

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)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
775.10	Amend
775.20	Amend
775.30	Amend
775.50	Amend
775.55	New Section
775.57	New Section
- 4) Statutory Authority: Authorized by the Grade A Pasteurized Milk and Milk Products Act [410 ILCS 635] and the Illinois Food, Drug and Cosmetic Act [410 ILCS 620].
- 5) A Complete Description of the Subjects and Issues Involved: This rulemaking will address the procedures for permitting and inspecting dairy farms that sell or distribute raw milk from the premises of the dairy farm directly to consumers. This practice has occurred for over 30 years without rules. Per the Act, the practice of selling raw milk from the premises of the dairy farm must be done in accordance with rules. In the absence of rules and with Illinois' adoption of the federal Pasteurized Milk Ordinance, raw milk sales are currently prohibited. This rulemaking will create a two-tiered permitting system for sales or distribution of raw milk from the premises of the dairy farm to consumers, given that certain requirements are met.
- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: This rulemaking references several documents that are incorporated by reference in the Grade A Pasteurized Milk and Milk Products rules. Documents used in developing this rulemaking include: the Grade A Pasteurized Milk Ordinance (PMO), EML, Standard Methods for the Examination of Dairy Products (17th Edition, 2004), 3-A Sanitary and Accepted Practices, National Mastitis Council position paper on somatic cell counts, incorporated sections of the Code of Federal Regulations, the Evaluation of Milk Laboratories, all published by the FDA, and raw milk rules and regulations from various states
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No

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- 9) Does this rulemaking contain incorporations by reference? No
- 10) Are there any other proposed rulemakings pending on this Part? Yes

<u>Section Numbers:</u>	<u>Proposed Action:</u>	<u>Illinois Register citation:</u>
775.20	Amendment	38 Ill. Reg. 1794; January 17, 2014
775.10	Amendment	38 Ill. Reg. 10853; May 23, 2014
775.20	Amendment	38 Ill. Reg. 10853; May 23, 2014
775.50	Amendment	38 Ill. Reg. 10853; May 23, 2014
775.115	New Section	38 Ill. Reg. 10853; May 23, 2014

- 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:

Written or e-mail comments may be submitted within 45 days after 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
rules@idph.state.il.us

- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not for profit corporations affected: Dairy Farms producing and selling raw milk to consumers
- B) Reporting, bookkeeping or other procedures required for compliance: Raw milk farms will be required to keep a log of each raw milk sale or transaction, have a written procedure for recalling products and notifying consumers, be able to provide the total number of gallons of raw milk sold in the previous 12 months if requested by the Department, post placards at the point of sale or distribution,

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provide consumer awareness information to consumers with each sale or transaction, and provide proper product labeling.

B) Types of professional skills necessary for compliance: None.

14) Regulatory Agenda on which this rulemaking was summarized: July 2013

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

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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 and Referenced Materials
775.30	Minimum Requirements
775.40	Local Government Implementation
775.50	Permits
<u>775.55</u>	<u>Tier I Permit</u>
<u>775.57</u>	<u>Tier II Permit</u>
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 (Repealed)
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 32 Ill. Reg. 8432, effective May 21, 2008; amended at 35 Ill. Reg. 14193, effective

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August 2, 2011; amended at 37 Ill. Reg. 7166, effective May 13, 2013; amended at 38 Ill. Reg. 11796, effective May 21, 2014; amended at 38 Ill. Reg. _____, effective _____.

Section 775.10 Definitions

In addition to the definitions contained in Section 1 of the Grade A Pasteurized Milk Ordinance (PMO), the following 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)

"Change of ownership" means a transaction whereby a new or different owner takes possession of a specified entity.

"Change of tenant" means a transaction whereby a new or different tenant rents or leases a specified entity such as a dairy farm.

"Consumer" means a person or group of people, such as a household or those under a distribution agreement, that purchase raw milk from the dairy farm for consumption.

