

Regulatory Analysis Form

(Completed by Promulgating Agency)



IRRC

Independent Regulatory Review Commission

SECTION I: PROFILE

(1) Agency: Department of Agriculture

(2) Agency Number: 02

Identification Number: 160

IRRC Number:

2777

(3) Short Title: Milk Sanitation

(4) PA Code Cite: Title 7, Chapters 59 and 59a

(5) Agency Contacts (List Telephone Number, Address, Fax Number and Email Address):

Primary Contact: Paul M. Hoge, Tel: (724) 443-1585; Pennsylvania Department of Agriculture, Region IV Office, 6 McIntyre Road, Gibsonia, PA 15044-9644 Fax: (724) 443-8150 E-Mail Address: phoge@state.pa.us

Secondary Contact: William E. Chirdon, Tel: (717) 787-4315; Pennsylvania Department of Agriculture, 2301 North Cameron Street, Harrisburg, PA 17110-9408 Fax: (717) 787-1873 E-Mail address: wchirdon@state.pa.us

(6) Primary Contact for Public Comments (List Telephone Number, Address, Fax Number and Email Address) – Complete if different from #5:

(All Comments will appear on IRRC'S website)

(7) Type of Rulemaking (check applicable box):

- Proposed Regulation
- Final Regulation
- Final Omitted Regulation
- Emergency Certification Regulation;
 - Certification by the Governor
 - Certification by the Attorney General

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(8) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The regulation will:

(a) reflect developments in the dairy industry, food science and food technology since 1985 – when the regulation was last revised;

(b) bring Pennsylvania’s sanitation standards for pasteurized milk into closer alignment with the *Grade “A” Pasteurized Milk Ordinance* – a model document published by FDA and recommended for adoption by all States;

(c) bring Pennsylvania’s standards for “milk for manufacturing” into closer alignment with the current *Milk for Manufacturing Purposes and its Production and Processing – Recommended Requirements* – a document issued by USDA; and

(d) consolidate and update provisions addressing the production of raw milk for human consumption.

(9) Include a schedule for review of the regulation including:

- | | |
|---|------------------|
| A. The date by which the agency must receive public comments: | May 1, 2009 |
| B. The date or dates on which public meetings or hearings will be held: | None to be held. |
| C. The expected date of promulgation of the proposed regulation as a final-form regulation: | September 2009 |
| D. The expected effective date of the final-form regulation: | September 2009 |
| E. The date by which compliance with the final-form regulation will be required: | September 2009 |
| F. The date by which required permits, licenses or other approvals must be obtained: | September 2009 |

(10) Provide the schedule for continual review of the regulation.

The regulation will be reviewed on an ongoing basis.

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SECTION II: STATEMENT OF NEED

(11) State the statutory authority for the regulation. Include specific statutory citation.

The act of July 2, 1935 (P.L. 589, No 210) (31 P.S. §§ 645-660g), as amended, commonly referred to as the Milk Sanitation Law, prescribes the powers and duties of the Pennsylvania Department of Agriculture (Department) with respect to milk sanitation, and (at 31 P.S. § 660c) authorizes the Department to adopt the regulations necessary to administer the provisions of that statute. The Food Act (31 P.S. §§ 20.1 – 20.18) includes milk within the definition of a “potentially hazardous food” and (in 31 P.S. § 20.13) provides the Department broad authority to regulate as necessary for the proper enforcement of that statute.

(12) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

No.

(13) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The public has a direct health and safety interest in the Department having regulatory milk sanitation standards that are current, and that reflect the state-of-the-science with respect to the safe production, processing and handling of milk and milk products. The current regulation is out-of-date with respect to various milk safety standards - including those related to drug residue avoidance, pasteurization equipment design, the dairy Hazard Analysis Critical Control Point (HACCP) program, and others.

In addition, the Food and Drug Administration (FDA) has put the Department on notice that the successful promulgation of this regulation is part of a Strategic Action Plan to bring Pennsylvania’s milk sanitation standards into-step with those of other States; and that if the regulation does not proceed, Pennsylvania would not be compliance with National Conference on Interstate Milk Shippers (NCIMS) standards, and might lose the right to vote as a member of NCIMS as a result.

In addition, with the dramatic increase in the number of operations that possess Department-issued permits allowing them to produce and sell raw (unpasteurized) milk for human consumption, it has become more important to have regulations that set clear, safe, comprehensive standards for the production of raw milk for human consumption.

The regulation will benefit nearly all Commonwealth residents, since the majority of Pennsylvania’s 12.4 million citizens are consumers of milk and dairy products.

Pennsylvania’s 8,500-plus dairy producers and 872-plus milk permit holders will also benefit from the regulation. In addition, approximately 120 raw milk producers, and the persons who acquire and consume raw milk from these producers, will benefit from the updated raw milk permit provisions that will clarify the requirements for obtaining and maintaining a raw milk permit and attempt to protect the health of raw milk consumers. The foregoing benefits are not readily quantifiable.

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(14) If scientific data, studies, references are used to justify this regulation, please submit material with the regulatory package. Please provide full citation and/or links to internet source.

None.

(15) Describe who and how many will be adversely affected by the regulation. How are they affected?

The Department does not expect that there will be adverse effects from these updated regulations.

Although a small group of dairy processors may have to incur additional costs for testing required by the regulation, it is expected these costs will be offset by the reduced risk of antibiotic residues in finished product. The affected group will be some of the dairy processors that *only process milk for in-state sales*. There are approximately 40 such dairy processors at present. It is estimated that approximately 30 of these dairy processors would incur additional testing costs of about \$1,440/year (\$120/month) associated with paying third party laboratories for required testing. It is estimated that approximately 10 of these dairy processors would purchase their own testing equipment, which would entail an initial outlay of about \$3,000 and about \$1,200/year (\$100/month) in maintenance and testing supply costs, going forward. Based upon these estimates, the approximate costs associated with the referenced dairy processors implementing this regulation would be \$85,200 in Year 1 and \$55,200 in subsequent years. This is reflected below, in the response to Question No. 20.

(16) List the persons, groups or entities that will be required to comply with the regulation. Approximate the number of people who will be required to comply.

The number of people directly involved with Pennsylvania's dairy industry is difficult to quantify, but the following provides an estimate: approximately 8,500 dairy farms that produce milk within the Commonwealth, approximately 40 Grade "A" milk processing plants, approximately 120 Grade "A" Bulk Tank Units (permitted farm groups), approximately 120 permitted raw milk facilities, approximately 80 dairy manufacturing (non-Grade A) facilities, 46 Interstate Milk Shippers program certified laboratory facilities, 57 drug residue testing facilities, and 26 manufacturers of single service containers and closures.

SECTION III: COST AND IMPACT ANALYSIS

(17) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The regulation does not require any great change in the way the dairy industry is currently operating. Although it updates standards, technical details and program details, most of Pennsylvania's dairy industry is already in substantial compliance with the sanitation standards for pasteurized milk described in the *Grade "A" Pasteurized Milk Ordinance* or the standards for "milk for manufacturing" described in the USDA's document titled *Milk for Manufacturing Purposes and its Production and Processing – Recommended Requirements*. Since the regulation moves Pennsylvania's standards into closer alignment with these national standards, the regulation is not expected to impose significant new costs on the regulated community.

A *small* group of dairy processors – those few that *only process milk for in-state sales* - may be required to incur new testing costs as a result of the regulation. This is addressed in the responses to Question Nos. 15 and 20.

The regulation may result in savings to dairy producers, who may not be required to dump two days' worth of their production following certain bacterial or antibiotic violations. This savings would only be realized if the subject milk is resampled and found to be in compliance with the standards set forth in the regulation. These savings are not quantifiable.

There may be some savings to the dairy industry associated with a reduction in lawsuits and legal claims related to milk-related food borne illness outbreaks. This risk reduction would be very small, though. These savings are not quantifiable.

