MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	12/02/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 1/8/2016

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	15	08	01-.21

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator
Michele Phinney

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5. Name of Person to Call About this Document
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6. Check applicable items:

X- New Regulations

X- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: June 24, 2015.

X- Repeal of Existing Regulations

_ Recodification

_ Incorporation by Reference of Documents Requiring DSD Approval

_ Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

_ Yes **X-** No

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

_ OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Claire Pierson, Assistant Attorney General, (telephone #410-767-6526) on November 24, 2015. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title	**Telephone No.**
Secretary	410-767-6500

Date

December 1, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 15 FOOD
10.15.08 Pilot Farmstead Cheese Program

Authority: Health-General Article, §§21-211, 21-234, 21-406, 21-416.1, 21-417, 21-418, 21-419, 21-428, [and] 21-434, 21-252— 21-256, 21-1202, 21-1203, and 21-1215, Annotated Code of Maryland

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .01, .03 and .05; repeal existing Regulations .02, .04 and .06—.10; and adopt new Regulations .02, .04, and .06—.21 under COMAR 10.15.08 Pilot Farmstead Cheese Program.

Statement of Purpose

The purpose of this action is to update regulations to reflect statutory changes, clarify certain existing producer requirements, and establishes an enforcement process. This proposal will expand Maryland's Pilot Farmstead Cheese Program by removing the "pilot" restrictions. This proposal expands the type of species that fall under these farmstead cheese permits and removes the limitations on the:
(1) Number of milk processor-farmstead cheese producer permits that the Department of Health and Mental Hygiene (DHMH) may issue;
(2) Permissible number of animals in the herd or flock; and
(3) Number of times a milk processor-farmstead cheese producer permit may be renewed.

Additionally, this proposal clarifies and provides additional details related to the following requirements:
(1) Sanitation inspections and reports;
(2) Standards for raw milk;
(3) Farmstead cheese finished products and water supplies;
(4) Labeling;
(5) Plan review and approval process;
(6) Plant construction submissions; and
(7) Personnel health.

This proposal also sets forth the enforcement process and penalties to milk processor-farmstead cheese producer who violate these regulations.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 8, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2016
B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:
This program is already in place and is being administered by DHMH. If the number of producers increases in the future, the Program could maintain current staffing levels for up to approximately 10 total producers, after which, the Program would require additional resources to ensure all regulatory requirements are met. At this time, DHMH anticipates that only one producer that currently does not have a milk processor-farmstead cheese producer permit will apply for a permit to produce farmstead cheese.
F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.
This program is already in place. There are currently three Milk Processor - Farmstead Cheese Producers in Maryland. Although the number of dairy farms participating in the Program could increase at any time, the Program estimates that participation will remain stable based on the current landscape in Maryland. This proposal allows these producers to expand their operation which could increase their revenues. This proposal requires the

producers to test their finished cheese product for pathogens four times per year rather than once a year. This will have minimal economic impact.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle FOOD

10.15.08 Pilot Farmstead Cheese Program

Authority: Health-General Article, §§21-211, 21-234, 21-406, 21-416.1, 21-417, *21-418, 21-419, 21-428,* **[**and**]** 21-434, *21-252— 21-256, 21-1202, 21-1203, and 21-1215,* Annotated Code of Maryland

10.15.08 (June 24, 2015)

.01 Scope.

This chapter:

A. Establishes a **[**pilot**]** farmstead cheese program; and

B. Sets forth the **[**standards**]** *regulation and enforcement process* for:

(1) **[**Plan**]** *The plan* review **[**of**]** *process for* facilities and equipment;

(2) The permitting process for the manufacture of cheese made from raw milk; **[**and**]**

(3) (text unchanged)

(a)—(c) (text unchanged)

(d) Inspections;

(e) Packaging;

(f) Distribution;

(g) Sale;

[(d)**]** *(h)* Sampling; **[**and**]**

[(e)**]** *(i)* Testing**[.]***; and*

(4) Assessment of the penalties pursuant Health-General Article, §§21-211, 21-252— 21-256, 21-418, 21-419, 21-428, 21-1202, 21-1203, and 21-1215, Annotated Code of Maryland.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Aging of cheese" means the storing and maturing of cheese under controlled conditions of temperature and humidity.

(2) "Aging period" means the aging of raw milk cheese for at least 60 calendar days at a temperature of not less than 35°F.

(3) "Aging room" means the area where the aging of cheese takes place.

(4) "Dairy farm" means a place or premises:

(a) Where one or more lactating animals, including cows, goats, sheep, water buffaloes, or other hooved mammals, are kept for milking purposes; and

(b) From which the milk is sold or offered for sale.

(5) "Department" means the Department of Health and Mental Hygiene.

(6) "Departmental inspection area" means the area in which the Department routinely makes inspections under Health-General Article, Title 21, Subtitle 4, Annotated Code of Maryland.

(7) "Drug Residue" means a substance that prevents the growth of bacteria in milk products.

(8) "Farmstead cheese" means a cheese made on a dairy farm:

(a) Using only the raw milk produced by the herd or flock on the dairy farm; and

(b) That meets the definitions and standards of a hard cheese, as set forth in 21 CFR Part 133.

(9) "Industry plant sampler" means:

(a) An individual responsible for the collection of official samples for regulatory purposes at a plant as outlined in the Grade "A" Pasteurized Milk Ordinance, Appendix N; and

(b) An employee of the plant who is evaluated a least once every 2 year period by a sampling surveillance officer or a properly delegated sampling surveillance official.

(10) "Milk" means the milk of a cow, goat, or other hooved mammals.

(11) "Official laboratory" means a laboratory that is a biological, chemical, or physical laboratory, which is under the direct supervision of the Department.

