STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein M.D., Secretary

October 24, 2013

The Honorable Martin O'Malley
Governor
100 State Circle
Annapolis, MD 21401-1991

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis, MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis, MD 21401-1991

RE: HB 243/SB 808, Chapters 610/609 (2009) - Milk Products – Pilot Farmstead Cheese Program – Repeal of Sunset

Dear Governor O'Malley, President Miller, and Speaker Busch:

Pursuant to HB 243 and SB 808, Chapters 610/609 of the Acts of 2009 – Milk Products – Pilot Farmstead Cheese Program – Repeal of Sunset, the Department of Health and Mental Hygiene respectfully submits the enclosed report on the status of the Farmstead Cheese Program.

If you should have any questions about the report or about the Farmstead Cheese Program, please do not hesitate to contact Ms. Marie Grant, Director of Governmental Affairs at 410-767-6481.

Sincerely,

Joshua M. Sharfstein, M.D.
Secretary

Enclosure

Cc: Laura Herrera, M.D., M.P.H.
Marie Grant, J.D.
Michelle Spencer, M.S.
Donna Gugel, M.H.S.
Clifford Mitchell, M.S., M.D., M.P.H.
Sarah Albert, MSAR #7904

Report on the Status of the Farmstead Cheese Program

HB 243/SB 808, Chapters 610/609 of the Acts of 2009

September 2013

MARTIN O'MALLEY
Governor

ANTHONY G. BROWN
Lieutenant Governor

JOSHUA M. SHARFSTEIN, MD
Secretary

Background

Pursuant to House Bill 243/Senate Bill 808, Chapters 610/609 of the Acts of 2009, the Department of Health and Mental Hygiene (the Department) is required to submit a report on the status of the farmstead cheese program to the Governor and, in accordance with §2-1246 of the State Government Article, the General Assembly.

With dairy farms declining across the State, dairy farmers are seeking ways to add value to their raw milk by processing the milk into safe, marketable products. In 2006, one dairy farm producer in Talbot County worked with local Delegates, the Department and the Maryland Department of Agriculture (MDA) to create a bill that would allow the manufacture of raw milk cheese. In 2007, House Bill 865, Chapter 437 – Milk Products – Farmstead Cheese Production – Pilot Study was passed, establishing a pilot study for this dairy farm producer to be permitted to process farmstead cheese. Farmstead Cheese is defined as a cheese that is made on a dairy farm using only the raw milk produced by the herd on the farm and meets the definitions and standards of a hard cheese, as set forth in the Code of Federal Regulations Title 21 Part 133. In the 2008 and 2009 legislative sessions the statue was amended with the following revisions:

HB 1624, Chapter 332 of the Acts of 2008

- Subject to the availability of sufficient inspection and testing staff, equipment, and other resources, authorized the Secretary to issue up to five milk processor – farmstead cheese producer permits under the pilot program;
- Limited the pilot study to five (5) years; and
- Established a Laboratory Testing Fund for the processing of laboratory specimens associated with the production of farmstead cheese.

HB 243/SB 808, Chapters 610/609 of the Acts of 2009

- Removed the limitation of five (5) milk producers to participate in the pilot program;
- Removed the five (5) year limitation on the pilot study program; and
- Required the Department to submit a report on the status of the farmstead cheese program.

The Department established a Farmstead Cheese Pilot Study program and developed regulations guiding the program (Pilot Farmstead Cheese Program – COMAR 10.15.08). This program is administered by the Department's Center for Milk and Dairy Product Safety (CMDPS).

The United States Food and Drug Administration (FDA) recognizes aging of hard cheese as an effective means of destroying bacteria. Hard cheese can be safely made from raw milk, using a specialized aging process of not less than sixty (60) days, where conditions such as pH, moisture, salt, time, temperature and other factors are carefully controlled and monitored to destroy pathogenic organisms which may be present. COMAR 10.15.08 requires the processor to monitor the pH, time, and temperature. The regulations also require the processor to add salt and to test for the presence of five (5) different pathogens at the end of the 60 day aging process.