(18) Provide a specific estimate of the costs and/or savings to **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The regulation is not expected to result in any such costs or savings.

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(19) Provide a specific estimate of the costs and/or savings to **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

The regulation is expected to result in some new costs to the Department. These costs are estimated at \$180,000 per year. The basis for this estimate is set forth in Answer No. 20a, below.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year 2008 - 09	FY +1 Year 2009 - 10	FY +2 Year 2010 - 11	FY +3 Year 2011 - 12	FY +4 Year 2012 - 13	FY +5 Year 2013 - 14
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
Regulated Community	0	85,200 (estimate)	55,200 (estimate)	55,200 (estimate)	55,200 (estimate)	55,200 (estimate)
Local Government	0	0	0	0	0	0
State Government	0	0	180,000 (estimate)	180,000 (estimate)	180,000 (estimate)	180,000 (estimate)
Total Costs	0	85,200 (estimate)	265,200 (estimate)	235,200 (estimate)	235,200 (estimate)	235,200 (estimate)
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

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(20a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3 2005 - 06	FY -2 2006 - 07	FY -1 2007 - 08	Current FY 2008 - 09
GGO	\$29,451,000	\$30,042,000	\$29,696,000	\$31,340,000

(21) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The benefits of the regulation clearly outweigh any adverse effects or costs. The regulation will enhance public health and safety, establish modern state-of-the-science milk sanitation standards in Pennsylvania, and provide clarity to holders of raw milk permits. These benefits far outweigh any costs or adverse impacts associated with the regulation.

(22) Describe the communications with and input from the public and any advisory council/group in the development and drafting of the regulation. List the specific persons and/or groups who were involved.

The Department regularly communicates with the dairy industry through many professional associations, and did so in the preparation of the regulation, as well. One of the more prominent of these organizations is the PA Association of Milk, Food, and Environmental Sanitarians (PAMFES). The PAMFES Liaison Committee has been consulted by the Department during the past two years, as the proposed regulation has been developed. The Department provided the PAMFES Liaison Committee an advanced draft of the regulation, and made revisions in response to comments received.

The regulation is technical in nature. For this reason, the Department has made an effort to seek and use the experience and technical expertise of the impacted segments of the dairy industry in developing the regulation.

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(23) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory provisions were considered. The Department is satisfied that the regulation that is the subject of this document is the least-burdensome acceptable approach to achieving the Department's objectives (which are summarized in the response to Question No. 8).

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

Sections 59a.19(b)(19) and 59a.21(c)(1) of the regulation reference a requirement that raw milk for pasteurization be cooled to 40°F within 2 hours of completion of milking. Although this cooling requirement is more stringent than the 45°F standard set forth in the FDA's current *Grade "A" Pasteurized Milk Ordinance*, the 40°F standard has long been required within Pennsylvania, and the dairy industry meets this standard and is quite capable of continuing to meet this standard – without adverse financial impact. The Department believes this standard enhances the safety of milk and does not see the need to soften this standard in the regulation.

Sections 59a.19(8) and 59a.405(8) of the regulation maintain a requirement that there be an appropriate backflow protection device on a water line feeding a dairy farm heat exchanger. This is not required under applicable Federal standards, but the Department believes it helps avoid water contamination problems.

(25) How does this regulation compare with those of other states? How will this affect Pennsylvania's ability to compete with other states?

The regulation is quite similar to the milk sanitation regulations of other states; and will not put Pennsylvania at a competitive disadvantage with other states. If anything, it will facilitate the flow of Pennsylvania-produced milk and milk products in interstate commerce. Most state food safety regulatory authorities view the recommended regulatory standards set forth in the FDA's current *Grade "A" Pasteurized Milk Ordinance* as the best approach to milk sanitation. Since the regulation will largely adopt the provisions of the current *Grade "A" Pasteurized Milk Ordinance*, it will bring Pennsylvania's milk sanitation standards into closer step with the milk sanitation standards of other states.

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(26) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No.

(27) Submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The regulation will not appreciably impact current record keeping requirements.

(28) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

No such special provisions have been developed.

**FACE SHEET
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WITH THE LEGISLATIVE REFERENCE
BUREAU**

(Pursuant to Commonwealth Documents Law)

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Copy below is hereby approved as to form and legality.
Attorney General

By: *Angela M. Elliott*
(Deputy Attorney General)

JUL 14 2009

DATE OF APPROVAL

Check if applicable.
Copy not approved. Objections attached.

Copy below is hereby certified to be true and
correct copy of a document issued, prescribed or
promulgated by:

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 2-160

DATE OF ADOPTION 10/21/08

BY *Denny C Wolff*
DENNIS C WOLFF

TITLE
SECRETARY
Pennsylvania Department of Agriculture

Copy below is hereby approved as to form and legality
Executive of Independent Agencies

BY *Andrew C. Clark*
Andrew C. Clark

DATE OF APPROVAL **APR 24 2009**

(Deputy General Counsel)
(~~Chief Counsel - Independent Agency~~)
(Strike inapplicable title)

Check if applicable. No Attorney General Approval
or objection within 30 days after submission.

Notice of Proposed Rulemaking

**Title 7 – AGRICULTURE
7 Pa. Code Chapters 59 and 59a**

Milk Sanitation

DEPARTMENT OF AGRICULTURE

PROPOSED RULEMAKING

DEPARTMENT OF AGRICULTURE

MILK SANITATION [7 PA. CODE CHS. 59 AND 59a]

The Department of Agriculture (Department) proposes to delete the current regulation at 7 Pa. Code Chapters 59 and establish a new regulation at 7 Pa. Code Chapter 59a, to read as set forth in Annex A.

Statutory Authority

The Milk Sanitation Law (31 P.S. §§ 645 - 660g) (Act) and the Food Act (31 P.S. §§ 20.1 – 20.18) provide the legal authority for this regulation.

The Act prohibits (in 31 P.S. § 645) the sale of milk, milk products or manufactured dairy products within this Commonwealth unless the seller has a Department-issued permit, and (in 31 P.S. § 660c) authorizes the Department to adopt regulations necessary for the proper enforcement of the Act.

The Food Act (in 31 P.S. § 20.2) includes milk within the definition of a “potentially hazardous food” and (in 31 P.S. § 20.13) provides the Department broad authority to regulate as necessary for the proper enforcement of that statute, but (in 31 P.S. § 20.16) limits the circumstances under which the regulations can be inconsistent with Federal acts and regulations addressing the same subject matter.

Purpose

The protection of the health and safety of persons who consume milk, milk products and manufactured dairy products is the primary purpose of the proposed regulation. The secondary purpose is to provide the regulated community – persons who produce milk, milk products and manufactured dairy products within this Commonwealth for sale – with clearer standards that facilitate the production and sale of Pennsylvania-produced dairy products. The regulated community is quite diverse, with the size and sophistication of dairy production and processing operations varying dramatically. The proposed rulemaking would provide the entire regulated community clearer and better guidance on the basic sanitation and safe production practices necessary to protect the health and safety of consumers and preserve the vitality of Pennsylvania’s diverse dairy industry.

The proposed rulemaking would update the Department’s milk sanitation regulations to reflect developments in food science and food technology since the regulations were last amended. Food safety science is an evolving body of knowledge; and the proposed

rulemaking would help bring Pennsylvania's standards into alignment with the current state of the science.

In addition, the proposed rulemaking would bring Pennsylvania's regulatory standards relating to pasteurized milk into closer alignment with those recommended in the current *Grade "A" Pasteurized Milk Ordinance* (Grade "A" PMO). The Grade "A" PMO is a model document issued and updated by the U. S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. That agency recommends the Grade "A" PMO for adoption by all States "...in order to encourage greater uniformity and a higher level of excellence of milk sanitation practice in the United States" and to "facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce."

