

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulation
Department of Health and Mental Hygiene
(DLS Control No. 15-389)**

Overview and Legal and Fiscal Impact

The regulations make numerous changes to existing regulations regarding the Pilot Farmstead Cheese Program. In general, the regulations repeal the “pilot” provisions of the program; remove limitations on the number of milk processor-farmstead cheese producer permits issued by the Department of Health and Mental Hygiene; remove limitations on the permissible number of animals in the milk producing dairy farm herd or flock; repeal limitations on permit renewal terms; establish standards for raw milk, farmstead cheese final products, physical plants, and sanitation; and establish an enforcement process.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Food: Pilot Farmstead Cheese Program: COMAR 10.15.08.01-.21

Legal Analysis

Summary of Regulation

The regulations repeal the “pilot” provisions of the program; remove limitations on the number of milk processor-farmstead cheese producer permits issued by the department and the permissible number of animals in the milk producing dairy farm herd or flock; repeal limitations on permit renewal terms; establish standards for raw milk, farmstead cheese final products, physical plants, and sanitation; and establish an enforcement process. More specifically, these regulations:

- alter the scope of the program to repeal the pilot provisions and expand the regulation of the farmstead cheese production process as well as establish an enforcement process (Regulation .01);
- define terms related to the production and processing of farmstead cheese (Regulation .02);

- incorporate by reference specified federal laws, regulations, and regulatory compliance guidance materials (Regulation .03);
- require the department to ensure that all inspections, sampling, testing, and enforcement actions performed by the State and production and processing actions performed by individuals are in compliance with State and federal laws and regulations (Regulation .04);
- amend the existing process to obtain a permit as a Milk Producer or Milk Processor-Farmstead Cheese Producer, including repealing milk producing dairy farm herd or flock number limitations, limitations on the number of permit renewal terms, and the limit on the number of permits that may be issued by the Secretary (Regulation .05);
- establish standards for the department to conduct sanitation inspections of farmstead cheese production plants, including the frequency and types of inspections, reinspection requirements for violations including penalties, and requirements for inspection reports (Regulation .06);
- establish sanitation inspection standards for a plant, including (1) standards for floors, walls and ceilings, doors and windows, lighting and ventilation, separate room requirements, toilet sewage disposal facilities, water supply, handwashing facilities, general plant cleanliness, and sanitary piping; (2) the construction, repair, cleaning, storage, and sanitation of containers, equipment, and other materials; and (3) standards for protection from contamination and cross-contamination, raw milk cooling and farmstead cheese processing, personnel sanitation, vehicles, and plant surroundings (Regulation .07);
- require a farmstead cheese producer to collect samples and pay for testing of raw milk and the farmstead cheese finished product at an official laboratory, establish quality standards for raw milk and farmstead cheese finished products, establish record keeping requirements, and require the department to collect and test samples of water used for the cooling and processing of farmstead cheese (Regulation .08);
- establish enforcement actions the department must take for violations of the raw milk and farmstead cheese finished product standards, including investigations, written notices of violation, permit suspension procedures, and the process for reinstatement of a suspended permit (Regulation .09);
- set forth the process for impounding milk or a milk product intended for human consumption due to improper handling, including issuing orders, imposing a civil monetary penalty and calculating the penalty, and the process for legal recourse by a person subject to impoundment (Regulation .10);
- set forth the labeling requirements for farmstead cheese products, including compliance with State and federal laws and regulations and the information required on each label (Regulation .11);

- restate the prohibition on the sale of raw milk for human consumption (Regulation .12);
- require all raw milk for farmstead cheese to meet the Animal Health requirements set forth in a specified provision of law (Regulation .13);
- set forth the requirements of a plan for the construction, reconstruction, or extensive alteration of a milk facility that must be submitted to the department (Regulation .14);
- set forth the physical requirements for plants, including water, hand sinks, sewage systems, plumbing, electrical systems, and lighting (Regulation .15);
- require an applicant for a permit to submit a plan to the department before construction, reconstruction, or extensive alteration of a plant and require the department to review the plan and provide a certain notice to the applicant (Regulation .16);
- prohibit individuals with a communicable disease capable of being transmitted through contamination of food from working at a plant if that brings the individual in direct contact with raw milk, a farmstead cheese product or food ingredient, or an associated raw milk and a food product contact surface (Regulation .17);
- establish procedures for handling the discovery of personnel with a communicable disease or a carrier of a communicable disease (Regulation .18);
- require the department to maintain the confidentiality of records submitted (Regulation .19);
- establish procedures for the suspension and revocation of permits, including notice provisions and the procedures for summary suspension of permits in emergency situations; (Regulation .20); and
- establish an appeals process and an opportunity for a hearing for a farmstead cheese producer whose plan review or permit has been denied, suspended, or revoked by the department (Regulation .21).

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The department cites §§ 21-211, 21-234, 21-252 – 21-256, 21-406, 21-416.1, 21-417, 21-418, 21-419, 21-428, 21-434, 21-1202, 21-1203, and 21-1215 of the Health – General Article as statutory authority for the regulations. Sections 21-1202, 12-1203, and 21-1215 of the Health – General Article are not directly relevant to these regulations.

Section 21-211 requires the Secretary to adopt rules and regulations that provide for the issuance of permits to food manufacturers, processors, or packers in any locality if, on investigation, the Secretary finds that the distribution in this State of any class of food manufactured, processed, or packed in that locality may be injurious to health because of possible contamination with microorganisms and the danger would not normally be determinable after the food has entered commerce. Sections 21-234 and 21-406 grant the Secretary general authority to adopt rules and regulations to carry out provisions of law relating to adulterated food and milk products, respectively. Sections 21-252 through 21-256 set forth the enforcement actions the Secretary may take regarding adulterated food.

Section 21-416.1 authorizes the Secretary to establish (1) a farmstead cheese program after the Secretary adopts regulations to implement the program and issues a milk-processor – farmstead cheese producer permit to a qualified applicant and (2) qualifications for the permit. Section 21-417 sets forth terms and renewal requirements for a milk-processor – farmstead cheese producer permit. Section 21-418 sets forth provisions on the suspension and revocation of milk-processor – farmstead cheese producer permits. Section 21-419 establishes hearing process requirements for appeal of the Secretary’s decisions regarding milk-processor – farmstead cheese producer permits. Section 21-428 requires the Secretary to impound a milk product that the Secretary has determined is a threat to public health. Section 21-434 prohibits the sale of raw milk for human consumption except for the sale of raw milk by a holder of a milk producer permit to a holder of a milk processor permit or the sale of a farmstead cheese.

The relevant cited authority is correct and complete. The regulations comply with the legislative intent of the law.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The department advises that the regulations have no impact on State or local governments. The Department of Legislative Services concurs and notes that the regulations implement Senate Bill 122 and House Bill 540 of 2015 (enacted as Chapters 14 and 15) and codify existing procedures for Maryland’s Farmstead Cheese Program. There is no fiscal impact on State or local governments beyond that anticipated in the fiscal and policy notes for that legislation, which anticipated that the department could continue to issue permits and conduct inspections with existing resources. Further, the fiscal and policy notes estimated that local health departments could handle the bills’ requirements as part of their regular inspections.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs as the regulations implement Senate Bill 122 and House Bill 540 of 2015 and codify existing procedures for Maryland's Farmstead Cheese Program; thus, the fiscal impact on small businesses was anticipated in the fiscal and policy notes for that legislation. The fiscal and policy notes noted a meaningful impact for dairy farms in the State that are producing, or wish to produce, dairy products under the Farmstead Cheese Program.

Contact Information

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