"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 or goats are kept, and from which a part or all of the milk or milk products are provided, sold*~~

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~~or offered for sale to a milk plant, transfer station, or receiving station.~~ (Section 3(b)(1) of the Act)

"Dairy farm" means any place or premises where one or more lactating animals (cows, goats, sheep, water buffalo, or other hoofed mammal) are kept for milking purposes, and from which a part or all of the milk or milk product is provided, sold or offered for sale to a consumer, milk plant, receiving station or transfer station.

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

"Distribution agreement" means a community supported agriculture (CSA) program where consumers purchase a membership from the dairy farm that entitles them to share the dairy farm's raw milk production, or a buying club where consumers order raw milk directly from the farm for pick-up by the consumer on the premises of the dairy farm.

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

"Downstream" means located after the automatic milk flow safety device in a high temperature short time (HTST) flow-diversion 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 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 current Grade A Pasteurized Milk Ordinance as adopted by

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the National Conference on Interstate Milk Shipments and the United States Public Health Service – Food and Drug Administration. 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)

"Herd share" means a consumer-signed agreement with the owner of the dairy farm, which offers partial ownership of one or more animals, stipulates the expected quantity of raw milk to be received, and requires ongoing payment by the consumer to the farmer for boarding the animal, animals or herd and service of milking for the consumer.

"High temperature short time flow-diversion device" or "HTST flow-diversion device" 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 or goats 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. (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 cream, heavy cream, heavy whipping cream, whipped cream, whipped light

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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.

"Pasteurization" or "pasteurized" or similar terms mean the process of heating every particle of milk or milk products, in properly designed and operated equipment, to one of the temperatures given in the charts in the Pasteurized Milk Ordinance (PMO) and held continuously at or above that temperature for at least the corresponding specified time.

"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)

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"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.

"Raw milk" means milk that has not been pasteurized.

"Raw milk dispenser" means equipment approved by 3-A standards and used to store, cool and provide a mechanism for self-service of bottled raw milk to the consumer. "Raw milk dispenser" does not mean household refrigerator or commercial refrigerator.

"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.

"Tier I permit" means a permit that allows a dairy farm to sell or distribute raw milk, for use or consumption to consumers, only on the premises of the dairy farm where the animal, animals or herd is located.

"Tier II permit" means a permit that allows a dairy farm to sell or distribute raw milk for use or consumption to consumers under a herd share or distribution agreement on the premises of the dairy farm.

"Transfer station" means any place, premise, or establishment where milk or milk products are transferred directly from one milk tank truck 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 and Appendix N of the PMO.

(Source: Amended at 38 Ill. Reg. _____, effective _____)

Section 775.20 Incorporated and Referenced Materials

- a) The following regulations, guidelines and standards are incorporated in this Part:

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- 1) Federal government guidelines:
 - A) 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, 2011 Revision (Publication 229). U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch (HFS-316), 5100 Paint Branch Parkway, College Park MD 20740-3835. 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) Evaluation of Milk Laboratories (2011 Revision), U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, Milk Safety Branch (HFS-316), 5100 Paint Branch Parkway, College Park MD 20740-3835.
 - C) Methods of Making Sanitation Ratings of Milk Supplies (2011 Revision), U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, Milk Safety Branch (HFS-316), 5100 Paint Branch Parkway, College Park MD 20740-3835.
 - D) Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (2011 Revision), U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, Milk Safety Branch (HFS-316), 5100 Paint Branch Parkway, College Park MD 20740-3835.
- 2) Private and professional standards:
 - A) 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).)