The proposed rulemaking would also bring Pennsylvania's regulatory standards relating to milk for manufacturing (milk that is produced for processing and manufacturing into products for human consumption that is not subject to the same requirements as milk for pasteurization) into closer alignment with those recommended in the current *Milk for Manufacturing Purposes and its Production and Processing – Recommended Requirements* (USDA Recommended Requirements) document issued by the U.S. Department of Agriculture, Agricultural Marketing Service, Dairy Program.

The proposed rulemaking would also consolidate and update provisions relating to the production of raw milk for human consumption.

The proposed regulation would help the regulated community by providing greater clarity, facilitating interstate commerce in pasteurized milk and bringing Pennsylvania's milk sanitation standards into alignment with well-known and well-regarded Federal standards.

Need for the Proposed Rulemaking

The proposed rulemaking is a much-needed update of the Department's milk sanitation regulations. The ultimate objectives of the proposed rulemaking are to help protect the health and safety of the consumer public, implement regulatory standards that align with national model standards and make the milk sanitation regulations more understandable to the regulated community.

The Department is satisfied there are no reasonable alternatives to proceeding with the proposed rulemaking. The Department is also satisfied the proposed rulemaking meets the requirements of Executive Order No. 1996-1, "Regulatory Review and Promulgation."

Overview of the Major Provisions of the Proposed Rulemaking

Proposed Subchapter A (relating to preliminary provisions) would lay the groundwork for the regulatory requirements that follow. Proposed § 59a.2 (relating to definitions)

contains various defined terms from the Act, the Food Act, the Grade "A" PMO, the current regulation at Chapter 59 and other sources. Proposed § 59a.4 (relating to approved inspectors) would establish the process by which a person may become an "approved inspector" authorized to conduct dairy farm inspections. Proposed § 59a.5 (relating to standards for Pennsylvania approved dairy laboratories, official laboratories and other laboratories; reports of results) would reference and adopt well-regarded national standards for the testing and examination of dairy products, and for the evaluation of dairy laboratories.

Proposed § 59a.11 (relating to adoption of Grade "A" PMO) would establish the standards of the Grade "A" PMO as those of the Department, except to the extent they are specifically contradicted by the Act, the Food Act or a specific provision in Chapter 59a. Although this single reference would suffice to incorporate the Grade "A" PMO standards as those of the Department, a number of other sections in Chapter 59a contain references to *specific provisions* of the Grade "A" PMO as guides to the regulated community.

Proposed § 59a.12 (relating to permits) would provide an overview of the process by which a person may obtain a permit from the Department, authorizing the lawful sale of milk, raw milk or manufactured dairy products.

Proposed § 59a.14 (relating to labeling: bottles, containers and packages of milk, milk products or manufactured dairy products) would provide detailed guidance on the type of product label information that would be helpful to the consumer.

Proposed § 59a.17 (relating to inspection of dairy farms and milk plants) would establish a requirement that dairy farm operations be inspected at least once every six months, and that milk plants and receiving stations be inspected at least once every three months. These inspection intervals derive from the Grade "A" PMO.

Proposed Subchapter C (relating to production and processing of milk for manufacturing purposes) would adopt the USDA Recommended Requirements as the Department's regulatory standards with respect to milk for manufacturing.

Proposed Subchapter D (relating to farms producing milk for manufacturing) would establish on-farm sanitation, equipment and procedural standards for farms that produce milk that is to be processed into manufactured dairy products for human consumption, but that is not subject to the same requirements as milk that is bound for fluid consumption.

Although Proposed Subchapter E (relating to manufacturing plants) would supplant current Subchapter 59(G), the result is basically an updating of current regulatory standards for plants that manufacture dairy products.

Proposed Subchapter F (relating to raw milk for human consumption) is intended to establish clear, reasonable standards for those dairy operations that produce

unpasteurized milk for human consumption. The current regulatory provisions addressing the production of raw milk for human consumption are spread throughout Chapter 59, are hard to find, and do not cover all of the subject matter that should be addressed in regulations on this subject. In recent years the Department has experienced a dramatic rise in the number of dairy operations that produce raw milk for human consumption under authority of Department-issued permits. The Department expects this new subchapter will provide raw milk permit holders a clear set of regulatory standards by which to operate.

Proposed § 59a.501 (relating to interrelatedness with Food Act) would make the important point that the Food Act provides the Department separate-but-related legal authority by which to address matters relating to milk (which is defined as a “potentially hazardous food” under the Food Act).

Affected Individuals and Organizations

The proposed rulemaking would benefit nearly all Commonwealth residents, since the majority of Pennsylvania’s 12.4 million citizens are consumers of milk and dairy products.

Pennsylvania’s 8,500-plus dairy producers and 872-plus milk permit holders will also benefit from the regulation. In addition, approximately 120 raw milk producers, and the persons who acquire and consume raw milk from these producers, will benefit from the updated raw milk permit provisions that will clarify the requirements for obtaining and maintaining a raw milk permit and attempt to protect the health of raw milk consumers. Also, approximately 40 Grade “A” milk processing plants, approximately 120 Grade “A” Bulk Tank Units (permitted farm groups), approximately 80 dairy manufacturing (non-Grade A) facilities, 46 Interstate Milk Shippers program certified laboratory facilities, 57 drug residue testing facilities, and 26 manufacturers of single service containers and closures will be impacted.

Fiscal Impact

Commonwealth: The proposed rulemaking is expected to impose approximately \$180,000-per-year in additional costs upon the Department, commencing with the 2010-2011 fiscal year.

Political Subdivisions: The proposed rulemaking would impose no costs and have no fiscal impact upon political subdivisions.

Private Sector: Most of the impacted regulatory community is familiar with the Grade “A” PMO and the USDA Recommended Requirements, and produces milk, milk products and manufactured dairy products to the standards prescribed by those documents. For these entities, the proposed regulation will have very little impact on day-to-day operations, and will not impose any appreciable new costs. In addition, the Department plans to help train the regulated community to minimize confusion and costs

related to implementing the new regulatory standards. A small section of the regulated community – approximately 40 dairy operations that process milk for in-state sales only - may need to acquire drug residue testing equipment in the initial year after the proposed regulation takes effect, or to incur costs related to testing by third party laboratories. The Department estimates these dairy operations would, in the aggregate, incur total costs of approximately \$85,200 in the first year after the proposed regulation takes effect, and costs of approximately \$55,200 in subsequent years.

General Public: The proposed rulemaking would impose no costs and have no fiscal impact on the general public. The proposal would enhance public safety.

Paperwork Requirements

The proposed rulemaking is not likely to appreciably impact upon the paperwork generated by the Department or the regulated community.

Effective Date

The proposed rulemaking will be effective upon publication in the *Pennsylvania Bulletin* as final-form rulemaking.

Sunset Date

There is no sunset date for the proposed rulemaking. The Department will review the efficacy of this regulation on an ongoing basis.

Public Comment Period / Contact Person

Interested persons are invited to submit written comments regarding the proposed regulation within 30 days following publication in the *Pennsylvania Bulletin*. Comments are to be submitted to the Department of Agriculture, Bureau of Food Safety, Division of Milk Sanitation, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: Paul Hoge.

Regulatory Review

The Department submitted a copy of the proposed regulation to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs on July 21, 2009, in accordance with section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)). The Department also provided IRRC and the Committees a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, “Regulatory Review and Promulgation.” A copy of this material is available to the public upon request.

If IRRC has an objection to any portion of the proposed regulation, it must so notify the Department within 30 days of the close of the public comment period.

The notification shall specify the regulatory criteria that have not been met by that portion. The Regulatory Review Act sets forth detailed procedures for review of these objections by the Department, the General Assembly and the Governor prior to the final publication of the proposed regulation.

DENNIS C WOLFF, *Secretary*

Annex "A"

Title 7

Chapter 59. MILK SANITATION

(This Chapter shall be rescinded in its entirety.)