(12) "Officially designated laboratory" means a laboratory that is a:

(a) Commercial laboratory authorized to do official work by the Department; or

(b) Milk industry laboratory officially designated by the Department for the examination of producer samples of raw milk for drug residue.

(13) "Plant" means any place, premise. or establishment where milk or milk products are collected, handled, processed, stored, packaged or otherwise prepared for distribution as a Farmstead cheese.

(14) "Raw milk" means unpasteurized milk.

(15) "Sanitation inspection" means an evaluation of the milk plant and associated processes in accordance with this chapter.

(16) "Sanitization" means:

(a) The application of any effective method or substance to properly clean surfaces for the destruction of pathogens and other microorganisms, as far as is practicable; and

(b) A treatment that:

(i) Does not adversely affect the equipment, the milk, milk product, or the health of consumers; and

(ii) Is acceptable to the Department.

.03 Incorporation by Reference.

In this chapter, the following documents are incorporated by reference:

A. (text unchanged);

B. 21 CRF Part 110, as amended;

[B.**]** *C.* 21 CFR Part 133, as amended; **[**and**]**

D. Nutrition Labeling and Education Act of 1990 (Public Law 101-535), as amended;

[C.**]** *E.* (text unchanged)

F. 21 USC §§ 401-423, as amended;

G. Food and Drug Administration Compliance Program Guidance Manual, Program 7303.803 (November 9, 2008); and

H. Grade "A" Pasteurized Milk Ordinance, 2013 Revision (U.S. Department of Health and Human Services, Public *Health Service, Food and Drug Administration), Section 8, Appendix D, Appendix G, Section I, Appendix H Section II, and Appendix N only.*

.04 General Requirements.

A. The Department shall ensure that all inspections, sampling, testing, and enforcement actions performed by the State are carried out as set forth and in compliance with the standards, requirements, and procedures specified in:

(1) Health-General Article, Title 21, Annotated Code of Maryland;

(2) Federal Food, Drug and Cosmetic Act, 21 USC §§341-350; and

(3) Nutrition Labeling and Education Act of 1990 (Public Law 101-535).

B. An individual engaged in an occupation involving farmstead cheese production shall conduct all farmstead cheese production activities as set forth at and in compliance with the standards, requirements, and procedures specified in:

(1) Health-General Article, Title 21, Annotated Code of Maryland;

(2) Federal Food, Drug and Cosmetic Act, 21 USC §§341-350; and

(3) Nutrition Labeling and Education Act of 1990 (Public Law 101-535).

.05 [Production of Farmstead Cheese] Permitting Requirements.

A. **[**Permitting.

(1) Pursuant to Health-General Article, §§21-410 *and 21-412,* Annotated Code of Maryland, a person shall obtain a permit from the Secretary to operate as a producer.

(2) A person may not operate as a producer without obtaining a permit from the Secretary.

(3) A person seeking a permit shall provide the Department with the plans and specifications set forth in Regulation .06 of this chapter.**]** *Pursuant to Health-General Article, §§21-410 and 21-412, Annotated Code of Maryland, a person shall obtain a permit from the Department and pay the required fee, as specified in COMAR 10.01.17, to the Department before the person may be a:*

(1) Milk producer; or

(2) Milk Processor—Farmstead Cheese Producer.

[(4)**]** *B.* The Department may grant or deny a permit based on the criteria, *as* set forth in this chapter.

[(5)**]** *C.* To qualify for a permit, **[**the**]** *an* applicant **[**may not operate a dairy farm with more than 120 cows or goats in the herd.**]** *shall:*

[(6) An applicant shall pay to the Department a fee of $100 for a permit.**]**

(1) Provide the Department with the plans and specifications set forth in Regulations .14, .15, and .16 of this chapter;

(2) Submit an application to the Department on the forms that the Department provides; and

(3) Pay the Department's required permit fee, as specified in COMAR 10.01.17.

[(7)**]** *D.* A permit **[**expires**]***:*

(1) Expires 1 year from the date of issuance**[.]***;*

[(8)**]** *(2)* **[**A producer may renew a permit**]** *May be renewed by a producer* for a 1-year period upon the payment of the required fee, as specified in COMAR 10.01.17 **[.]***; and*

[(9)**]** *(3)* [A permit may**]** *May* not be transferred from one person to another person or from one farmstead cheese facility to another.

[(10) The Secretary may only issue a permit to the first five applicants who meet the requirements set forth in this chapter.**]**

[B. Labeling. A producer shall mark:

(1) Each farmstead cheese product with a label that conforms to the standards and requirements established by 21 CFR Part 101; and

(2) Conspicuously all packages containing farmstead cheese with the:

(a) Name of the product;

(b) Ingredients, in order of predominance;

(c) Identity of the facility where the farmstead cheese was produced; and

(d) The number of days of aging required by 21 CFR Part 133.