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- B) Official Methods of Analysis of the Association of Official Analytical Chemists (18th Edition, 2010, 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 (2011). (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 (2011). (See Section 775.10, the definition of "violative drug residue".)
 - C) 40 CFR 180, Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food (2011). (See Section 775.140(a)(1).)
- b) The following rules and statutes are referenced in this Part:
 - 1) Illinois Plumbing Code (77 Ill. Adm. Code 890), Illinois Department of Public Health. (See Section 775.30(c)(4).)
 - 2) Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100), Illinois Department of Public Health. (See Section 775.90.)
 - 3) Food Service Sanitation Code (77 Ill. Adm. Code 750)
 - 43) The Veterinary Medicine and Surgery Practice Act of 2004 [225 ILCS 115].
 - 54) Illinois Administrative Procedure Act [5 ILCS 100].
 - 6) Food Handling Regulation Enforcement Act [410 ILCS 625]
- c) 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 subsequent to the date specified.

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- d) All citations to federal regulations in this Part concern the specified regulation in the 2011 Code of Federal Regulations, unless another date is specified.
- e) 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 38 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 PMO and Appendices A through R (with the exception of Sections 16 and 17) of the PMO. (See Section 775.20.)
- b) The production, handling, sale, distribution, labeling, sampling and testing requirements and quality standards for raw milk, the inspection of dairy farms, and the suspension, revocation and reinstatement of permits of dairy farms shall be regulated in accordance with Section 775.55, Section 775.57 and Section 775.60.
- c)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 regulated in accordance with the provisions of the PMO and Appendices A through R (with the exception of Sections 16 and 17 of the PMO). (See Section 775.20.)
- d)e) In addition to subsections (a), ~~and (b), and (c),~~ the following provisions shall apply:
 - 1) In addition to Section 7, item 15p of the PMO:

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- A) All raw milk piping and equipment shall 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 cleaned 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 re-pasteurized.
 - C) Blending of pasteurized milk or milk products may occur downstream from the HTST 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 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 of lines that are or can be removed for cleaning shall be individually labeled.
 - ii) Cultured dairy products are exempt from this requirement.
- 2) In addition to complying with Section 6 of the PMO, each approved milk plant shall 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 PMO (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 cooling requirements of the PMO (see Section 7, Table 1 of the PMO).

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- 3) In addition to Section 7, items 8r and 7p, of the PMO, the Illinois Plumbing Code shall apply.

(Source: Amended at 38 Ill. Reg. _____, effective _____)

Section 775.50 Permits

It shall be unlawful for any person to establish, maintain, conduct, or operate a dairy farm, milk plant, receiving station, or transfer station processing milk or milk products, to establish and operate a cleaning and sanitizing facility or milk tank truck, to haul or sample milk, or to act as a certified pasteurizer sealer within this State, or to bring in and distribute from out-of-state milk and milk products without first obtaining a permit from the Department. (Section 5 of the Act)

- a) The Department will grant and renew a permit for persons who maintain, conduct, or operate a milk plant, receiving station, transfer station, or cleaning and sanitizing facilities within the State of Illinois upon completion of an inspection that establishes compliance with the Act and this Part and upon payment of the fee required by Section 5.1 of the Act. Milk plants that maintain cleaning and sanitizing facilities on the same site as the plant do not have to obtain a separate permit for those facilities.
- b) The Department will grant and renew a permit for persons who bring into and distribute pasteurized milk or milk products from another state that has administrative rules or requirements that provide for clean, sanitary and safe handling and processing of pasteurized milk and milk products to ensure protection equivalent to that provided by this Part upon receipt of an inspection report that establishes compliance with that state's administrative rules or requirements and upon payment of the fee required by Section 5.1 of the Act.
- c) A permit will be granted to a milk hauler-sampler when the following conditions are met:
 - 1) An inspection establishes that the milk hauler-sampler's equipment is in compliance with the provisions of the Act and this Part;
 - 2) The milk hauler-sampler has successfully completed an examination administered by the Department; and