CHAPTER 59a. MILK SANITATION

Subchapter A. PRELIMINARY PROVISIONS

Sec.

- 59a.1. Scope.
- 59a.2. Definitions.
- 59a.3. Contacting the Department.
- 59a.4. Approved inspectors.
- 59a.5. Standards for Pennsylvania approved dairy laboratories, official laboratories and other laboratories; reports of results.

§ 59a.1. Scope.

This chapter establishes the minimum requirements for the following:

- (1) The production, transportation, processing, handling, sampling, examination, labeling, and sale of milk, milk products and manufactured dairy products;
- (2) The inspection of dairy farms, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, milk tank trucks and bulk milk haulers/samplers;

(3) The issuing, suspension, and revocation of permits to milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, and distributors.

§ 59a.2. Definitions.

(a) *Terms.* The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

3-A Sanitary Standards—The latest standards for dairy equipment promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection and the Milk Safety Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services, or as otherwise defined in the Grade “A” PMO.

Act—The act of July 2, 1935 (P.L. 589, No 210), as amended (31 P.S. §§ 645-660g).

Adulterated—As defined in the Food Act, at 31 P.S. § 20.8.

Approved inspector—A person who has been licensed by the Department in accordance with § 59a.4 (relating to approved inspectors) to perform dairy farm inspections required under this Chapter in a capable and efficient manner.

Approved sampler—A person certified by the Department to obtain samples of milk or milk products for analysis by a Pennsylvania approved dairy laboratory.

Bulk tank unit (BTU)—A specified group of dairy farms from which milk for pasteurization or for manufacturing purposes is collected by a milk tank truck.

CIP--Cleaned in place—The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned, provided that:

(i) Components of the equipment which are not designed to be cleaned-in-place are removed from the equipment to be cleaned out-of-place or manually cleaned.

(ii) Product contact surfaces can either be readily inspected by the department or, with respect to product contact surfaces that cannot be readily inspected (such as permanently installed pipelines and silo tanks), their cleanability by cleaned-in-place cleaning has been accepted by the department.

Canned milk—Condensed, evaporated or concentrated milk in hermetically sealed containers or for manufacturing purposes.

Certified industry inspector—An approved inspector who has been licensed by the Department in accordance with subsection 59a.4(h) (relating to approved inspectors) to inspect dairy farms on which milk is produced for an interstate milk shipper. A certified industry inspector is the equivalent of a “certified industry inspector,” for purposes of conducting certified industry inspections described in the Grade “A” PMO.

Classification of farm sanitation compliance—

(i) *Passing*—A general compliance with sanitary standards established for the production of milk.

(ii) *Reinspect*—A significant noncompliance with sanitary standards

established for the production of milk requiring remedial action and a subsequent review to determine conformity.

(iii) *Suspend*—Major noncompliance with sanitary standards or evidence of conditions that would render the milk unsafe for human consumption, or if on the reinspection it is found that sufficient progress has not been made on the previously recommended corrections.

Commingled milk—Milk from two or more producers; in a milk plant, a representative sample of all daily sources of milk prior to pasteurization.

Dairy farm—A place or premise where one or more cows are kept, and a part of all the milk from which is sold or delivered to any person.

Department—The Pennsylvania Department of Agriculture.

FDA—The Food and Drug Administration of the United States Department of Health and Human Services, Public Health Service.

Food Act— The act of July 7, 1994 (P.L. 421, No. 70), as amended (31 P.S. §§ 20.1–20.18).

Food establishment—A retail food store and a room, building or place or portion thereof or vehicle maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, baking, canning, freezing, packing or otherwise preparing or transporting or handling food. The term includes those portions of public eating and drinking licensees which offer food for sale for off-premises consumption, except those portions of establishments operating exclusively under milk or milk products permits.

Grade "A" PMO— means the most current revision of the *Grade "A" Pasteurized Milk Ordinance* and its appendices, as published by the United States Department of Health and Human Services, Public Health Service/Food and Drug Administration. The Department maintains a link to an electronic copy of this document on its website: www.agriculture.state.pa.us.

Growth inhibitor—Any antimicrobial adulterant, including but not limited to antibiotics.

HACCP or Hazard Analysis Critical Control Point—The systematic approach to the identification, evaluation, and control of significant milk or milk product safety hazards, as described in the Grade "A" PMO.

Manufactured dairy products—Butter, cheese (natural or processed), dry whole milk, nonfat dry milk, dry buttermilk, dry whey, evaporated milk (whole or skim), condensed whole and condensed skim (plain or sweetened), and such other products for human consumption, as may be designated by the secretary.

Milk—Milk, skimmed milk, cream, sour milk, sourcream, buttermilk, and all other fluid derivatives of milk.

Milk for manufacturing purposes—Milk produced for processing and manufacturing into products for human consumption but not subject to requirements of milk for pasteurization.

Milk for pasteurization—Milk which conforms with relevant provisions of this chapter and is used in the preparation of pasteurized milk and milk products.

Milk plant or plant—Any place or premise or establishment where milk, milk for manufacturing purposes or milk for pasteurization is collected, separated,

processed, stored, bottled, pasteurized, or prepared in any manner for sale as milk, milk products or manufactured dairy products.

Milk products—Ice cream, ice cream mix, custard ice cream, french ice cream, frozen custard, and other similar frozen products, and all dairy products used in the manufacture thereof.

Misbranded—As defined in the Food Act, at 31 P.S. § 20.9.

Municipality—Any city, borough, town, or township in this Commonwealth.

NCIMS—The National Conference of Interstate Milk Shippers.

Official laboratory—A biological, chemical, or physical laboratory which is under the direct supervision of the Department.

PMO-defined milk products—Milk products that fit within the following description, or as otherwise defined in the Grade “A” PMO. The term includes the following:

- (i) Milk products including cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated (condensed) milk, concentrated (condensed) milk products, concentrated (condensed) and dry milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, buttermilk products, whey, whey products, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt,

nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk products as defined in the Grade "A" PMO, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products described in this definition.

(ii) Those dairy foods made by modifying the federally standardized products described in this definition, in accordance with 21 CFR 130.10 (relating to requirements for foods named by use of a nutrient content claim and a standardized term).

(iii) Milk and milk products described in this definition, which have been aseptically processed and then packaged.

(iv) Milk and milk products which have been retort processed after packaging or which have been concentrated (condensed) or dried if they are either:

(A) used as an ingredient to produce any milk or milk product described in this definition; or

(B) they are labeled as Grade "A" as described in the Grade "A" PMO.

(v) Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” dairy products, such as cottage cheese dressing mixes or starter media for cultures used to produce various Grade “A” cultured products if they meet the requirements of the Grade “A” PMO. If used as an ingredient in Grade “A” products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” requirements. Grade “A” powder blends must be made from Grade “A” powdered dairy products, except that small amounts of functional ingredients, (total of all ingredients shall not exceed 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e., sodium caseinate. This is similar to the existing FDA position that such dairy ingredient in small cans of freeze-dried starter culture need not be Grade “A.”

The term is not intended to include dietary products other than as described in the Grade “A” PMO, infant formula, ice cream or other frozen desserts, butter or cheese.

Pennsylvania approved dairy laboratory—

(i) A commercial or regulatory laboratory approved and certified by the Department within the preceding two years to do official analyses of milk and milk products.

(ii) A milk industry laboratory approved and certified by the Department within the preceding two years for the examination of

producer samples of raw milk for pasteurization or of commingled raw milk for pasteurization for the detection of drug residues, bacterial limits and somatic cell count.

Pennsylvania approved dairy laboratory director—An individual who has satisfactorily demonstrated competency by achieving a minimum score of eighty (80) percent on the written examination(s) and has demonstrated the necessary experience to direct the analytical and administrative activities of a Pennsylvania approved dairy laboratory in accordance with the methods and procedures adopted by the Department in § 59a.5 (relating to standards for Pennsylvania approved dairy laboratories, official laboratories and other laboratories; reports of results).