C. Testing.

(1) A producer:

(a) Is responsible for the cost associated with the sampling and testing of raw milk and the farmstead cheese product;

(b) Shall test all raw milk for the presence of inhibitors before processing;

(c) If raw milk is found to test positive for inhibitors, may not use it for production of farmstead cheese unless confirmatory testing proves that the raw milk does not contain inhibitors;

(d) Shall maintain a written log of the inhibitory testing done on the farm;

(e) Shall test monthly samples of raw milk used in the manufacture of farmstead cheese for:

(i) Standard plate count;

(ii) Somatic cell count;

(iii) Inhibitors;

(iv) Temperature;

(v) Odor; and

(vi) Appearance;

(f) Shall use raw milk to produce farmstead cheese that meets the quality and test requirements in COMAR 10.15.09.11;

(g) Shall have the first three batches of each cheese product tested by a certified laboratory for the presence of:

(i) Salmonella;

(ii) Escherichia coli;

(iii) Listeria monocytogenes;

(iv) Staphylococcus aureus; and

(v) Enterohemorrhagic E. coli (0157:H7);

(h) After three consecutive batches of each farmstead cheese product are found by testing to be in compliance with quality and test requirements in this regulation, shall test each cheese product once annually for the presence of:

(i) Salmonella;

(ii) E. coli;

(iii) Listeria monocytogenes;

(iv) Staphylococcus aureus; and

(v) Enterohemorrhagic E. coli (0157:H7);

(i) Shall test the water used in the manufacture of farmstead cheese every 6 months to assure that the water is potable as set forth in Regulation .06C of this chapter; and

(j) Shall ensure that the results of all testing of raw milk and cheese product are submitted to the Department's Laboratory Evaluation Officer.

(2) The Department may request the producer to have the producer's farmstead cheese products tested, as needed, as set forth in the United States Food and Drug Administration Food Compliance Program, "Domestic and Imported

Cheese and Cheese Products", to assure compliance with the standards found in COMAR 10.15.09.11 and this regulation.

D. Record Keeping. A producer shall:

(1) Establish and use a process to identify each batch of farmstead cheese for the purpose of traceability; and

(2) Maintain a written record of the:

(a) Date and results of testing of raw milk for inhibitors;

(b) Date and results of testing of farmstead cheese;

(c) Date each batch entered the aging room;

(d) Batch identification;

(e) Measure of acidity in each batch at 24 hours and 60 days; and

(f) Origins of all ingredients used in the processing of farmstead cheese.**]**

E. Subject to the availability of sufficient inspection and testing staff, equipment, and other resources, the Department shall issue a permit entitled Milk Processor—Farmstead Cheese Producer:

(1) To an applicant in accordance with Health-General Article, §§21-415 and 21-416.1, Annotated Code of Maryland; and

(2) For the purpose of performing the specific process or processes to the specific milk or milk products as indicated on the plan review and permit applications.

.06 Sanitation Inspection Frequencies and Reports for Plants.

A. A farmstead cheese processor shall meet the standards set forth in this chapter.

B. The Department shall conduct sanitation inspections of a plant within the Departmental Inspection Area and any other area designated by the Department:

(1) At the start-up of farmstead cheese processing;

(2) Once every 6 months; and

(3) In response to a complaint received by the Department or a local health department.

C. Once a year a water supply survey shall be conducted to ensure that the requirements in Regulation .14 and .15 of this chapter are met.

D. Reinspections.

(1) If an inspection discloses the existence of a critical or repeat violation of a requirement set forth in this chapter, the Department shall reinspect within 30 days to determine compliance with the requirements of this chapter.

(2) If the Department finds on the second inspection a violation of the same requirement of this chapter, the Department shall issue a notice of intent to suspend the permit or a compliance schedule.

(3) If the Department finds a violation of the same requirement as specified on the notice of intent to suspend the permit or the compliance schedule as specified in the notice, the Department shall:

(a) Suspend the permit in accordance with Regulation .20 of this chapter and Health-General Article, §§21-418 and 21-419, Annotated Code of Maryland; or

(b) Initiate appropriate court action.

E. Inspection Reports.

(1) The Department shall give one copy of the inspection report to the permit holder or other responsible person or post the inspection report in a conspicuous place on an inside wall of the establishment immediately after the conclusion of the inspection.

(2) The permit holder:

(a) May not deface the inspection report; and

(b) Shall make the inspection report available to the Department upon request.

.07 Sanitation Inspection Standards for a Plant.

A plant shall meet the sanitation inspection standards set forth in this regulation:

A. Floor – Construction.

(1) The floor of each room in which product containers, utensils, equipment, milk, or cheese products are handled, processed, packaged, stored, or washed shall be:

(a) Constructed of concrete or other equally impervious and easily cleanable material; and

(b) Smooth, properly sloped, provided with trapped drains, and kept in good repair.

(2) Floor drains are not required in cold storage rooms used for storing milk and cheese products when the floor is sloped to drain to one or more exits.

(3) A storage room for storing dry ingredients, packaged dry ingredients, and packaging materials may have:

(a) Floor drains; and

(b) Floors constructed of tightly joined wood.

B. Wall and Ceiling – Construction. The wall and ceiling of each room in which milk or cheese products is handled, processed, packaged, or stored shall:

(1) Have a smooth, washable, light colored surface; and

(2) Be in good repair.

C. Door and Window.

(1) The plant shall provide effective means to prevent access by insects and rodents.

(2) An opening to the outside shall:

(a) Have solid doors or glazed windows; and

(b) Be closed during weather conditions that may result in particulate matter entering the facility.

D. Lighting and Ventilation. Each room shall be well lit and well ventilated where:

(1) Milk and cheese products are:

(a) Handled;

(b) Processed;

(c) Packaged; or

(d) Stored; or

(2) Milk containers, utensils, and equipment are washed.

E. Separate Room.

(1) There shall be a separate room for:

(a) Receiving farmstead cheese;

(b) Processing farmstead cheese;

(c) Cooling farmstead cheese;

(d) Aging farmstead cheese;

(e) Packaging farmstead cheese; and

(f) Cleaning raw milk cans and containers brought in from the farm.

(2) A room may not open directly into a stable or room used for a domestic purpose where:

(a) Milk or a farmstead cheese product is:

(i) Received;

(ii) Handled;

(iii) Processed;

(iv) Stored; or

(v) Packaged; or

(b) Containers, utensils, or equipment are washed or stored.

(3) A room shall be of sufficient size for their intended purposes.