History of the Program

The Department's CMDPS worked cooperatively with the MDA and other states that regulate raw milk cheese processing to develop a Farmstead Cheese Program in Maryland. As a result, CMDPS established criteria for participation in the program and developed the Pilot Farmstead Cheese Program regulations, COMAR 10.15.08.

The Department established the following criteria for participation in the Pilot Farmstead Cheese Program:

- The milk producer may not operate a dairy farm with more than 120 cows, goats or sheep in the herd;
- The cheese that is made on the dairy farm can only be from the raw milk produced by the dairy herd on that farm;
- Only hard cheese that meets the definitions and standards as set forth in the Code of Federal Regulations Title 21 Part 133, can be produced; and
- The milk producer must obtain a milk processor – farmstead cheese producer permit from Department as set forth in regulation.

In June of 2008 and 2009, CMDPS staff visited licensed raw milk cheese processors in Pennsylvania and New Jersey. Currently forty-five (45) states allow the production of raw milk cheese. Each state has their own set of regulation and policies. CMDPS spoke with milk program managers in other states to learn how raw milk cheese is made and regulated. This allowed the Department to review regulations in other states and criteria used to evaluate the manufacturing of raw milk hard cheeses, paying particular attention to hazard analysis, equipment usage, pH testing, salt content, moisture content, and bacteria that may be present. CMDPS staff received training from an expert raw milk cheese consultant. This training emphasized raw milk cheese production safety precautions. The Department studied FDA research papers and compliance guidelines, the Journal of Food Protection documents, Dairy Practice Council guidelines to Farmstead Cheesemaking, and United State Department of Agriculture guidance documents for Inspection and Sanitation regarding food safety in raw milk cheese processing. Based on the information learned, CMDPS promulgated COMAR 10.15.08, Pilot Farmstead Cheese Program. These regulations established a pilot farmstead cheese program and set forth standards for:

- Plan review of facilities and equipment;
- The permitting process for the manufacture of cheese made from raw milk; and
- Farmstead cheese production, labeling, record keeping, sampling and testing to ensure a safe finished product.

Specifically, the regulations require:

- All raw milk must be tested for the presence of inhibitors (antibiotics) prior to processing;
- The raw milk must be tested monthly for quality parameters (Standard Plate Count and Somatic Cell Count, Temperature, Odor, and Appearance);
- The finished, aged cheese must be annually tested for the presence of the following most common pathogens found in raw milk cheese: Salmonella, Escherichia coli, Listeria monocytogenes, Staphylococcus aureus and Enterohemorrhagic E. coli (0157:H7);

- The pH of every batch of cheese must be measured at twenty-four (24) hours and at sixty (60) days;
- The water used in the manufacturing of farmstead cheese must be tested every six (6) months to assure the water is potable;
- Detailed recordkeeping and process make records; and
- Product label requirements.

While CMDPS was developing the program and promulgating the regulations, MDA launched an outreach program to inform the dairy industry about the new Farmstead Cheese Program. After the regulations were established, CMDPS sent an interest letter to all persons who inquired about the program, setting a deadline of June 1, 2010 for plan review submittal.

Current Program

There are currently three (3) Maryland permitted milk processor-farmstead cheese producers participating in the Pilot Farmstead Cheese program, producing six (6) different types of hard raw milk cheeses. They are located in Talbot County, Prince George's County, and Carroll County.

The Department conducts a thorough analysis of the cheese making process at each site to help ensure safe food handling practices in an effort to prevent foodborne disease outbreaks. Each cheese producer must submit detailed plans which include: plant drawings, Standard Sanitation Operating Procedures (includes cleaning and sanitizing procedures, step-by-step processing, recipes, and testing procedures), label examples, pest control and preventive maintenance plans, equipment information, and record keeping procedures.

To ensure that all regulatory requirements are met, the Department's inspectors conduct inspections of the milk processor-farmstead cheese producer operation:

- During the plan review process (2-4 on-site inspections);
- At the start-up of farmstead cheese processing;
- Once every 6 months; and
- In response to complaints received by the Department or a local health department.

