part H~~, Section 7, items 10r and 11r₂ or item 12p and Appendix F₂ of the PMO. A cleaning and sanitizing tag shall be attached to all milk tank trucks used to haul Grade A Milk and Milk Products. In addition, the tag must reflect the name of ~~the~~ substance hauled in the milk tank truck prior to being cleaned and sanitized.

(Source: Amended at 31 Ill. Reg. _____, effective _____)

Section 775.130 Action Levels for Added Water in Milk

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

DRAFT NOTICE OF PROPOSED AMENDMENTS

The presence of added water in raw or pasteurized milk constitutes adulteration. The violative level for added water in either raw or pasteurized milk is equal to or higher than 3% when converted from a milk cryoscope reading on the Hortvet or Centigrade scale when tested in accordance with the ~~17th-16th~~ edition of the Standard Methods for the Examination of Dairy Products. After two occurrences of adulterated milk within a six-month period, the plant or producer ~~shall will be required to~~ show cause and reason for the addition of water. After a third occurrence, the Department will institute administrative proceedings to revoke the plant or producer's permit.

(Source: Amended at 31 Ill. Reg. _____, effective _____)