(4) Each designated area or room shall be provided for receiving, handling, and storage of a returned packaged or farmstead cheese not suitable for sale.

F. Toilet Sewage Disposal Facility.

(1) Each toilet facility shall conform to the regulations of the local health department.

(2) Each toilet facility may not open directly into a room where milk or cheese products are processed.

(3) Each toilet facility shall be completely enclosed and have a tight fitting, self-closing door.

(4) Each dressing room, toilet room, and fixture shall be:

(a) Kept in a clean condition;

(b) Kept in good repair;

(c) Well ventilated; and

(d) Well lit.

(5) Sewage and other liquid waste shall be disposed of in a sanitary manner.

G. Water Supply. Water for plant purposes shall be:

(1) From a supply properly located, protected, and operated;

(2) Easily accessible;

(3) Adequate; and

(4) Of a safe, sanitary quality.

H. Handwashing Facility. A hand washing facility shall:

(1) Provide:

(a) Either:

(i) Hot and cold running water; or

(ii) Warm running water;

(b) Soap; and

(c) Individual sanitary towels.

(2) Be kept in a clean condition and in good repair.

I. Plant Cleanliness.

(1) A room shall be kept clean, neat, and free of evidence of insects and rodents where:

(a) Milk and a farmstead cheese product is:

(i) Handled;

(ii) Processed; or

(iii) Stored; or

(b) Containers, utensils, or equipment are washed or stored.

(2) Only equipment directly related to processing operations or the handling of containers, utensils, and equipment shall be permitted in a room where:

(a) Receiving;

(b) Processing;
(c) Cooling;
(d) Aging;
(e) Packaging;
(f) Bulk milk is stored; or
(g) A cheese product is stored.

J. Sanitary Piping.

(1) The material of a sanitary piping fitting and connection exposed to milk, cheese products, or liquids drawn into milk and cheese products shall be:

(a) Smooth;
(b) Impervious;
(c) Corrosion resistant;
(d) Nontoxic;
(e) Easy cleanable; and
(f) An approved surface for food product contact.

(2) All piping shall be in good repair.

K. Construction and Repair of Containers and Equipment.

(1) A multiuse container and equipment that milk and a farmstead cheese product comes into contact with shall be:

(a) Constructed of smooth, impervious, corrosion resistant, and nontoxic material;
(b) Constructed for ease of cleaning; and
(c) Maintained in good repair.

(2) A single service container, closure, gasket, and other article that milk and a farmstead cheese product come in contact with shall be:

(a) Nontoxic; and
(b) Manufactured, packaged, transported, and handled in a sanitary manner.

(3) Articles intended for single service use may not be reused.

L. Clean and Sanitation of Containers and Equipment.

(1) The contact surface of a multiuse container, utensil, and equipment used in the farmstead cheese process from receiving through packaging shall, before each use, be effectively cleaned and sanitized.

(2) Sanitization:

(a) May not adversely affect the equipment, the milk or milk product, or the health of consumers; and
(b) Shall be acceptable to the Department.

(3) A cloth used for cheese making shall be cleaned and sanitized at intervals, and in accordance with the Department.

M. Storage of Cleaned Containers and Equipment. After cleaning, a multiuse milk or farmstead cheese product container, utensil, and equipment shall be:

(1) Transported and stored to assure complete drainage; and
(2) Protected from contamination before use.

N. Storage of Single Service Containers, Utensils, and Materials. A wrap, liner, bag, container, gasket, and other single service article in contact with milk and a farmstead cheese product shall be:

(1) Purchased and stored in a sanitary tube, wrapping, or carton;
(2) Kept in a clean, dry place until used; and
(3) Handled in a sanitary manner.

O. Protection from Contamination.

(1) The facility, plant operation, and equipment shall be located and used in a manner to prevent contamination of a milk and farmstead cheese product, ingredient, container, utensil, and equipment.

(2) A milk or a farmstead cheese product ingredient shall be discarded if:

(a) Spilt;
(b) Overflowing;
(c) Leaking; or
(d) Dropped or has fallen onto an unsanitized contact surface or nonproduct contact surface.

(3) The processing or handling of a product other than milk or a farmstead cheese product in the plant, shall be performed to preclude the contamination of such milk and farmstead cheese products.

(4) The storage, handling, and use of a poisonous or toxic material shall be performed to preclude the contamination of:

(a) A milk and a farmstead cheese product;
(b) An ingredient of milk and a farmstead cheese product; or
(c) The product contact surface of a container, utensil, and equipment.

P. Cross Contamination.

(1) During processing, a pipeline and equipment used to contain or conduct milk and a farmstead cheese product shall be effectively separated from each tank or circuit containing cleaning or sanitizing solutions.

(2) Separation shall be accomplished by:

(a) Physically disconnecting a connection point between each tank or circuit containing a cleaning or sanitizing solution from a pipeline and equipment used to contain or conduct a milk or farmstead cheese product; or

(b) A method approved by the Department.

(3) The farmstead cheese processor shall provide a means to prevent contamination of milk and a farmstead cheese product, container, utensil, and equipment from dripping, spillage, and splash from an overhead piping, platform, or mezzanine.

(4) A product that may create a public health hazard may not be handled in the plant.

(5) Permission to handle a product other than farmstead cheese or to conduct an operation in equipment or a room, other than those designated, shall be provisional and subject to revocation if found objectionable.

Q. Raw Milk Cooling and Farmstead Cheese Processing.

(1) Raw milk shall be maintained at 7ºC (45ºF) or less until processed.

(2) Farmstead cheese shall meet the definition of a hard cheese as found in 21 CFR 133.150 which states hard cheese:

(a) Contains not more than 39 percent of moisture; and

(b) Solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in 21 CFR 133.5(a), (b), and (d).