Challenges Identified in the Program

Great care must be taken to ensure the safety of public health in the processing of farmstead cheese. Each time a farmstead cheese producer started a new operation, the Department expended a significant amount of time and resources to assist the facility in ensuring the highest quality and safety of the cheese product. While the Farmstead Cheese Program has been a success, CMDPS has spent many hours, including on the phone and on the farm site, educating the processor about how to operate a processing plant, in addition to reviewing plans, and ensuring regulation compliance. As a result other regulatory duties, such as mandated inspections of milk tank trucks and mandated evaluations of bulk milk hauler samplers, were not completed in a timely manner. If the Farmstead Cheese Program expands, additional resources would be needed to maintain compliance with other requirements delegated to CMDPS.

Adequate resources are imperative to provide the oversight needed to ensure a safe product. One foodborne disease outbreak from consuming raw milk cheese could have a negative impact on the Farmstead Cheese Program.

Knowledge of safe cheese making is necessary. Therefore, it is crucial for the applicant to attend approved training, which is not currently available in Maryland due to limited resources. Previously, the University of Maryland offered training, but as a result of budget constraints is no longer able to provide this service. Additional resources dedicated to the CMDPS would enable trainings to be offered on a more regular basis. Otherwise the required training would be incurred as an additional expense to participating producers.

Findings and Recommendations

During the pilot study critical factors that determine the safety of raw milk cheese were monitored. Moisture control, pH control and salt content inhibit growth of pathogenic bacteria. Acidification (pH) is the most critical factor in testing and monitoring. Before aging the raw milk cheese, the pH must drop to 5.0 – 5.9 to help prevent pathogens from multiplying. With the addition of salt during the aging process, the moisture in the product is bound, to further prevent the multiplication of pathogens. As the product ages and dries, the pH may stay acidic or return to 6.5 – 7.0 depending on the type of cheese. The pH was monitored at all three permitted facilities participating in the pilot study. The pH results were satisfactory (See Table 1a-f attached for results). Table 1 shows the results of the pH testing done by the facility for each batch of cheese made. The pH was tested at 24 hours and again at 60 days. The results show that the cheese is acidic at 24 hours and then the cheese either stays acidic or returns to 6.5 – 7.0 depending on the type of cheese. It is crucial that the cheese is acidic within 24 hours to kill most pathogens. The pH results demonstrate the cheese making process is being done correctly by each facility.

The first three batches of each new raw milk cheese made were tested at 60 days (the end of the aging process) for the presence of Salmonella, Escherichia coli, Listeria monocytogenes, Staphylococcus aureus and Enterohemorrhagic E. coli (0157:H7). The cheese then was tested annually at 60 days for the same five (5) pathogens. The participants in the study complied with these testing requirements. All tests were negative for all five pathogens (See Table 2 attached for results). Table 2 shows the results of the required pathogen testing of each cheese made. No pathogens were found in any of the cheese that was tested.

The Farmstead Cheese Program participants have been successful in marketing and selling the cheese, although it has been a challenge to balance their resources. Operating both a dairy operation and a milk processing operation has, at times, been challenging for participants because of the amount of time and resources it takes to properly operate the production of raw milk cheese.

The issue of extending the aging process requirement from 60 to 90 days is under consideration at the federal level. The FDA is currently studying the sixty (60) day aging process of raw milk cheese to determine if the aging process should be extended. The FDA has not indicated when results of this study will be released or if existing guidance will be revised.

Currently forty-five (45) states allow the production of raw milk cheese. The safety of raw milk cheese is reliable when production methods follow national standards and confirmed by laboratory testing. Based on the findings of this study, Maryland farmstead raw milk cheese processors were able to replicate the success of other state producers and produce a safe product for human consumption.

The Farmstead Cheese Program has been successful and well received by the producers and the community. The Department makes the following recommendations for the continuance of the program:

- Continuation of the existing Maryland farmstead raw milk program, and
- At the request of the pilot study participants, revise some of the existing language in COMAR 10.15.08 to provide a clearer understanding of the testing requirements.

