

TITLE 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

Chapter 217. Milk and Dairy

Subchapter A. Grade Specifications and Requirements for Milk

New §§217.1 - 217.2

Repeal §§217.1 - 217.3

Subchapter C. Rules for the Manufacture of Frozen Desserts

New §§217.41 - 217.51

Repeal §§217.61 - 217.71

Subchapter D. Bulk Milk Regulations

New §§217.61 - 217.65

Repeal §§217.81 - 217.85

New Subchapter E. Dairy Products and Milk for Manufacturing Purposes

New §§217.71 - 217.81

Repeal Subchapter E. Permits, Fees and Enforcement

Repeal §§217.91 - 217.92

New Subchapter F. Permits, Fees and Enforcement

New §§217.91 - 217.92

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes the repeal of §§217.1 - 217.3, 217.61 - 217.71, 217.81 - 217.85, and 217.91 - 217.92 and new §§217.1 - 217.2, 217.41 - 217.51, 217.61 - 217.65, 217.71 - 217.81, and 217.91 - 217.92 concerning the milk and dairy program.

BACKGROUND AND PURPOSE

The repeal and new sections are a result of Senate Bill (SB) 1714, 80th Legislature, Regular Session, 2007, which amended Health and Safety Code, Chapter 435. The permit and inspection fees are mandated by Health and Safety Code, §435.009(b). In addition, costs to upgrade facilities and equipment are also required by state statute and federal regulations. SB 1714 amends Health and Safety Code, §435.003(a), to require for the first time that all non-Grade A dairy products be handled and produced in accordance with Health and Safety Code, Chapter 435 standards. Dairy products regulated under Health and Safety Code, Chapter 435, must comply with federal standards in §435.003(b). Federal standards include the Grade A Pasteurized Milk Ordinance, which is adopted by the Food and Drug Administration.

The proposed new rules update language for Grade Specifications and Requirements for Milk (proposed new Subchapter A), Rules for the Manufacture of Frozen Desserts (proposed new Subchapter C), Bulk Milk Regulations (proposed new Subchapter D), and Permits, Fees, and Enforcement (proposed new Subchapter F). New language for Dairy Products and Milk for Manufacturing Purposes (proposed new Subchapter E) implements SB 1714. Subchapter B, §§217.21 - 217.33 of Chapter 217, relating to Grade A Raw for Retail Milk and Milk Products,

is not being revised at this time and therefore remains in effect as is currently published in the Texas Administrative Code.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 217.1 - 217.3, 217.61 - 217.71, 217.81 - 217.85, and 217.91 - 217.92 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

Throughout new Subchapters A and C - F of Chapter 217: sections are reformatted and/or renumbered to meet Texas Register format; references to "§403(h)(3)" are changed to "§343(h)(3)" to correct the citation of the Federal Food, Drug and Cosmetic Act; all references to "Grade A Condensed and Dry Milk Ordinance," "Imitation frozen dessert," and "Imitation frozen dessert mix" are deleted because the definitions are obsolete; all references to "PMO" or "Pasteurized Milk Ordinance" or "U.S. Public Health Service Grade A Pasteurized Milk Ordinance" are changed to, "Grade A Pasteurized Milk Ordinance" for consistency; and other minor grammatical changes are made for clarification.

All sections of new Subchapters A and C - F of Chapter 217 are renumbered due to the addition of new §§217.71 - 217.81.

The rules in §§217.1 - 217.3 are being repealed and proposed as new §§217.1 - 217.2 which updates, adds, and deletes definitions and provides for the continued adoption of the requirements for the Grade A Pasteurized Milk Ordinance.

Concerning new §217.1, the following definitions are revised to be consistent with terms used throughout the chapter: "Bulk milk hauler" is revised to read, "Bulk milk hauler/sampler;" "Concentrated milk" is revised to read, "Concentrated (condensed) milk;" "Concentrated milk products" is revised to read, "Concentrated (condensed) milk products;" "Frozen low fat yogurt" is revised to read, "Frozen low fat yogurt and mix;" and "Frozen low fat yogurt mix" is revised to read, "Frozen low fat yogurt dry mix."

Concerning new §217.1, the following definitions are added and subsequent definitions were renumbered: "Dairy product manufacturer" and "Federal Food Drug and Cosmetic Act (FFDCA)."

Concerning new §217.1, the following definitions are deleted because they are obsolete and subsequent definitions were renumbered: "Grade A Condensed and Dry Milk Ordinance" and "Imitation frozen dessert mix."