Permit holder—A person holding a permit issued by the Department to sell milk, PMO-defined milk products, milk products, or manufactured dairy products.

Person—Includes singular and plural, masculine and feminine, and any individual, firm, copartnership, institution, association, or corporation thereof.

Producer--The person or persons who exercise control over the production of the milk delivered to a plant, and who receives payment for this product. A “new producer” is one who is initiating the shipment of milk from a farm.

Raw milk—Milk that is not pasteurized and may be sold to consumers without further treatment or processing, provided that it conforms to the relevant provisions of this Chapter.

Secretary—The Secretary of Agriculture of this Commonwealth, or his authorized representative.

Standard Methods for the Examination of Dairy Products—the current edition of the *Standard Methods for the Examination of Dairy Products*, a publication of the American Public Health Association, 1015 Fifteenth Street, NW, Washington, D.C.20005.

“To sell,” “for sale” or “sold” and similar terms--The selling, exchanging, delivering, or having in possession, care, control, or custody with intent to sell, exchange, or deliver, or to offer or to expose for sale.

USDA Recommended Requirements -- The most current revision of the *Milk for Manufacturing Purposes and its Production and Processing – Recommended Requirements*, as published by the United States Department of Agriculture, Agricultural Marketing Service, Dairy Program.

Weigher/sampler—A bulk milk pick-up driver or a milk plant person certified by the Department or the Pennsylvania Milk Marketing Board to take official samples of producers’ milk for chemical, antibiotic, somatic cell and bacteriological analyses.

(b) *Additional terms used in this chapter and defined in the Grade “A” PMO.* Any word or term used in this chapter and not otherwise defined in subsection (a) shall have the meaning ascribed to it in the Grade “A” PMO.

(c) *Additional terms used in the Grade “A” PMO.* Any applicable word or term used in the Grade “A” PMO shall have the meaning ascribed to it in the Grade “A” PMO, with the exception of the term “Regulatory agency,” which shall mean the Department.

§ 59a.3. Contacting the Department.

For purposes of this Chapter, the Department may be contacted as follows:

(a) By mail, at the following address:

Pennsylvania Department of Agriculture
Bureau of Food Safety and Laboratory Services
ATTN: Division of Milk Sanitation
2301 North Cameron Street
Harrisburg, PA 17110-9408

(b) By telephone, as follows: (717) 787-4315

(c) Through the following website address: www.agriculture.state.pa.us

§ 59a.4. Approved inspectors.

(a) *Application.* A person may apply to the Department to be licensed as an “approved inspector” for purposes of the Act and this chapter. The Department shall provide application forms, or the renewal forms described in subsection (d), upon request to the address or website identified in § 59a.3 (relating to contacting the Department). An application fee of \$50 (or as otherwise prescribed by statute) shall accompany the application.

(b) *Criteria for approval.* An applicant must be at least 18 years of age, must have attended a PDA-approved seminar as described in subsection (e) within 12 months preceding the date of the application, and must demonstrate to the satisfaction of the

Department to be of good character and to have adequate education and/or experience to carry-out dairy farm and milk plant inspection in a capable and efficient manner.

(c) *License.* The Department shall issue a license to any person who follows the application process described in this section and meets the criteria for approval set forth in subsection (b).

(d) *Duration of license; renewal.* A license shall expire each year, as of January 1. Applications for renewal of a license shall be accompanied by a fee of \$20 (or as otherwise prescribed by statute), and confirmation that the applicant for renewal has attended a PDA-approved seminar as described in subsection (e) within 12 months preceding the date of the application, and shall be returned to the Department not later than December 31st of each year.

(e) *Education requirement.* PDA shall convene an approved inspector educational seminar on at least two separate dates each calendar year, and shall provide current approved inspectors written notice of the dates, times and locations of these seminars. As described in subsections (b) and (d), attendance at an educational seminar is a requisite to the Department issuing or renewing a license.

(f) *Status of approved inspectors.* An approved inspector is not an employee, agent or authorized representative of the Department, and shall not represent himself or herself to be any of these.

(g) *Refusal, revocation or suspension of certificate.* The Department may, upon written notice and opportunity for a hearing, refuse, revoke or suspend a license for cause.

(h) *Certified industry inspectors.* The Department may designate on the license of an approved inspector that the approved inspector is a certified industry inspector who may,

in addition to conducting the inspection activities of an approved inspector, inspect dairy farms on which milk is produced for an interstate milk shipper under the NCIMS Interstate Milk Shippers Program and the Grade "A" PMO.

§ 59a.5. Standards for Pennsylvania approved dairy laboratories, official laboratories and other laboratories; reports of results.

(a) *General standards.* A Pennsylvania approved dairy laboratory, an official laboratory or another laboratory that conducts sampling or laboratory examinations for purposes of this chapter shall conform that sampling or testing to the applicable standards and procedures set forth in the *Standard Methods for the Examination of Dairy Products*, the current edition of the *Official Methods of Analysis of the Association of Official Analytical Chemists*, or other methods approved by the Secretary. Procedures, including laboratory examination procedures and the certification of sample collectors, shall be evaluated in accordance with the current *Evaluation of Milk Laboratories, Recommendations of the United States Public Health Service/Food and Drug Administration.*

(b) *Reports of results.* If a Pennsylvania approved dairy laboratory issues a report of the results of laboratory examinations for purposes of this chapter, the report shall be signed by the laboratory director or a person designated by the laboratory director to sign these reports.

Subchapter B. PERMIT REQUIREMENTS

Sec.

- 59a.11. Adoption of Grade "A" PMO.
- 59a.12. Permits.
- 59a.13. Adulterated or misbranded milk, milk products of manufactured dairy products.
- 59a.14. Labeling: Bottles, containers and packages of milk, milk products or manufactured dairy products.
- 59a.15. Labeling: Milk dating.
- 59a.16. Markings, sealing and documentation for vehicles containing milk and milk products.
- 59a.17. Inspection of dairy farms and milk plants.
- 59a.18. Sampling and examination.
- 59a.19. Standards for grade "A" raw milk for pasteurization, ultra-pasteurization or aseptic processing.
- 59a.20. Standards for grade "A" pasteurized, ultra-pasteurized and aseptically processed milk and milk products.
- 59a.21. Standards.
- 59a.22. Animal health.
- 59a.23. Milk and milk products which may be sold.
- 59a.24. Transferring; delivery containers; cooling.
- 59a.25. Milk, milk products and manufactured dairy products from points outside the Commonwealth of Pennsylvania.

- 59a.26. Plans for construction and reconstruction.
- 59a.27. Personnel health.
- 59a.28. Procedure when infection or high risk of infection is discovered.

§ 59a.11. Adoption of Grade “A” PMO.

(a) *General adoption of the Grade “A” PMO.* The provisions, terms, procedures, appendices and standards of the Grade “A” PMO are adopted as the regulatory standards of the Department to the extent they do not conflict with:

- (1) the Act;
- (2) the Food Act; or
- (3) a provision of this chapter.

(b) *Specific references to applicable provisions of the Grade “A” PMO.* The provisions of this chapter contain, as guidance, references to the applicable provisions of the Grade “A” PMO.

§ 59a.12. Permits.

(a) *Permit required.* A person shall not sell milk, milk products or manufactured dairy products within the Commonwealth of Pennsylvania without having a current, valid permit from the Secretary, unless the person is exempt from this permit requirement under subsection (b). A separate permit shall be obtained for each milk plant, milk distributor, receiving station, transfer station and bulk tank unit, and by every producer of raw milk in accordance with Subchapter F (relating to raw milk for human consumption).

(b) *Exceptions.* The permit requirement of subsection (a) shall not be applicable to the following:

(1) A person selling or delivering milk directly from a dairy farm to a milk plant.