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- 3) The milk hauler-sampler has paid the fee required by Section 5.1 of the Act.
- d) A renewal permit will be granted to a milk hauler-sampler when an inspection establishes that the milk hauler-sampler's equipment and sampling procedures are in compliance with the provisions of the Act and this Part and upon payment of the fee required by Section 5.1 of the Act.
- e) Dairy Farm Permits
 - 1) A dairy farm permit is necessary when a farm does not presently hold a permit, when a change of ownership occurs and only the farm owner's name was on the permit, or when a change of tenant occurs and only the former tenant's name was on the permit.
 - 2) A dairy farm permit will be granted to a dairy farm upon the completion of an inspection that establishes compliance with the Act and this Part. The inspection includes procedures for the establishment of a quality record. The quality record is established by the results of four samples taken at a rate of not more than two per week and on separate days within a three-week period.
 - 3) A dairy farm with a dairy farm permit may sell or offer for sale for human consumption raw milk on the premises of the dairy farm in accordance with Section 775.55 or on the premises of the dairy farm in accordance with Section 775.57.
 - 4) It is unlawful for any person who does not possess a dairy farm permit in accordance with Section 775.50, Tier I permit in accordance with Section 775.55 or Tier II permit in accordance with Section 775.57 to produce, process, sell, offer for sale, or distribute raw milk for human consumption.
 - 5) Donations, bartering, free samples and gifts or any type of transaction that is not considered the sale of raw milk are prohibited.
 - 6) A dairy farm producing raw milk for consumption only by family members living on the dairy farm shall be exempt from Section 775.55.

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(Source: Amended at 38 Ill. Reg. _____, effective _____)

Section 775.55 Tier I Permit

- a) The consumption of raw milk increases the risk of foodborne illness because the milk may contain harmful organisms (bacteria, parasites, etc.). Clinical and epidemiological studies have established a direct association between gastrointestinal illness and the consumption of raw milk. Proper pasteurization of raw milk is the only proven, reliable method to decrease the amount of harmful organisms to levels safe for human consumption.
- b) A Tier I permit shall be obtained for a dairy farm to sell raw milk on the premises of the dairy farm in accordance with Section 775.50 and this Section. The dairy farm owner shall notify the Department when a change of ownership occurs or when a change of tenant occurs. Dairy farms selling or distributing raw milk will be listed on the Department website (www.idph.state.il.us).
 - 1) The Department will inspect a dairy farm for compliance with the Act and this Part prior to issuance of a Tier I permit. Inspections will be in accordance with subsection (f).
 - 2) A dairy farm participating in only Tier I sales or distribution of raw milk shall comply with the quality count requirements and standards in subsection (g) and Section 775.50(e)(2) prior to the issuance of the permit and at all times.
- c) Sales or Distribution of Raw Milk Procedures
 - 1) Raw milk shall be sold or distributed only on the premises of the dairy farm.
 - 2) All transactions shall take place physically on the premises of the dairy farm. Raw milk sold on the dairy farm shall not be re-sold or re-distributed. Distribution agreements, herd shares or any other contractual arrangements or exchanges are prohibited under Tier I permitted dairy farms.
 - 3) Raw milk shall be offered for sale only within five days after production.

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- 4) Consumers may bring their own containers for their raw milk. If the farm provides the containers for consumer transport, the containers shall meet the requirements of subsection (f)(2)(D).
 - 5) The dairy farm owner shall have a written procedure for recalling products and notifying consumers in accordance with the Illinois Food, Drug and Cosmetic Act, which shall be made available to the Department upon request. The dairy farm owner shall maintain a log of each raw milk sale or transaction with consumer name, address, phone number and date of sale for one year from the date of sale. The dairy farm owner shall report consumer complaints received to the Department.
 - 6) A dairy farm shall not make milk products, such as, but not limited to, cheese or yogurt, from raw milk for sale to consumers. Consumers may make milk products from the purchased raw milk but shall not sell, barter or distribute these products.
 - 7) Raw milk that is sold, bartered, or distributed for pet or animal consumption is not to be re-directed for human consumption.
 - 8) The dairy farm shall submit to the Department, upon request, a statement of the total gallons of raw milk sold the previous 12 months.
- d) Signage and Consumer Advisory
- 1) A dairy farm that participates in Tier I sales or distribution of raw milk shall post a placard at the point of sale or distribution that is noticeable to consumers. The placard shall read: "Notice: Raw Milk that is not pasteurized is sold or distributed here. This dairy farm is not inspected routinely by the Illinois Department of Public Health." The placard shall be written in a legible font, such as Arial, and in black ink. The size of the letters on the placard shall be no less than 2 inches in height.
 - 2) A dairy farm that participates in sales or distribution of raw milk shall post a placard at the point of sale or distribution that is noticeable to consumers that reads: "WARNING: This product has not been pasteurized and, therefore, may contain pathogens that cause serious illness, especially in children, the elderly, women who are pregnant and in persons with