(3) Farmstead cheese shall be cured at a temperature of not less than 35˚F for not less than 60 days.

R. Personnel Sanitation.

(1) An individual shall wash their hands thoroughly before commencing a plant function and as often as may be required to remove soil and contamination.

(2) An employee may not resume work after visiting the toilet room without thoroughly washing their hands.

(3) An individual shall wear clean outer garments while engaged in the:

(a) Handling of raw milk and ingredients;

(b) Processing of a farmstead cheese product;

(c) Storage of a farmstead cheese product;

(d) Transportation of a farmstead cheese product;

(e) Packaging of a farmstead cheese product; and

(f) Handling of a container, utensil, and equipment.

(4) An individual, while engaged in the processing of milk or a farmstead cheese product, shall:

(a) Wear an adequate hair covering;

(b) Abstain from tobacco use;

(c) Wear clean and sanitized footwear;

(d) Maintain trim and clean fingernails and not wear false fingernails; and

(e) Abstain from any activity that may contaminate food.

(5) The farmstead cheese processor shall ensure that education and training is provided to an employee in:

(a) Food processing and handling;

(b) Personal hygiene; and

(c) Plant sanitation.

S. Vehicles.

(1) A vehicle used for the transportation of raw milk and a farmstead cheese product shall be constructed and operated so that the milk and the farmstead cheese product is maintained at 7ºC (45ºF) or less and is protected from contamination.

(2) A vehicle used to transport milk and a farmstead cheese product may not be used to transport or contain a substance that may be toxic or harmful to humans.

T. Surroundings.

Plant surroundings shall be kept neat, clean, and free from conditions which:

(1) Attract or harbor flies, other insects, or rodents; or

(2) Otherwise constitute a nuisance.

.08 Examination and Standards of Raw Milk, Farmstead Cheese Finished Products, and Water Supply.

A. Raw Milk Sampling and Testing Standards.

(1) The farmstead cheese processor is responsible for the collection and cost associated with the sampling and testing of raw milk used for the manufacture of farmstead cheese;

(2) Sampling shall be conducted by an industry plant sampler;

(3) The raw milk used for the manufacture of farmstead cheese shall be tested monthly for:

(a) Bacteria;

(b) Drug residue;

(c) Temperature;

(d) Odor; and

(e) Appearance.

B. Raw Milk Quality Standards.

(1) A standard plate count of raw milk for farmstead cheese may not exceed 500,000 per milliliter;

(2) Raw milk shall meet the following drug residue standards:

(a) Raw milk for farmstead cheese shall be negative for drug residue.

(b) Before processing, the industry plant sampler shall collect a representative sample of raw milk used in the manufacture of farmstead cheese; and

(c) An official laboratory or officially designated laboratory shall conduct drug residue testing for the presence of drug residue in accordance with the Grade "A" Pasteurized Milk Ordinance, Appendix N.

(3) Raw milk shall meet the following temperature standards:

(a) Raw milk for farmstead cheese shall be cooled to 7˚C (45°F) or less within two hours after initial milking;

(b) The blend temperature after the first and subsequent milkings may not exceed 10°C (50°F).

(c) Raw milk for farmstead cheese shall be cooled to and maintained at a temperature not to exceed 7°C (45°F).

(4) The appearance and odor of raw milk used for farmstead cheese shall be free from:

(a) Objectionable feed;

(b) Off odors; and

(c) Abnormalities.

(5) In accordance with the Department, an official laboratory or officially designated laboratory shall test a composite milk sample and shall rate it "acceptable for use" if there is no actionable residue for:

(a) Radionuclides;

(b) Pesticides; and

(c) Herbicides.

(6) Added water shall be tested on an individual producer's milk in accordance with the Department's official laboratory or officially designated laboratory and rated "acceptable for use" if the test result is-0.540˚H or less.

C. Farmstead Cheese Finished Product Sampling.

(1) The farmstead cheese processor is responsible for the collection and cost associated with the sampling and testing of a finished farmstead cheese product;

(2) Sampling shall be conducted by an industry plant sampler;

(3) The initial three finished products of each farmstead cheese shall be tested for:

(a) Salmonella;

(b) Escherichia coli (E. coli);

(c) Listeria monocytogenes;

(d) Staphylococcus aureus;

(e) Enterohemorrhagic E. coli (0157:H7); and

(f) Percent moisture.

(4) The finished product of each farmstead cheese shall be tested annually and is in accordance with §C(3) of this regulation.

D. Farmstead Cheese Finished Product Quality Standards. The farmstead cheese finished product:

(1) Shall test negative for Salmonella, Enterohemorrhagic E. coli (0157:H7), and Listeria monocytogenes;

(2) Shall test less than 10 cfu/gram for E. coli and Staphylococcus aureus; and

(3) May not be greater than 39 percent moisture.

E. Farmstead Cheese Processing Standards. The farmstead cheese:

(1) Finished product shall be aged at least 60 calendar days before offering for sale;

(2) Shall be aged or cured at a temperature of not less than 35˚F; and

(3) Finished product may not contain more than 39 percent moisture at the end of the aging period.

F. The farmstead cheese processor shall ensure that the result of all tested farmstead cheese finished products are submitted and approved by the Department before further processing or sale of the farmstead cheese.

G. The Department may request that the farmstead cheese processor have the farmstead cheese finished product tested, as needed, as set forth in the United States Food and Drug Administration Food Compliance Program, "Domestic and Imported Cheese and Cheese Products," to ensure compliance with this regulation.