(2) A dairy farm producing and selling milk for pasteurization or milk for manufacturing shall not be required to obtain a permit.

(3) A person selling milk or milk products from a store, when the milk or milk products have been purchased from a person already in possession of a permit to sell milk or milk products.

(4) A hotel, restaurant, soda fountain, boarding house or other place where milk or milk products are to be consumed on-premises, and have been purchased from a person already in possession of a permit to sell milk or milk products.

(5) A person producing and selling milk from a single cow, and exempted from the permit requirement in accordance with the Act.

(c) *Obtaining a permit.* A person seeking a permit may obtain a permit application and additional information by contacting the Department through the means described in § 59a.3 (relating to contacting the Department). An entity that meets the requirements of § 59a.25 (relating to milk, milk products and manufactured dairy products from points outside the Commonwealth of Pennsylvania) shall be issued a permit.

(d) *Requirements for initial issuance of permit.* Within 30 days of receiving a complete application for an initial permit, the Department shall inspect the applicant's operation to determine whether it is in compliance with the standards of the Act and this chapter that

would be applicable if the applicant received the permit applied for. These standards must be met in order for the Department to issue the permit.

(e) *Requirements for issuance of a successor permit.* If an applicant seeks a permit that is to take effect upon the expiration of a predecessor permit, the Department shall approve the permit application if the dairy operation and the milk, milk products or manufactured dairy products produced from that dairy operation meet the requirements of the Act and this chapter.

(f) *Duration of permit.* A permit shall be valid for no more than one year. Each permit shall expire as of September 1 each year, unless revoked or suspended earlier by the Department.

(g) *Ownership of milk permit.* A permit is and remains the property of the Department – even when it is in the physical custody of the permit holder. If a milk permit is suspended or revoked, the person in possession of the milk permit shall immediately return or surrender that permit to the Department. In the case of a permit suspension, the Department shall promptly return the permit to the permit holder at the end of the suspension period.

(h) *Refusal, revocation or suspension of a permit.*

(1) *Authority.* The Department may refuse, revoke or suspend a permit issued under the Act or this section upon a finding that the applicant or permit holder has violated a provision of the act or this chapter.

(2) *Notice and opportunity for a hearing.* The Department shall notify an applicant or permit holder of a proposed refusal, revocation or suspension of a permit by written notification, and shall deliver it by personal service or certified

mail. The notice shall afford the recipient at least 5 days within which to request an administrative hearing on the proposed action. If no hearing is requested, the Department may enter its final order refusing, suspending or revoking the permit. If a hearing is requested, the Department shall conduct the hearing within 30 days of receipt of the request.

(i) *Reinstatement of a suspended permit.* A person whose permit has been suspended by the Department may make written application to the Department for reinstatement of the permit. The permit holder shall coordinate with the Department to address and resolve the basis for the suspension.

(j) *Reference to applicable provisions of the Grade "A" PMO.* The provisions of the Grade "A" PMO and, in particular, Section 3 of that document (relating to permits), are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.13. Adulterated or misbranded milk, milk products of manufactured dairy products.

(a) *Sales of adulterated or misbranded milk prohibited.* A person shall not sell adulterated or misbranded milk, milk products or manufactured dairy products.

(b) *Seizure, condemnation, denaturing or destruction of milk, milk products or manufactured dairy products.* Adulterated or misbranded milk may be seized, condemned, denatured and destroyed by the department if the Secretary considered the substance unsafe or a menace to public health.

(c) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO and, in particular, Section 2 of that document (relating to adulterated or misbranded milk or milk products), are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO).

§ 59a.14. Labeling: Bottles, containers and packages of milk, milk products or manufactured dairy products.

(a) *Department approval required.* A permit holder shall, before using a milk, PMO-defined milk product, milk product or manufactured dairy product label in commerce, apply for and obtain the approval of the Department for the use of that label. Labels in commercial use as of the effective date of this chapter shall have six months from the effective date of this chapter within which to come into compliance with this registration requirement.

(b) *Approval process.*

(1) A permit holder seeking the Department’s approval of a milk, PMO-defined milk product, milk product or manufactured dairy product label shall apply to the Department at the address provided in § 59a.3 (relating to contacting the Department). The applicant may use an application form that the Department will provide upon request, or may apply by letter requesting label approval. The application shall include clear, accurate copies of all labels for which approval is sought.

(2) The Department shall approve the use of a milk, PMO-defined milk product, milk product or manufactured dairy product label if it meets the requirements of the Act and this chapter, including the specific requirements of this section.

(3) The Department shall, within 10 business days of receiving a complete application, mail the applicant its written approval or denial of the application.

(i) If the application is denied, the written denial shall set forth the basis for denial, and afford the applicant notice and opportunity for an administrative hearing on the denial.

(ii) If the application is granted, the written approval shall contain a copy of the label and assign a unique serial number to each label approved under the application. The Department shall retain copies of these approvals.

(c) *Changes of approved labels.* If a label is approved under this section, colors and graphics may be changed without requiring re-approval of the label. If the text, type size or wording is to be changed, the label must be submitted to the Department for approval in accordance with subsection (b).

(d) *Label requirements.* All bottles, containers and packages enclosing milk or milk products offered for sale shall be labeled. The label shall be approved by the Department in accordance with this section, and shall contain the following information:

(1) The name of the food.

(2) The net contents.

(3) If the milk or milk product is or is made from milk other than cow's milk, the common name of the hooved mammal producing the milk preceding the name of the milk or milk product.

(4) If the milk or milk product is aseptically processed, the words "keep refrigerated after opening."

(5) If the milk or PMO defined milk product is conventionally pasteurized or ultra-high temperature (UHT) pasteurized, the words "keep refrigerated."

(6) The words "Grade 'A'" on the exterior surface, except for bottles, containers and packages of milk and milk products that are not eligible for certification as Grade "A" or that are eligible for certification but are not currently certified. Type size may not be larger than letters in basic product name.

(7) The identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed, condensed or dried. When the name and address of a distributor appears in lieu of that of the processor, such words as "Mfg. for," "Dist. by," or "Packed for" shall also appear on the label. Milk or milk products showing a general address or the name and address of a distributor shall be further labeled to identify the processing plant by assigned numerical code or the plant name and address.

(8) The identity of the plant where processed.

(9) If the milk product is made by reconstitution or recombination, the word "reconstituted" or "recombined," immediately preceding or immediately following the name of the product, in type at least half the size of name of the product which has been reconstituted.

(10) If the milk or milk product is concentrated milk or milk product, the volume or proportion of water to be added for reconstitution or recombination.

(11) In descending order of predominance, a listing of additives, such as flavors, sweeteners, milk solids, lactose, stabilizers, emulsifiers, vitamins and minerals if used.

(12) If vitamins, minerals or milk solids have been added to the milk or milk product, the quantity or percentage of United States Recommended Daily Allowance (U.S. RDA) per serving.

(13) If the milk or milk product has been pasteurized, the word "Pasteurized," in type not less than one-fourth the height of the letters in the basic product name. If desired, letters used in modifying terms and "pasteurized" may be the same size, but never larger than the product name. Printing shall be readily legible.

(14) If the milk or milk product has been homogenized, the word "Homogenized."

(15) If the milk or milk product is a protein fortified dairy product, the words "Protein Fortified" immediately preceding or immediately following the name of the product which has been fortified, in type at least half the size of name of the product which has been fortified. The label shall include the percentage of milk solids not fat added or the percentage of U.S. RDA of protein, vitamins and minerals per serving on the information panel of the container.

(16) If an artificial color is used for a flavored milk other than chocolate, the words "Artificially Colored."

(17) If an artificial flavor is used for artificially flavored milk, the words “Artificially (Name of flavor imitated) Flavored Milk” in type at least half the size of the name of the product imitated.