At this time, the Department is uncertain as to how many dairy producers would be interested in participating in the Farmstead Cheese Program if it were expanded. Three facilities have inquired about participating in the program over the past few years. However, the Department has no specific plans to expand the program beyond the current pilot program. In order to do so, the Department would require the following additional resources:

- 1 full-time inspector;
- 1 state vehicle; and
- Testing equipment including: thermometer, water bath, mite light, black light, laptop computer, printer, coolers, and sampling equipment.

The Department looks forward to continue to work with the existing Farmstead Cheese Pilot Study participants to ensure the success of the program. The Department recognizes the value of expanding the ability of Maryland farmers to produce and market safe and value-added farm products in different ways.

Farmstead Cheese Table 1a

pH at 24 hrs. and 60 Days

Blue Cheese

Make Date	24 Hours	60 Days	
		Interior	Exterior
9/29/2009	4.82	ND*	7.10
10/3/2009	4.90	ND*	6.25
10/7/2009	4.70	ND*	ND*
10/19/2009	4.80	ND*	7.21
9/1/2010	5.31	ND*	5.71
6/30/2010	4.87	ND*	6.81**
5/11/2011	5.02	ND*	ND*
5/9/2013	4.70	6.90	6.80
5/15/2013	4.60	5.80	6.60
5/16/2013	4.70	6.10	6.60
7/31/2013	4.70	ND*	ND*
5/1/2011	4.85	6.85	6.95
5/3/2013	4.85	7.05	7.15
5/8/2013	4.85	6.95	6.50
4/7/2012	5.00	7.05	8.10
5/1/2013	5.20	5.42	7.05

* No Data ** performed 11/4/10

Farmstead Cheese Table 1b

pH at 24 hrs. and 60 Days

Cheddar

Make Date	24 Hours	60 Days
6/20/2011	5.30	5.26
6/25/2011	5.30	5.45
7/3/2011	5.40	5.86
4/16/2012	5.01	5.85
4/29/2013	5.30	5.05

Farmstead Cheese Table 1c

pH at 24 hrs. and 60 Days

Dreamy Creamy

Make Date	24 Hours	60 Days	
		Interior	Exterior
11/17/2011	4.99	7.05	4.89
11/25/2011	5.08	*7.10	*4.80
12/1/2011	5.10	**6.85	**5.90
4/10/2012	4.98	5.25	7.20
4/18/2012	4.98	4.87	7.30
4/25/2012	4.85	5.19	7.33
5/8/2013	4.82	5.05	5.76

*77 days

**84 days

Farmstead Cheese Table 1d

pH at 24 hrs. and 60 Days

Aquasco Jack Cheese

Make Date	24 Hours	60 Days
5/21/2012	5.20	5.25
5/28/2012	5.01	5.23
6/14/2012	4.84	4.97
5/31/2013	5.04	4.95

Farmstead Cheese Table 1e

pH at 24 hrs. and 60 Days

Tomme

Make Date	24 Hours	60 Days
8/6/2011	4.82	ND*
8/9/2011	5.10	ND*
8/12/2011	5.18	ND*
4/13/2012	5.53	5.38
4/16/2012	5.52	5.34
4/19/2012	5.66	5.39
4/13/2013	5.47	5.29

*No Data

Farmstead Cheese Table 1f

pH at 24 hrs. and 60 Days

Colby

Make Date	24 Hours	60 Days
5/9/2012	5.87	5.69
5/12/2012	5.78	5.52
6/4/2012	5.80	5.49
5/3/2013	5.80	5.47

