

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
775.50	Amend
775.115	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 incorporate administrative procedures for the certified pasteurizer sealer program and the issuance of the certified pasteurizer sealer permit.

The certified pasteurizer sealer program allows the Department to authorize a permitted certified sealer, or an employee of the milk plant, to test and temporarily seal pasteurization equipment. The Department will then re-test and re-seal within 10 days.

The industry acknowledges that product produced could be recalled if the product was not pasteurized correctly during the time period from when the certified sealer tests and seals the pasteurization equipment to when the Department re-checks the equipment.

This rulemaking also makes a technical change to update a referenced document, the Grade A Pasteurized Milk Ordinance, to the most current version.

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: Several documents that are incorporated by reference in this Part were used to compose this rulemaking. Documents that were used 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

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Shipments and the incorporated sections of the Code of Federal Regulations and the Evaluation of Milk Laboratories, all published by the FDA.

- 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
- 10) Are there any other proposed rulemakings pending on this Part? Yes

<u>Section Number</u>	<u>Proposed Action</u>	<u>Ill. Reg. Citation</u>
775.20	Amend	38 Ill. Reg. 1794; January 17, 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:

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
rules@idph.state.il.us

- 13) Initial Regulatory Flexibility Analysis:
 - A) Types of small businesses, small municipalities and not for profit corporations affected: Grade A Dairy Plants
 - B) Reporting, bookkeeping or other procedures required for compliance: There will be no change in the reporting, bookkeeping or other procedures required for compliance.

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- C) 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
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
<u>775.115</u>	<u>Certified Pasteurizer Sealer Program</u>
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] and the Illinois Food, Drug and Cosmetic Act [410 ILCS 620].

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

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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].

"Applicant" means a person who formally applies to be a certified pasteurizer sealer or bulk milk hauler/sampler.

"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)

"Certified pasteurizer sealer" means a person who has satisfactorily completed a course of instruction and has demonstrated the ability to satisfactorily conduct all pasteurization control tests, as required by this Part. (Section 3(b)(17) of the Act and Section 2.39 of the Illinois Food, Drug and Cosmetic 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 or goats 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)

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"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 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)

"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)

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"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 plant" means any place, premise, or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, condensed, dried, or prepared for distribution. (Section 3(b)(3) of the Act)

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

"Permit" means a document awarded to a person for compliance with the

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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.

"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 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:

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, ~~2013~~ 2014 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

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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).)
 - 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".)

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- 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) The Veterinary Medicine and Surgery Practice Act of 2004 [225 ILCS 115].
 - 4) Illinois Administrative Procedure Act [5 ILCS 100].
- 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.
- 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 775.50 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)

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- 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 ~~and~~ examination administered by the Department; and
 - 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.

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- 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.

- f) Certified Pasteurizer Sealer Permits will be issued in accordance with Section 775.115.

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

Section 775.115 Certified Pasteurizer Sealer Program

The Department will authorize milk plant personnel to test and temporarily seal pasteurization equipment, provided that the conditions in Item 16p(D), Pasteurization Records, Equipment Tests and Examinations, 2- Equipment Tests and Examinations, of the Pasteurized Milk Ordinance (PMO) and the provisions of this Section are met. All milk plants with pasteurization equipment shall have one certified pasteurizer sealer by July 1, 2015.

- a) The applicant shall contact the Department Regional Office responsible for the oversight of the milk plant where the applicant is employed. The application for a certified pasteurizer sealer permit shall consist of the following:
 - 1) The name and address of the applicant;
 - 2) The location of the milk plant where the applicant is employed; and
 - 3) The type of pasteurization equipment that the applicant is applying to be certified to test and seal, in accordance with the Pasteurized Milk Ordinance Item 16p.(D).
- b) Training, Examination and Evaluation Procedures
 - 1) The certified pasteurizer sealer examination and evaluation shall consist of a training course and both a written examination and practical evaluation of testing and sealing pasteurization equipment as referenced in Appendix I of the PMO.
 - 2) Training