(18) If the milk or milk product has been cultured or acidulated after pasteurization it may, at the applicant’s option, be labeled “Made from pasteurized dairy products.”

(19) If a milk product contains an “artificial dairy product” as defined in § 57.1 (relating to definitions) as an ingredient which replaces portions of basic compositional ingredients in the milk product, the phrase “Contains artificial _____,” with the blank filled in with names of the basic compositional ingredients being simulated, immediately following the name of the food.

(20) Any sell-by date information required under § 59a.15 (relating to labeling: milk dating).

(e) *Exception.* The label requirements prescribed by this section shall not be applicable to milk tank trucks and storage tanks, which are addressed in § 59a.16 (relating to markings, sealing and documentation for vehicles containing milk and milk products). These requirements shall also not apply to cans of raw milk from individual dairy farms, which shall be identified by name or number of the producer.

(f) *False or misleading material.* False or misleading marks, words or endorsements upon the label are prohibited. In determining whether labeling is false or misleading, the Department shall take into account not only the specific representations made on the label but also the extent to which the labeling fails to reveal facts that are material in light of such representations. The Department may issue guidance documents addressing false or

misleading label statements or any other aspect of labeling under this section. Registered trade designs or terms may be permitted on the container cap or label provided they are not misleading and do not obscure the required labeling.

(g) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO and, in particular, Section 4 of that document (relating to labeling), are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO).

§ 59a.15. Labeling: Milk dating.

(a) *Label requirement.* The cap or nonglass container of pasteurized milk held in retail food stores, restaurants, schools or similar food establishments for resale shall be conspicuously and legibly marked in a contrasting color with the designation of the “sell-by” date—the month and day of the month after which the product may not be sold or offered for sale. The designation may be numerical—such as “8-15”—or with the use of an abbreviation for the month, such as “AUG 15 or AU 15.” The words “Sell by” or “Not to be sold after” shall precede the designation of the date, or the statement “Not to be sold after the date stamped above” shall appear legibly on the container. This designation of the date may not exceed 17 days beginning after midnight on the day on which the milk was pasteurized.

(b) *Prominence of sell-by date on label.* The sell-by date shall be separate and distinct from any other number, letter or intervening material on the cap or non-glass container.

(c) *Prohibition.* Pasteurized milk may not be sold or offered for sale if the milk is sold or offered for sale after the sell-by date designated on the container.

(d) *Exemption.* The following pasteurized dairy products are exempt from the requirements of this section:

- (1) Ultra-pasteurized dairy products.
- (2) Cultured dairy products.
- (3) Aseptically processed dairy products.
- (4) Dairy products that have undergone higher heat shorter time pasteurization.
- (5) Milk sold or offered for retail sale on the same premises at which it was processed.

Provided, that the cap or container of all pasteurized dairy products shall contain a lot number or manufacturing date code that is acceptable to the Department and can be used for product traceability in the marketplace.

(e) *Monitoring by the Department.*

(1) The Department will periodically sample containers of pasteurized milk in the possession of the processor or distributor. This sampling may occur at any time before the pasteurized milk is delivered to the store or the customer. The Department will sample at least one milk product from each processor each calendar year.

(2) The samples described in paragraph (1) shall be analyzed by the Department or a Pennsylvania approved dairy laboratory, applying a methodology set forth in the most current edition of Dairy Practices Council Guideline No. 10, entitled “Guidelines for Maintaining and Testing Fluid Milk Shelf Life,” to determine whether the bacterial test results exceed the bacterial limits for

pasteurized milk described in § 59a.21 (relating to standards) prior to the expiration of the sell-by date designated on the retail container.

(3) When two or more samples demonstrate a processor cannot produce pasteurized milk that remains consistently within the bacterial limits referenced in paragraph (2) during a 17-day sell-by period, the Department will require a processor to use a sell-by date of something less than the 17-day period described in subsection (a). The Department will calculate this revised sell-by date so that bacterial growth in the milk will not exceed the referenced bacterial limits within that sell-by period if the milk is maintained in accordance with the temperature standards for pasteurized milk in § 59a.21.

(4) A processor may submit samples to the Department for analysis to obtain approval to resume a 17-day sell-by period for the product sampled. The Department will approve resumption of a 17-day sell-by period when analysis of a sample demonstrates that bacterial growth in the milk will not exceed the referenced bacterial limits within that sell-by period if the milk is maintained in accordance with the temperature standards for pasteurized milk in § 59a.21.

§ 59a.16. Markings, sealing and documentation for vehicles containing milk and milk products.

(a) *Marking requirements.* A vehicle or milk tank truck 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.

(b) *Seal requirement.* A vehicle or milk tank truck transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station shall be marked with the name and address of the milk plant from which the milk or milk products are transported, and shall be sealed.

(c) *Documentation requirements.* A vehicle or milk tank truck transporting raw, heat-treated or pasteurized milk or milk products to a milk plant from another milk plant, receiving station or transfer station shall be accompanied by a legible shipping statement containing the following information:

(1) Shipper's name, address, and permit number. A milk tank truck containing milk shall include on the weigh ticket or manifest the IMS Bulk Tank Unit (BTU) identification number(s) or - for farm groups listed with a milk plant - the IMS Listed Milk Plant Number.

(2) Permit identification of hauler, if not an employee of the shipper.

(3) Point of origin of shipment.

(4) Tanker identification number.

(5) Name of product.

(6) Weight of product.

(7) Temperature of product when loaded.

(8) Date of shipment.

(9) Name of supervisory regulatory agency at point of origin of shipment.

(10) Whether the contents are raw, pasteurized or in the case of cream, lowfat milk or skim milk – whether it has been heat-treated.

(11) Seal number on inlet, outlet, wash connections and vents.

(12) Grade of product.

(d) *Cans of raw milk.* All cans of raw milk from individual dairy farms shall be identified by the name or permit number of the individual milk producer.

(e) *Additional documentation.* Milk transport tank trucks transporting bulk milk and dairy products shall be accompanied by documentation, such as a weigh ticket or manifest, which shall include the NCIMS BTU Identification Number or the NCIMS Listed Milk Plant Number, for farm groups listed with a milk plant.

(f) *Reference to applicable provisions of the Grade "A" PMO.* The provisions of the Grade "A" PMO and, in particular, Section 4 of that document (relating to labeling), are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.17. Inspection of dairy farms and milk plants.

(a) *General inspection requirement.* Dairy farms shall be inspected by an approved inspector at intervals of no greater than six months, unless the dairy farm produces raw milk under a raw milk permit, in which case the inspection shall be as prescribed in Subchapter F (relating to raw milk for human consumption). Grade "A" dairy farms shall be inspected by a certified industry inspector. Milk plants shall be inspected by an approved inspector at intervals of no greater than three months, or as otherwise prescribed by the Grade "A" PMO, as referenced in subsection (d).

(b) *Inspection frequency.* Each producer of milk for pasteurization will be inspected initially and on any change of market by an approved inspector, and shall have a passing score before the first milk is shipped. All producers shall be inspected no less than once

in each 6-month period by an approved inspector, and an accurate record of farm inspections and quality control testing shall be maintained on forms acceptable to the Department. The records of farm inspections shall include the date of inspection, any noted deficiencies, whether the inspection resulted in a passing score, suspension or reinspection. The records of quality control testing shall include bacterial count, somatic cell count, drug residue screening results, temperature results, records of water supply testing, copies of warning letters and suspension letters and information required under Appendix N of the Grade "A" PMO (relating to drug residue testing and farm surveillance).

(c) *Notification of producer status.* A permit holder shall, within 24 hours of its initial instatement of a producer, its suspension of a producer or its reinstatement of a producer, provide the Department the name and address of the producer and the specific action taken by the permit holder.

(d) *Reference to applicable provisions of the Grade "A" PMO.* The provisions of the Grade "A" PMO and, in particular, Section 5 of that document (relating to inspection of dairy farms and milk plants), are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.18. Sampling and examination.