H. Water Samples.

(1) Samples for bacteriological testing of the plant water supply and, if applicable, any other water used for cooling and processing shall be collected:

(a) Upon the initial approval of the physical structure;

(b) Every six months thereafter; and

(c) When any repair or alteration to the water supply system has been made.

(2) Plant water for testing shall be obtained from a potable water supply system that complies with Regulation .15A of this chapter.

(3) Samples shall be taken by the Department and examined by an official laboratory.

I. Record Keeping Required.

(1) Current written step by step standard operating procedures are required for:

(a) Product trace back;

(b) Product recalls;

(c) Drug residue testing;
(d) Cleaning of the equipment and facility;
(e) Sanitizing equipment and product contact surfaces;
(f) Receiving, processing, aging, storage, and packaging of each type of farmstead cheese produced;
(g) Pest control and preventative maintenance; and
(h) Employee training including personal hygiene practices;
(2) Processing records shall include the:
(a) Product being manufactured;
(b) Drug residue testing as set forth in the Grade "A" Pasteurized Milk Ordinance, Appendix N;
(c) Date and result of the raw milk testing;
(d) Date and result of the finished farmstead cheese product tested;
(e) The pH of each batch after inoculation at 5 hours, 24 hours, and the end of aging; and
(f) Raw ingredient:
(i) Origin;
(ii) Storage;
(iii) Transportation; and
(iv) Other information required by the Department; and
(g) Temperature, as set forth in Regulation .07 of this chapter.
(3) For each batch of farmstead cheese produced, a make record shall be maintained and include:
(a) The name of the product being produced;
(b) The temperature of the milk being used;
(c) A unique identifier assigned at the start of the production of that batch of cheese shall be:
(i) Used to track each batch of cheese through the production process; and
(ii) Included on the product label;
(d) The amount of product being produced;
(e) The name and amount of each ingredient added;
(f) The cook temperature;
(g) The pH of the product after inoculation at 5 hours, 24 hours, and the end of aging; and
(h) The production date for the product which is the date the batch entered the aging room to start the aging process; and
(4) Each record shall be available to the Department for review during each inspection.

.09 Enforcement Actions.
A. Raw Milk Enforcement.
(1) When two of the last four consecutive bacterial count or cooling temperatures, taken on separate days, exceed the limit for raw milk, as set forth in this chapter, the Department shall:
(a) Send to the permit holder a written notice of intent to suspend the permit which shall remain in effect as long as two of the last four consecutive samples exceed the limit of the standard; and
(b) Take an additional sample within 21 days of the written notice of intent to suspend, but not before 3 days have elapsed.
(2) When the standard set forth in Regulation .08 of this chapter is violated three of the last five consecutive bacterial counts or cooling temperature tests the Department shall immediately suspend the permit in accordance with this section, Regulation .20 of this chapter, and Health-General Article, §21-418, Annotated Code of Maryland.
(3) The Department shall conduct an investigation and take enforcement action in accordance with the Grade "A" Pasteurized Milk Ordinance, Appendix N, when a drug test is positive.
(4) When an odor and appearance evaluation results in rejection of milk:
(a) The Department shall conduct an investigation to determine the reason for the rejection; and
(b) A person may not offer the rejected milk for sale.
(5) When a pesticide, herbicide, or radionuclide residue test is positive:
(a) The Department shall conduct an investigation to determine the cause and the cause shall be corrected;
(b) An additional sample shall be taken and tested for the pesticide, herbicide, or radionuclide, and no milk shall be used for processing or offered for sale until it is shown by a subsequent sample to be free of the positive residue; and
(c) The Department may suspend a permit based on the presence of pesticide, herbicide, or radionuclide residue.
B. Farmstead Cheese Finished Product Enforcement.
(1) When the pathogen testing result exceeds the limits set forth in Regulation .08 of this chapter, the cheese in violation may not be offered for sale, and the:
(a) Department shall conduct an investigation to determine the cause; and
(b) Cause shall be corrected prior to resumption of processing.
(2) A person may not offer for sale a farmstead cheese product if the processing requirement is in violation of this chapter at the end of the aging period:

(a) Days of aging;
(b) Temperature during aging; or
(c) Percent moisture.
(3) Cheese may be detained and further pathogen testing may be required to show compliance.
C. Reinstatement of Permits.
(1) To reinstate a permit that is suspended for either a bacteria count or cooling violation the permit holder shall:
(a) Submit a written application for the reinstatement of the permit;
(b) Successfully complete a Department inspection of the facility within 1 week of a reinstatement request to ensure that the condition responsible for the violation is corrected;
(c) Accept a temporary permit if it has determined that the facility is in compliance; and
(d) Complete an accelerated sampling program at the rate of no more than two samples per week on separate days within a 3 week period to confirm that the violation has been corrected.
(2) The Department shall fully reinstate the permit upon compliance with the appropriate bacteria and temperature standard as determined in accordance with Regulation .08 of this chapter.
(3) To reinstate a suspended permit for violations other than bacteriological, drug residue test, or cooling temperature standards, the permit holder shall:
(a) Notify the Department that the violation has been corrected; and
(b) Successfully complete a Department inspection of the facility within 1 week of a reinstatement request to ensure that the condition responsible for the violation is corrected.
(4) When a permit suspension has been due to a positive drug residue, the permit shall be reinstated in accordance with the provisions of the Grade "A" Pasteurized Milk Ordinance, Appendix N.

.10 Improper Handling of Milk Products.
A. Pursuant to Health-General Article, §21-428, Annotated Code of Maryland, the Department shall impound milk or a milk product intended for human consumption due to improper handling.
B. The Department may:
(1) Issue an order to make the milk or milk product unusable for consumption before disposing of the milk or milk product; and
(2) Impose a civil monetary penalty, as set forth in §C of this regulation.
C. The Department shall determine the amount of the civil monetary penalty by multiplying the volume of the milk listed on the shipping documents by the current milk price of the applicable market, as set by the Federal Milk Market Administrator on the date of the impounding.
D. A person subject to an impoundment order may seek legal recourse, as set forth in Health-General Article §21-428, Annotated Code of Maryland, by:
(1) Appealing a civil penalty; or
(2) Bringing an action for damages.