Regarding new §217.2, the department name is updated and the current physical address is added to inform stakeholders where they may obtain copies of referenced documents.

The rules in §§217.61 - 217.71 are being repealed and proposed as new §§217.41 - 217.51 which update rules for the Manufacture of Frozen Desserts. References to imitation frozen desserts mix and imitation frozen desserts were deleted throughout the subchapter because the products are obsolete.

New §217.44 changes the inspection interval each frozen desserts plant must undergo following the issuance of a permit from "once every six months" to "once every three months" to be consistent with national regulatory standards.

New §217.45(a) specifies the frequency of the examination and standards for frozen desserts to be collected during any consecutive six months. At least four samples of raw milk intended for use in the manufacture of frozen desserts shall be collected and examined by the department. "Raw cream" and "raw milk products" are removed from the list of products that must be sampled.

New §217.45(e) adds "provided, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by the United States Food and Drug Administration (FDA) as provided in §343(h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department." to clarify that only FDA-recognized processes will be considered by the department.

New §217.46(e)(1)(I) adds "The milk plant, frozen dessert plant, containers, utensils, and equipment shall be used for no purpose other than the processing of milk, cream, milk products, mix, and frozen desserts, and the operation incident thereto, except as may be approved in writing by the department." to clarify that department approval shall be in writing.

New §217.46(e)(6) states that written permission from the department shall be obtained for milk or milk products to be received from a transport tank that appears to be damaged, dirty, or does not have a cleaning tag attached.

New §217.46(l) is revised to include specific frequencies and requirements for cleaning of multi-use containers and utensils and to require the necessary documentation be submitted in writing to the department for review and approval.

New §217.46(p)(1) adds a heating and holding temperature of 180 degrees Fahrenheit for not less than 15 seconds to be consistent with national regulatory standards.

New §217.46(p)(3) adds "Nothing shall be construed as barring any other process found equivalent to pasteurization for milk and milk products, which has been recognized by the United States Food and Drug Administration (FDA) as provided in §343(h)(3) of the Federal Food, Drug and Cosmetic Act. Only such FDA recognized processes and no other shall be considered by the department." to clarify that only FDA-recognized processes will be considered by the department.

New §217.46(y) adds new raw product storage requirements for the sanitation standards of frozen desserts plants to be consistent with national regulatory standards.

New §217.51(c) clarifies that adequate medical examination of an infected person or potentially infected person shall be performed before returning to frozen dessert handling.

The rules in §§217.81 - 217.85 are being repealed and proposed as new §§217.61 - 217.65, update rules for Storage and Transportation of Bulk Milk.

New §217.61(a)(2) redefines the minimum passing score for examination for bulk milk hauler/sampler certifications and adds new specifications for the examination criteria.

New §217.61(a)(3)(B) specifies that acceptance of the training program will be indicated in a letter issued by the department.

New §217.61(a)(5) adds language to allow official milk samplers, and bulk milk haulers/samplers the option to be evaluated by the authorized Regulatory Agency of another state.

New §217.61(b)(1) adds a reference to §217.2 of this title, which specifies the procedure and handling requirements for bulk milk pickup tankers.

New §217.61(b)(2) is changed to require that a copy of the load manifest be provided and adds that the hauler/sampler name and driver's license number be provided for each route pickup load.

New §217.62(d) adds a requirement that farm bulk milk tanks shall comply with the Grade A Pasteurized Milk Ordinance.

New §217.63(a) adds language to allow official milk samplers, and bulk milk haulers/samplers the option to be permitted by the authorized Regulatory Agency of another state and clarifies that failure to obtain a permit may result in the milk tank truck and its contents being immediately removed from Grade A or food use.

New §217.63(b) is revised to read, "All vehicles and milk tank trucks containing milk or milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents. The permit sticker issued by the department shall be placed near the outlet valve of the tanker truck or trailer." to be consistent with national regulatory standards.

New §217.63(c) is changed to clarify that the owner or manager of the milk transportation company report to the department verbally or in writing within 10 days any tanks taken out of service or damaged.

New §217.64(a)(4) specifies that agitation of milk in the transport tank should be done for a minimum of 15 minutes prior to obtaining samples; clarifies that samples must be collected only

by a certified milk sampler; and allows the department to approve alternative procedures to achieve adequate agitation.

New §217.64(b)(1) adds "All milk tank trucks that transport milk and milk products as permitted by the department, shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility." to be consistent with national regulatory standards.