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weakened immune systems." The placard shall be written in a legible font, such as Arial, and in black ink. The size of the letters on the placard shall be no less than 2 inches in height.

- 3) The dairy farm shall provide the consumer with Department-approved consumer awareness information with each sale or transaction. The Department will also post the information on the Department website.

e) Department-approved Labeling and Receipt Information

- 1) The name, address and permit number of the permit holder and product date shall be affixed to the container.

- 2) The following shall be provided to the consumer either through container labeling or product receipt:

A) The words "not pasteurized" or "unpasteurized" in addition to "raw" preceding the name of the product;

B) The quantity of contents;

C) The production date and the last date the container may be offered for sale, which shall be within five days after the production date;

D) The type of animal preceding the term "raw milk" for example "cow raw milk" or "goat raw milk";

E) The statement "WARNING: This product has not been pasteurized and, therefore, may contain pathogens that cause serious illness, especially in children, the elderly, women who are pregnant and in persons with weakened immune systems"; and

F) Instructions for the consumer to notify the local health department for the area in which the consumer resides of a consumer complaint or suspected foodborne illness or to notify the Department of a complaint of farm sanitary conditions.

f) Inspection Standards for Tier I Permitted Dairy Farms

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- 1) Dairy animal health and cleanliness
 - A) Lactating animals that show evidence of the secretion of milk with abnormalities in one or more udders, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment, and the milk shall be discarded (not offered for sale or for human consumption).
 - B) Clean bedding material shall be provided for all lactating dairy animals.
 - C) Cow yard and loafing areas adjacent to lactating dairy animal housing shall be graded and drained and shall have no standing pools of water or accumulation of organic waste.
 - D) Swine or poultry shall not be housed with lactating dairy animals.
- 2) Equipment construction and storage
 - A) All multi-use containers, utensils and equipment used in handling, storing, or transporting milk shall be made of smooth, nonabsorbent and corrosion-resistant food-grade material. Containers, utensils and equipment shall be in good repair. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single use shall not be reused.
 - B) All multiple-use containers, utensils and equipment that are exposed to milk or milk products, or from which liquids may drip, drain or be drawn into milk or milk products, shall be made of smooth, impervious, nonabsorbent, safe materials of the following types:
 - i) Stainless steel of the American Iron and Steel Institute (AISI) 300 series; or
 - ii) Equally corrosion-resistant non-toxic metal; or

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- iii) Heat-resistant glass; or
 - iv) Plastic or rubber and rubber-like materials that are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; that are non-toxic, fat resistant, relatively nonabsorbent, and relatively insoluble; that do not release component chemicals or impart flavor or odor to the product; and that maintain their original properties under repeated use conditions.
 - C) Milk cans shall have umbrella lids.
 - D) All containers, utensils and equipment used in handling or storing milk or transporting milk by the consumer, unless stored in sanitizing solution, shall be stored to assure complete drainage and shall be protected from contamination prior to use. These requirements do not apply to containers furnished by the consumer.
- 3) Milking practices
 - A) The flanks, udders, bellies and tails of all lactating dairy animals shall be free from visible dirt. The udders and teats of all lactating dairy animals shall be clean and dry before milking. Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking.
 - B) The product contact surfaces of all multi-use containers, equipment and utensils used in handling or storing milk shall be cleaned after each use.
 - C) The product contact surfaces of all multi-use containers, equipment and utensils used in handling or storing milk and transporting milk by the consumer shall be sanitized before each use.
 - i) Complete immersion in hot water at a temperature of at least 77°C (170°F) for at least five minutes; or exposure to a flow of hot water at a temperature of at least 77°C

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(170°F), as determined by the use of a calibrated thermometer, at the outlet for at least five minutes.

ii) Chemical compounds contained in 40 CFR 180.940 shall be used in accordance with label directions for sanitizing milk utensils, containers and equipment.