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- A) Prior to taking the certified pasteurizer sealer written examination, the applicant shall attend a certified pasteurizer sealer training course approved and conducted by the Department.
 - B) The training shall be a minimum of eight hours in length, including an examination.
 - C) The Department will approve the training course based on the following criteria for course content:
 - i) Instruction on purpose and methodology for pasteurization equipment testing;
 - ii) Review of pasteurization and Appendix I of the Pasteurized Milk Ordinance;
 - iii) Overview of requirements for testing of pasteurization equipment;
 - iv) Evaluation of definitions of processes used in pasteurization and explanation of components and instrumentation;
 - v) Analysis of flow diagrams and discussion of safe systems operation guidelines and importance; and
 - vi) Assessment of adjustments of each access point on the pasteurization equipment.
- 3) Written Examination
- A) The written examination shall be administered at the Department Regional Office responsible for the oversight of the milk plant where the applicant is employed or at a location designated by the Department.
 - B) The minimum passing score for the written examination shall be 80%. If the applicant passes the examination, the Department will issue a training and examination certificate enabling the applicant to then complete the practical exam.

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- C) If the applicant fails the written examination, the Department will send a letter of failure. Once the applicant receives the letter of failure, the applicant shall contact the Department Regional Office responsible for oversight of the milk plant where the applicant is employed to schedule to re-take the examination.
 - D) The applicant shall be allowed to retake the examination twice in a six month time period from the date of the applicant's receipt of the examination letter of failure. The applicant shall not be allowed to retake the examination on the same day that the applicant fails the examination.
- 4) Practical Evaluation
- A) The practical evaluation will be administered after the applicant has completed the Department-approved training course and passed the written examination. The Department will provide a copy of the certified pasteurizer sealer training course certificate and written examination to the Department Regional Office responsible for oversight of the milk plant where the applicant is employed to schedule the practical evaluation.
 - B) The practical evaluation will be administered on the pasteurization equipment at the milk plant where the applicant is employed and will be evaluated by the Department.
 - C) The practical evaluation will take place when the Department performs the quarterly pasteurizer equipment checks on each pasteurization system at the milk plant or plants where the applicant is employed.
 - D) The applicant shall demonstrate proficiency in all pasteurization control test procedures.
 - E) If the applicant passes the practical evaluation, the Department will issue a certified pasteurizer sealer permit.
 - F) If the applicant fails the practical evaluation, the Department will issue a letter of failure.

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- G) Once the applicant receives the letter of failure, the applicant shall contact the Department Regional Office responsible for oversight of the milk plant where the applicant is employed to re-schedule a practical evaluation. The applicant shall present the letter of failure to the Department Regional Office sanitarian in order to retake the practical evaluation.
 - H) The applicant shall be allowed to retake the practical evaluation twice in a six month time period from the date of the applicant's receipt of the letter of failure.
 - I) If the milk plant where the certified pasteurizer sealer is employed obtains a new pasteurizer, the certified pasteurizer sealer must pass a practical test on that new equipment to be approved to seal. Upon successful completion of the practical, the new equipment will be added to the certified pasteurizer sealer's permit.
 - J) The applicant shall be required to take the practical evaluation every 12 months to receive a renewed certified pasteurizer sealer permit.
- c) Issuance of a Certified Pasteurizer Sealer Permit
- 1) The permit shall be valid only to the person to whom it is issued and shall not be subject to transfer.
 - 2) The permit shall be issued to an applicant who has attended a minimum eight hour training course, passed the written examination and demonstrated proficiency in all pasteurization control test procedures.
 - 3) The permit will list all of the pasteurization equipment that the applicant was certified to test and reseal.
 - 4) The permit will expire on December 31 of each year. For applicants who receive their permits after September 1, the permit will expire on December 31 of the following year.
 - 5) A renewal permit will be issued upon completion of an annual practical and payment of a \$100 fee.

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