New §217.64(b)(3)(F) corrects the term "pressure recorder" with "pressure indicator."

New §217.64(b)(5) clarifies the ability to pick up multiple loads in a milk tank truck within a 24-hour period as long as the milk tank truck is washed after each day's use.

New §217.64(b)(6) revises the time interval to re-sanitize a milk tank truck and appurtenances to be consistent with national regulatory standards.

New §217.64(b)(7) changes the standards for the accountability of the cleaning and sanitizing tag for milk tank trucks to maintain equivalent national regulatory standards.

New §217.65 adds a reference to §217.2 of this title, which specifies the duties and responsibilities of the bulk milk hauler/sampler.

New §217.71 - §217.81 provide new rules for the manufacture of non-Grade A dairy products and add requirements for dairy products and milk for manufacturing purposes as a result of SB 1714 which amended Health and Safety Code, Chapter 435. The dairy products include instant nonfat dry milk, nonfat dry milk, dry whole milk, dry buttermilk, dry whey, and other dry milk products; butter and related products; cheese, pasteurized cheese and related products; and evaporated or condensed milk products.

The rules in Subchapter E, §§217.91 - 217.92 are being repealed and proposed as new Subchapter F, §§217.91 - 217.92 which update rules for issuance of licenses, collection of fees, and enforcement provisions of Chapter 217 relating to Milk and Dairy. New permit and inspection fees for non-Grade A dairy products have been added to new §217.91.

New §217.91(a) clarifies that the term of the permit/license is for two years required by Health and Safety Code, §435.009(d).

New §217.91(a)(1) adds clarifying language that approval by the department is based on an inspection prior to the issuance of a permit.

New §217.91(a)(3) adds language to include that past due or late inspection fees shall be paid in order for a permit to be issued.

New §217.91(b) updates the department name and adds the current physical address is to inform stakeholders where they may obtain copies of referenced documents.

New §217.91(c)(1) updates all fees to reflect the new two-year permit term as required by Health and Safety Code, §435.009, and modifies language to apply fees to facilities and operations located outside Texas to reflect the application of permit and license fees for those dairy products regulated under new §§217.71 - 217.81.

New §217.91(d) updates the deadline for submitting a permit/license renewal application to reflect the new two-year permit term as required by Health and Safety Code, §435.009.

New §217.91(c)(1) and (h)(3) add permit and inspection fees for those dairy products regulated under new §§217.71 - 217.81.

FISCAL NOTE

Susan E. Tennyson, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five years the sections are in effect, there will be fiscal implications to the state as a result of enforcing or administering the sections as proposed. The effect on state government will be an increase in revenue to the state of approximately \$47,380 the first year, \$25,380 the second year, \$67,380 the third year, \$45,380 the fourth year, and \$87,380 the fifth year due to the new two-year license requirement and inspection fees on dairy products. Costs to the state are estimated to be approximately \$40,880 the first year, \$31,380 for the second year, \$31,880 for the third year and \$32,380 for each of the following two years to conduct inspections and collect samples at the dairy products facilities that will now be required to comply with the new dairy products regulations. Implementation of the proposed sections will not result in any fiscal implications for local governments.

SMALL AND MICRO-BUSINESS ECONOMIC IMPACT ANALYSIS

Ms. Tennyson has also determined that there are anticipated economic costs to persons who are manufacturers of non-Grade A dairy products. These manufacturers include large, small and micro-businesses. Most manufacturers of non-Grade A dairy products (e.g., cheese and butter) are currently licensed as food manufacturers and pay approximately \$104 to \$150 for a two year license. Under the proposed rules, all non-Grade A dairy manufacturers will pay \$800 for a two year permit. They will also pay an inspection fee of at least \$60 per year based on volume of sales. Of the approximately 40 facilities that will now be required to comply with these rules, approximately 30 of the facilities would be considered small and micro-businesses. These small and micro-businesses will pay the same permit fees as the larger manufacturers because the fees are required by statute. Their inspection fees based on volume of sales are anticipated to be smaller because their sales are anticipated to be smaller. In addition, some of the small and micro-businesses that are non-Grade A dairy manufacturers will incur costs ranging from \$10,000 to \$25,000 to bring their facility and equipment into compliance with the mandatory national standards incorporated in the proposed new §§217.71 - 217.81. The department believes the larger manufacturers already have complying facilities and equipment and will, therefore, not incur these costs. There is no anticipated impact on local employment.