D) The milking operator shall wash his or her hands and dry the hands on a disposable towel prior to beginning milking.

E) Milk shall be cooled to 45°F or below within four hours after beginning milking. If milk is not sold or distributed to the consumer within four hours after beginning milking, it shall be immediately cooled to 41°F or below.

F) Wet hand milking is prohibited.

4) Milking Environment

A) Milking shall take place in an area with overhead protection to prevent contamination of the raw milk; walls and floors shall be made of a smooth, easily cleanable material, and the area shall have sufficient lighting to visually inspect flanks, teats and equipment. This area shall be cleaned prior to milking.

B) Milking equipment shall be washed and sanitized using a safe, potable water supply.

C) All milking equipment shall be stored in a dust-tight room with smooth and easily cleanable walls, or in a sealed storage vessel that protects the food contact surfaces of the equipment. The storage room shall be maintained in a clean state.

g) Quality Count Requirements and Standards

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- 1) Quality Counts and Standards shall be performed in a certified laboratory in accordance with Section 775. 20(a)(1)(A) and (B), Section 775.100, and Appendix B of the PMO. The results shall be sent to the Department.
 - 2) The samples shall be collected by a certified sampler in accordance with the Act and this Part.
 - 3) Sampling and testing shall be conducted prior to issuance of a permit in accordance with Section 775.50(e)(2) and at least four times during every six consecutive months. A permit will not be issued until all of the following standards are met.
 - A) Coliform shall be less than 10 coliforms per milliliter of raw milk.
 - B) Bacteria count shall be less than 20,000 bacteria per milliliter of raw milk.
 - C) The milk supply shall not contain any drug residues.
 - D) The somatic cell count shall be less than or equal to 400,000 cells per milliliter of raw milk.
 - E) The dairy farm water supply shall be free of coliform bacteria.
 - 4) In response to a foodborne outbreak or when a high risk of infection exists, the Department will require pathogen testing to be performed on the raw milk.
 - 5) For every day of a sale or distribution transaction, two raw milk samples shall be kept a minimum of 14 days. One sample shall be stored between 32°F and 40°F in a sanitary container, be at least 6 ounces and be labeled with the date of the production. The second sample shall be kept in a frozen state, be at least 6 ounces and be labeled with the date of production.
- h) Enforcement of Standards and Quality Counts
- 1) The Department will issue a warning when two out of the last four coliform, bacteria or somatic cell counts are in violation of the standards established in subsection (g)(3). The raw milk permit will be suspended when three out of the last five coliform, bacteria or somatic cell counts are

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in violation of the standards.

- 2) The Department will suspend the permit when drug residues are detected in the raw milk supply.
- 3) The Department will suspend the permit when coliforms are detected in the water supply.
- 4) The Department will suspend or revoke the dairy farm permit whenever the Department has reason to believe that a public hazard exists; or whenever the dairy farm has interfered with the Department in performance of its duties; or whenever the dairy farm has violated any of the procedures in subsections (a) or (f)(3); Section 775.60(a),(b),(c),(d) or (e); Section 775.80; Section 775.130; or Section 775.150.

i) Reinstatement of Permit

The Department will reinstate the permit

- 1) when an inspection of the dairy farm does not reveal violations; and
- 2) when the dairy farm is in compliance with subsection (g).

j) The Department will conduct an inspection of the dairy farm at any time or in response to a consumer complaint, product complaint, or reported suspected foodborne illness pursuant to Section 775.70. The inspection may include collection of samples and notification to consumers. The Department will suspend sales if a confirmation test reveals the presence of a pathogen.

k) The Grade A Pasteurized Milk Ordinance does not apply to this Section.