.11 Labeling of Farmstead Cheese.
A. A farmstead cheese processor shall:
(1) Ensure all labels for a farmstead cheese product conform to the standards and requirements established by:
(a) The Federal Food, Drug, and Cosmetic Act, 21 USC, §§341—350f;
(b) The Nutrition Labeling and Education Act of 1990 (Public Law 101-535);
(c) 21 CFR Parts 101 and 133; and
(d) Health-General Article, §21-424, Annotated Code of Maryland; and
(2) Conspicuously mark each package containing farmstead cheese with the:
(a) Name of the product;
(b) Name of the manufacturer that made the farmstead cheese;
(c) Address of the manufacturer if:
(i) Listed in the local phone book, the address may consist of the city and state; or
(ii) Not listed in the local phone book, the street address shall be included;
(d) Plant license number;
(e) Each ingredient in order of predominance;
(f) Net weight of the product in English and metric units;
(g) Batch identification of the product;
(h) Required nutritional information;
(i) Statement:
(i) "Cured or aged for 60 days at a temperature not less than 35˚F;" or
(ii) A variation of this phrase that conveys the fact that the product has been aged at least 60 days; and
(j) Statement that the milk was not pasteurized, using terms such as "raw milk" or "not pasteurized."

.12 Sale of Raw Milk.

Pursuant to Health-General Article, §21-434, Annotated Code of Maryland, a person may not sell raw milk for human consumption.

.13 Animal Health.

All raw milk for farmstead cheese shall meet the Animal Health requirements as set forth in the Grade "A" Pasteurized Milk Ordinance, Section 8.

.14 Plant Construction and Plan Submission.

Pursuant to Health-General Article, §§21-410, 21-411, and 21-413 for construction, reconstruction, or extensive alteration of a milk facility, a person shall submit to the Department:

A. A plan and specification before:

(1) A plant is constructed, reconstructed, or extensively altered;

(2) An existing building or structure is converted or remodeled for use as a plant;

(3) A plant process is added, replaced, relocated, or modified; or

(4) A clean-in-place (CIP), other washing system, or part of a CIP is added, modified, or replaced;

B. A plan and drawing bearing the name of a professional engineer or a representative of the company performing the work;

C. Contact information for the facility, including:

(1) The full name, title, and telephone number of each applicant;

(2) The name of the plant;

(3) The mailing address;

(4) The location; and

(5) Directions to the site;

D. A narrative describing the scope and purpose of the project, including a projected timeline from start to completion;

E. An estimate of the finished product output per day;

F. A sample product label for each product;

G. A list of the:

(1) Type of raw milk cheese to be processed and sold;

(2) Each raw ingredient and the ingredient source; and

(3) Single service container source;

H. A scale drawing showing the layout and arrangement of an area within and around the plant, including the:

(1) Processing area;

(2) Chemical storage;

(3) Dry storage;

(4) Ingredient and product storage;

(5) Receiving area;

(6) Load out area;

(7) Laboratory space;

(8) Office;

(9) Restroom facility;

(10) Locker or similar storage facility for the storage of personal items; and

(11) Separate area for employees to eat and drink beverages;

I. A scale drawing showing the location of all equipment, including the:

(1) Milk processing equipment;

(2) Milk tank and silo;

(3) CIP system;

(4) Glycol water tank;

(5) Recirculating cooling water tank;

(6) Boiler; and

(7) Boiler makeup tank;

J. A scale drawing showing the location of plumbing and each plumbing fixture, including the:

(1) Water line;

(2) Sewer line;

(3) Hand sink;

(4) Toilet;

(5) Utility sink;

(6) Utensil washing sink;

(7) Floor drain;

(8) Floor sink;

(9) Hose station; and

(10) Back flow prevention device;

K. A legend for each drawing;

L. Specifications for:
(1) Ventilation, including, but not limited to, the type and location of:
(a) An air filter;
(b) An air pump; and
(c) A compressor; and
(2) Construction material for the building and interior finish;
M. A list and description of boiler, glycol, and recirculating water additive and water treatment;
N. A description of the:
(1) Type of disposal for wastewater and sewage;
(2) Source and system for the facility's potable water supply;
(3) Lighting fixture and placement; and
(4) Recirculating cooling system;
O. Each specification sheet, including manufacturer and model number of the plant equipment;
P. A document that lists the flow for a products through the plant identifying each functional piece of equipment and each process used in processing and packaging;
Q. A CIP flow diagram from the makeup tanks through all equipment;
R. Information and drawings on how separation from product lines will be accomplished, if applicable;
S. Written step by step standard operating procedures for:
(1) Receiving, processing, aging, storing, and packaging of each type of farmstead cheese product;
(2) Drug residue testing;
(3) Cleaning and sanitization for all equipment;
(4) Cleaning and sanitization for the facility;
(5) Product trace back, inclusive of production/make sheet; and
(6) Product recall;
T. Pest and mite control program;
U. A specification and standard operating procedure for how wood shelving used in the aging of cheese will be:
(1) Designed;
(2) Installed;
(3) Used;
(4) Cleaned;
(5) Sanitized;
(6) Maintained; and
(7) Inspected by the farmstead cheese processor; and
V. Employee training and personal hygiene practices.