Farmstead Cheese Table 2

Pathogen Test Results

Test Date	Batch lab #	Make Date	Salmonella	E.Coli o157:H7	Listeria moncytogenes	Staph Aureus	Enter. E. Coli
Blue Cheese							
12/22/2009	093BC	9/29/2009	neg.	neg.	neg.	<10	<10
12/22/2009	089BC	10/3/2009	neg.	neg.	neg.	<10	<10
12/22/2009	085BC	10/7/2009	neg.	neg.	neg.	<10	<10
11/4/2010	181	6/30/2010	neg.	neg.	neg.	<10	<10
8/18/2011	131	5/11/2011	neg.	neg.	neg.	<10	<10
6/16/2012	Bay Blue 81	3/21/2012	neg.	neg.	neg.	<10	<10
5/10/2013	31	1/31/2013	neg.	neg.	neg.	<10	<10
5/17/2011	5/1/2011	5/1/2011	neg.	neg.	neg.	<10	<10
5/17/2011	5/3/2011	5/3/2011	neg.	neg.	neg.	<10	<10
5/17/2011	5/8/2011	5/8/2011	neg.	neg.	neg.	<10	<10
9/21/2011	6/12/2011	6/12/2011	neg.	neg.	neg.	<10	<10
9/21/2011	7/8/2011	7/8/2011	neg.	neg.	neg.	<10	<10
9/21/2011	8/4/2011	8/4/2011	neg.	neg.	neg.	<10	<10
6/14/2012	20110407	4/17/2012	neg.	neg.	neg.	<10	<10
7/13/2013	20130501	5/1/2013	neg.	neg.	neg.	<10	<10
Cheddar							
12/23/2011	6/20/2011	6/20/2011	neg.	neg.	neg.	<10	<10
12/23/2011	6/25/2011	6/25/2011	neg.	neg.	neg.	<10	<10
12/23/2011	7/3/2011	7/3/2011	neg.	neg.	neg.	<10	<10
7/13/2013	20130429	4/29/2013	neg.	neg.	neg.	<10	<10

Test Date	Batch lab #	Make Date	Salmonella	E.Coli O157:H7	Listeria moncytogenes	Staph Aureus	Enter. E. Coli
		Dreamy Creamy					
2/14/2012	12/8/2011	12/8/2011	neg.	neg.	neg.	<10	<10
2/14/2012	11/25/2011	11/25/2011	neg.	neg.	neg.	<10	<10
2/14/2012	12/1/2011	12/1/2011	neg.	neg.	neg.	<10	<10
6/14/2012	20110410	4/10/2011	neg.	neg.	neg.	<10	<10
7/13/2013	20130508	5/8/2013	neg.	neg.	neg.	<10	<10
8/7/2012	20120521	5/21/2012	neg.	neg.	neg.	<10	<10
8/7/2012	20120604	6/4/2012	neg.	neg.	neg.	<10	<10
8/7/2012	20120611	6/11/2012	neg.	neg.	neg.	<10	<10
7/13/2013	20130503	5/3/2013	neg.	neg.	neg.	<10	<10
		Aquasco Jack Cheese					
8/7/2012	20120521	5/21/2012	neg.	neg.	neg.	<10	<10
8/7/2012	20120604	6/4/2012	neg.	neg.	neg.	<10	<10
8/7/2012	20120611	6/11/2012	neg.	neg.	neg.	<10	<10
7/13/2013	20130503	5/3/2013	neg.	neg.	neg.	<10	<10
		Tomme					
11/28/2011	2080511	8/6/2011	neg.	neg.	neg.	<10	<10
11/28/2011	3081011	8/9/2011	neg.	neg.	neg.	<10	<10
12/6/2011	2080011	8/12/2011	neg.	neg.	neg.	<10	<10
6/29/2012	1041312	4/13/2012	neg.	neg.	neg.	<10	<10
6/29/2012	2041612	4/16/2012	neg.	neg.	neg.	<10	<10
6/29/2012	2041912	4/19/2012	neg.	neg.	neg.	<10	<10
7/3/2013	4041313	4/13/2013	neg.	neg.	neg.	<10	<10
		Colby					
8/9/2012	1050912	5/9/2012	neg.	neg.	neg.	<10	<10
9/5/2012	2051212	5/12/2012	neg.	neg.	neg.	<10	<10
9/5/2012	4060412	6/4/2012	neg.	neg.	neg.	<10	<10
7/3/2013	12050313	5/3/2013	neg.	neg.	neg.	<10	<10