(Source: Added at 38 Ill. Reg. _____, effective _____)

Section 775.57 Tier II Permit

For the purposes of this Section, “premises” means the dairy farm or farms and one receiving station under the control and responsibility of the dairy farm owner that is part of the dairy farm operations. The premises of a dairy farm does not include any property located within the

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incorporated area of a municipality, within 1.5 miles of an incorporated municipality, or within an unincorporated urban area.

- a) A dairy farm permit shall be obtained for a dairy farm to sell or distribute raw milk on the premises of the dairy farm in accordance with Section 775.50 and with the requirements set forth in this Section. The owner shall notify the Department when a change of ownership occurs or when a change of tenant occurs. Dairy farms selling raw milk will be listed on the Department website (www.idph.state.il.us).
- 1) All provisions of Section 775.55 apply to Tier II dairy farms. If more stringent in Section 775.55 than the PMO, Tier I requirements shall supersede the PMO.
- 2) Tier II raw milk transport shall be limited to the premises of the dairy farm, and sales or distribution shall be in accordance with a distribution agreement between the dairy farm and the consumer. The dairy farm owner shall keep these agreements on file and make them available to the Department upon request. Distribution agreements are allowed only under a Tier II permit. All sales and distribution transactions shall occur on the premises of the dairy farm. Tier II is exempt from Section 775.55(c)(1) and (3).
- 3) The Department will inspect a dairy farm for compliance with the Grade A Pasteurized Milk and Milk Products Act and this Part before issuing a Tier II permit.
- 4) A dairy farm shall not make milk products, such as, but not limited to, cheese or yogurt, from raw milk for sale to consumers. Consumers may make milk products from the purchased raw milk but shall not sell or distribute these products.
- 5) Monetary transactions shall not occur at a receiving station located on the premises of a Tier II dairy farm.
- b) Raw milk shall be transported in approved single-service containers or containers approved in accordance with Item 12p in the PMO as long as the containers are properly cleanable and shall be protected from contamination in a sanitary manner

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in accordance with the PMO. The temperature of the product shall be maintained at 41°F or below. The containers shall be labeled in accordance with the PMO.

- c) The Department will issue a permit for a receiving station on the premises of the dairy farm where raw milk is being stored for sale or distribution in compliance with the requirements of this Section and in accordance with Section 775.50. The receiving station shall be accessible for inspection every three months in accordance with the PMO and upon the Department's receiving any complaints. The storage place for raw milk shall be protected from contamination, be kept in a sanitary manner and maintained at a temperature of 41°F or below. The Department will notify the local health department of the issuance of a permit for a receiving station located in the local health department's jurisdiction.
- d) The raw milk dispenser used for refrigeration of bottled raw milk on the premises of the dairy farm shall be in compliance with the 3-A standards in accordance with the PMO Item 9r and Item 11p. A household refrigerator or commercial refrigerator is an option for refrigeration and is exempt from 3-A standards. The Tier II dairy farm shall notify the Department before purchasing the raw milk dispenser. The raw milk dispenser must be preapproved by the Department before being used in compliance with 3-A standards in accordance with the PMO Item 9r and Item 11p. The raw milk dispenser shall be kept clean, shall protect the product from contamination, and shall maintain the raw milk temperature at 41°F or below.
- e) Raw milk shall not be sold to, or offered for sale at, locations including, but not limited to, food service establishments as defined by the Food Service Sanitation Code or farmers' markets as defined by the Food Handling Regulation Enforcement Act. For the purposes of this Section, lodging facilities, public roadside markets and public food vending machines shall not sell raw milk.

(Source: Added at 38 Ill. Reg. _____, effective _____)