REGULATORY FLEXIBILITY ANALYSIS

Of the approximately 40 facilities that will now be required to comply with this rule, approximately 30 of the facilities would be considered small and micro-businesses that make non-Grade A products such as cheese and butter. These businesses will incur increased costs because of increased permit fees, inspection fees, and costs to bring their facility and equipment into compliance with national standards. The permit and inspection fees are mandated by SB 1714 in the amendments to Health and Safety Code, §435.009(b). Consequently, any variance from these legislative rates would not be consistent with health, safety and environmental welfare and no alternative regulatory methods have been considered.

In addition, costs to upgrade facilities and equipment are also required by state statute and federal regulations. SB 1714 amends Health and Safety Code, §435.003(a), to require for the first time that all non-Grade A dairy products be handled and produced in accordance with Chapter 435 standards. Dairy products regulated under Health and Safety Code, Chapter 435, must comply with federal standards in §435.003(b). Federal standards include the Grade A Pasteurized Milk Ordinance, which is adopted by the Food and Drug Administration. In order to comply with the federal Grade A Pasteurized Milk Ordinance standards, upgrades that cost a minimum of \$10,000 are now required. Consequently, any variance from these federal Grade A Pasteurized Milk Ordinance standards would not be consistent with health, safety and environmental welfare and no alternative regulatory methods have been considered. The rules, however, do not require companies to own or purchase the equipment. They may rent or share equipment as long as they remain in compliance with the federal Grade A Pasteurized Milk Ordinance standards incorporated in the Texas rules.

PUBLIC BENEFIT

In addition, Ms. Tennyson has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is to enhance the safety of dairy products manufactured in Texas by establishing a program in which all dairy products are regulated in a consistent manner that is based on national standards.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Gene Wright, Environmental and Consumer Safety Section, Division of Regulatory Services, Department of State Health Services, MC 1987, P.O. Box 149347, Austin, Texas 78714-9347, (512) 834-6770, extension 2570, or by email to MilkRules@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

PUBLIC HEARING

A public hearing to receive comments on the proposal will be scheduled after publication of this proposal in the *Texas Register*, and will be held on Tuesday, September 29, 2009 at 8:30 a.m. at the Department of State Health Services, 1100 West 49th Street, Austin, TX 78756 in room K-100. The meeting date and location will be posted on the Milk and Dairy Group website (www.dshs.state.tx.us/milk/rules.shtm). Please contact Gene Wright at (512) 834-6770, extension 2570, or Gene.Wright@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed repeal and new sections are authorized by Health and Safety Code, §12.0111, which requires the department to charge fees for issuing or renewing a license sufficient to recover costs; §12.0112, which requires the term of each license issued to be two years; Health and Safety Code, §§431.241, 435.009(c), and 440.006, which provide the department with the authority to adopt necessary regulations pursuant to the enforcement of Chapters 431, 435, and 440; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. Review of the rules implements Government Code, §2001.039.

The proposed repeal and new sections affect the Health and Safety Code, Chapters 12, 431, 435, 440, and 1001; and Government Code, Chapters 531 and 2001.

Sections for Repeal:

Subchapter A. Grade Specifications and Requirements for Milk.

§217.1. Definitions.

§217.2. Grade A Pasteurized Milk Ordinance.

§217.3. Grade A Condensed and Dry Milk Ordinance.

Subchapter C. Rules for the Manufacture of Frozen Desserts.

§217.61. Introduction.

§217.62. Permits.

§217.63. Labeling.

§217.64. Inspection of Frozen Desserts or Imitation Frozen Desserts Plants.

§217.65. Examination and Standards for Frozen Desserts.

§217.66. Sanitation Standards for Frozen Desserts Plants.

§217.67. Frozen Desserts Which May Be Sold.

§217.68. Transferring and Dispensing Frozen Desserts.

§217.69. Mix and Frozen Desserts from Points Beyond the Limits of Routine Inspection.

§217.70. Future Frozen Desserts Plants.

§217.71. Procedure When Infection Is Suspected.

Subchapter D. Bulk Milk Regulations.

§217.81. Bulk Milk Hauler Qualifications and Requirements.

§217.82. Bulk Milk Holding Tanks.

§217.83. Milk Tank Trucks.

§217.84. Unloading Stations and Milk Tank Truck Cleaning Facilities.

§217.85. Training Outline and Responsibilities of the Bulk Milk Hauler/Sampler.

Subchapter E. Permits, Fees and Enforcement.

§217.91. Milk Facilities and Operations Permit and Frozen Dessert License Procedures.

§217.92. Enforcement.