.15 Physical Plant Requirements for Plants.
A. Water used at a farmstead cheese facility shall:
(1) Be obtained from a potable water supply system that complies with:
(a) Environment Article, Title 9, Annotated Code of Maryland;
(b) COMAR 26.04.04; and
(c) The Grade "A" Pasteurized Milk Ordinance, Appendix D;
(2) Be installed in a manner that prevents backflow or back siphoning;
(3) Be separate from a nonpotable water supply system so that nonpotable water can be drawn or discharged into the potable water supply system;
(4) Provide hot and cold running water in an area where milk processing equipment is washed; and
(5) Have sufficient water capacity, pressure, and hot water generation and distribution to meet peak demands throughout the washing system;
B. Hand sinks shall have:
(1) Either:
(a) Hot and cold running water; or
(b) Warm running water;
(2) A supply of hand cleaning soap or detergent; and
(3) A sanitary means of drying hands, such as individual towels or a hand drying device;
C. A sewage system shall be constructed and operated in conformance with applicable State and local laws, ordinances, and regulations;
D. Plumbing shall be sized, installed, and maintained in accordance with applicable State and local plumbing laws, ordinances, and regulations; and
E. Electrical systems at the facility shall:
(1) Comply with State and local electrical laws, ordinances, and regulations;
(2) Provide adequate lighting sources that furnish at least 30 foot candles of light in all working areas and rooms where:
(a) Milk or a milk product is handled, processed, packaged, or stored; or

(b) A container, utensil, and equipment are washed; and

(3) Provide adequate lighting sources that furnish at least five foot candles of light in dry storage and cold storage rooms.

.16 Plan Review and Approval Process.

A. An applicant may not construct, reconstruct, or extensively alter a plant without prior plan approval from the Department.

B. An applicant for a permit shall submit a plan to the Department that includes the requirements set forth in Regulations .14 and .15 of this chapter.

C. The Department shall:

(1) Review the plan submitted under this regulation to ensure compliance with the requirements set forth in Regulations .14 and .15 of this chapter; and

(2) Inform the applicant:

(a) That the plan has been received;

(b) If additional information is required to complete the plan review;

(c) Whether the plan is approved or denied; and

(d) Of the appeal process, if the plan is denied.

.17 Personnel Health.

No individual affected with any disease capable of being transmitted to others through the contamination of food shall work at a plant in any capacity which brings them into direct contact with:

A. Raw milk, a farmstead cheese product, and a food ingredient; or

B. Associated raw milk and a food product contact surface.

.18 Procedure When Infection or High Risk of Infection is Suspected or Discovered.

In accordance with Health-General Article, §§18-102, 21-253, 21-254, and 21-435, Annotated Code of Maryland, when an individual working at a plant has a communicable disease or is a carrier of a communicable disease the Department:

A. Shall immediately exclude the:

(1) Individual from handling milk, milk products, milk containers, and milk equipment; and

(2) Milk supply that is handled by the infected individual from distribution and use; and

B. May require medical and biological examination of the individual and the individual's bodily discharges.

.19 Confidentiality.

The Department shall maintain confidentiality of records submitted by a person in accordance with §4-335 of the General Provisions Article, Annotated Code of Maryland.

.20 Suspension and Revocation of Permits.

A. When a farmstead cheese processor is found in violation of this chapter, the Department may suspend or revoke a permit as set forth in this regulation and Health-General Article, §§21-211, 21-418, or 21-419, Annotated Code of Maryland.

B. Except as otherwise provided in this regulation, before suspending a permit, the Department shall give to the farmstead cheese processor notice of intent to suspend as provided by Health-General Article, §21-418, Annotated Code of Maryland.

C. The Department may suspend a permit if the farmstead cheese processor fails or neglects to correct a violation within the specified time period.

D. If a permit has been suspended more than once, the Department may revoke the permit.

E. When an immediate and substantial danger is found to exist to public health, safety, or welfare that requires emergency action, pursuant to Health-General Article, §21-418(c) and State Government Article, §10-226(c)(2), Annotated Code of Maryland, the:

(1) Department shall:

(a) Summarily suspend the permit;

(b) Order the farmstead cheese processor to cease operation immediately; and

(c) Promptly provide the farmstead cheese processor with:

(i) A written notice of the suspension of the permit;

(ii) The reasons for the suspension; and

(iii) An opportunity to be heard; and

(2) The farmstead cheese processor shall immediately cease operation upon the receipt of the summary suspension order.

.21 Appeals Process.

In accordance with the Administrative Procedures Act and Health-General Article, §21-419 the Department shall ensure that an opportunity for a hearing is provided to a farmstead cheese processor whose plan review or permit has been:

A. Denied;
B. Suspended; or
C. Revoked.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene

Incorporation by Reference
APPROVAL FORM

Date: October 29, 2015
COMAR: 10.15.08.03

Michele Phinney, Director
DHMH – Office of Regulation and Policy Coordination
201 West Preston Street
Room 512
Baltimore, MD 21201

Dear Michele:

The following documents are approved for incorporation by reference:
1. Grade "A" Pasteurized Milk Ordinance, 2013 Revision; and
2. Food and Drug Administration Compliance Program Guidance Manual, Program 7303.803 (November 9, 2008).

Please note the following special instructions: None

Attach a copy of this approval form when submitting an emergency or proposed regulation to the AELR Committee and when submitting a proposed regulation to DSD for publication in the Maryland Register. If submitting through ELF, include as part of the attachment.

Any future changes to the incorporated documents do not automatically become part of the regulation. If there are subsequent changes to the incorporated documents, and the agency wishes those changes to become a part of its regulations, the agency must amend the regulation incorporating the documents.

Please call us if you have any questions.

Sincerely,
Gail S. Klakring
Senior Editor