(a) *Sampling and testing costs.* Sampling and testing required under this section shall be at the expense of the permit holder or permit applicant, and shall be conducted by a Pennsylvania approved dairy laboratory or the Department.

(b) *Certified milk plants, receiving stations and transfer stations; milk plants and transfer stations that receive Grade "A" milk.* A milk plant, receiving station or transfer station shall comply with the provisions of Appendix N of the Grade "A" PMO (relating to drug residue testing and farm surveillance) if it is certified under the NCIMS Interstate Milk Shippers Program, or if it receives Grade "A" milk

(c) *Non-certified milk plants and transfer stations.* Milk plants that are not certified under the NCIMS Interstate Milk Shippers Program, and which do not receive Grade "A" milk, shall obtain a representative sample of commingled milk for pasteurization each processing day. The sample shall be collected by certified industry plant sampler and analyzed for *Beta lactam* drug residues in an approved laboratory.

(d) *Drug residue testing.* Drug residue screening shall be completed at the direction of the Department and records of all such testing shall be maintained on file by the permit holder.

(e) *Reference to applicable provisions of the Grade "A" PMO.* The provisions of the Grade "A" PMO and, in particular, Section 6 and Appendix N of that document (relating to examination of milk and milk products, and drug residue testing and farm surveillance, respectively), are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.19. Standards for grade "A" raw milk for pasteurization, ultra-pasteurization or aseptic processing.

(a) *Applicability.* The standards prescribed by this section are applicable to a dairy farm that produces milk for pasteurization, ultra-pasteurization or aseptic

processing regardless of whether the dairy farm is certified under the NCIMS Interstate Milk Shippers Program.

(b) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO and, in particular, the *Standards for Grade “A” Raw Milk for Pasteurization, Ultra-Pasteurization or Aseptic Processing* set forth in that document and Section 7 of the Grade “A” PMO (relating to standards for Grade “A” milk and milk products) are incorporated by reference as regulations authorized under the Act, to the extent they do not conflict with the Act or any provision of this chapter. This includes all of the Items listed under the referenced Grade “A” PMO provisions, including the following:

- (1) Item 1r. Abnormal milk
- (2) Item 2r. Milking Barn, Stable or Parlor - Construction
- (3) Item 3r. Milking Barn, Stable or Parlor - Cleanliness
- (4) Item 4r. Cowyard
- (5) Item 5r. Milkhouse – Construction and Facilities
- (6) Item 6r. Milkhouse - Cleanliness
- (7) Item 7r. Toilet
- (8) Item 8r. Water Supply, with the additional requirement that a plate heat exchanger or tubular cooler installed and in use on a dairy farm shall be equipped with an appropriate backflow prevention device
- (9) Item 9r. Utensils and Equipment - Construction
- (10) Item 10r. Utensils and Equipment - Cleaning
- (11) Item 11r. Utensils and Equipment - Sanitization

- (12) Item 12r. Utensils and Equipment - Storage
- (13) Item 13r. Milking – Flanks, Udders and Teats
- (14) Item 14r. Protection from Contamination
- (15) Item 15r. Drug and Chemical Control
- (16) Item 16r. Personnel – Handwashing Facilities
- (17) Item 17r. Personnel - Cleanliness
- (18) Item 18r. Raw Milk Cooling, with the exception that raw milk for pasteurization shall be cooled to 4°C (40°F) within two (2) hours after completion of milking, and shall be delivered to the plant within 72 hours of the initial milking
- (19) Item 19r. Insect and Rodent Control

§ 59a.20. Standards for grade “A” pasteurized, ultra-pasteurized and aseptically processed milk and milk products.

(a) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO and, in particular, the *Standards for Grade “A” Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products*, and Section 7 of the Grade “A” PMO (relating to standards for Grade “A” milk and milk products), are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO). This includes all of the Items listed under the referenced Grade “A” PMO provisions, including the following:

- (1) Item 1p. Floors - Construction

- (2) Item 2p. Walls and Ceilings - Construction
- (3) Item 3p. Doors and Windows
- (4) Item 4p. Lighting and Ventilation
- (5) Item 5p. Separate Rooms
- (6) Item 6p. Toilet-Sewage Disposal Facilities
- (7) Item 7p. Water Supply
- (8) Item 8p. Handwashing Facilities
- (9) Item 9p. Milk Plant Cleanliness
- (10) Item 10p. Sanitary Piping
- (11) Item 11p. Construction and Repair of Containers and Equipment
- (12) Item 12p. Cleaning and Sanitizing of Containers and Equipment
- (13) Item 13p. Storage of Cleaned Containers and Equipment
- (14) Item 14p. Storage of Single-Service Containers, Utensils and

Materials

- (15) Item 15p. Protection from Contamination
- (16) Item 16p. Pasteurization and Aseptic Processing
- (17) Item 17p. Cooling of Milk and Milk Products
- (18) Item 18p. Bottling, Packaging and Container Filling
- (19) Item 19p. Capping, Container Closure and Sealing and Dry Milk

Product Storage

- (20) Item 20p. Personnel – Cleanliness
- (21) Item 21p. Vehicles
- (22) Item 22p. Surroundings

(b) *Applicability.* The standards prescribed by this section are applicable to a milk plant regardless of whether it is certified under the NCIMS Interstate Milk Shippers Program.

§ 59a.21. Standards.

(a) *Standards for milk and PMO-defined milk products.* The standards that are applicable to milk and PMO-defined milk products are as set forth in Section 7 of the Grade “A” PMO, in Table 1 (relating to chemical, physical, bacteriological, and temperature standards).

(b) *Standards for milk for manufacturing and manufactured dairy products.* The standards that are applicable to milk for manufacturing and manufactured dairy products are as set forth in Subchapter C (relating to production and processing of milk for manufacturing purposes). Other fluid derivatives of milk (including condensed milk and milk products, nonfat dry milk and milk products, condensed whey and whey products, and buttermilk and buttermilk products) may be processed according to the standards and requirements for manufactured grade milk and milk products provided that they meet all applicable requirements of Subchapter C (relating to production and processing of milk for manufacturing purposes).

(c) *Standards for ice cream and frozen dessert mixes.* Frozen desserts—vanilla, chocolate, and one other flavor where applicable—shall be tested at least monthly for the standard plate count and coliform group. Frozen desserts mix shall be tested at least monthly for the standard plate count, coliform group, and

phosphatase activity. The following are the specific standards for ice cream and frozen dessert mixes:

(1) *Temperature*: Cooled to 45°F (7°C) or less and maintained thereat.

(2) *Bacterial limits applicable to all but cultured products*: 50,000 per gram.

(3) *Coliform*: Not to exceed 10 per gram. When fruit or nuts and flavoring are added after pasteurization, the count shall not exceed 20 per gram.

(4) *Phosphatase*: Less than 350 milliunits per liter by approved electronic phosphatase procedures.

(d) *Reference to applicable provisions of the Grade "A" PMO*. The provisions of the Grade "A" PMO and, in particular, Section 7 and Appendix N of that document (relating to examination of milk and milk products, and drug residue testing and farm surveillance, respectively), are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.22. Animal health.

The provisions of the Grade "A" PMO and, in particular, Section 8 of that document (relating to animal health) are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.23. Milk and milk products which may be sold.

The provisions of the Grade “A” PMO and, in particular, Section 9 of that document (relating to milk and milk products which may be sold) are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO).

§ 59a.24. Transferring; delivery containers; cooling.

The provisions of the Grade “A” PMO and, in particular, Section 10 of that document (relating to transferring; delivery; containers; cooling) are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO).

§ 59a.25. Milk, milk products and manufactured dairy products from points outside the Commonwealth of Pennsylvania.

(a) *General requirement.* Milk, milk products and manufactured dairy products originating from outside the Commonwealth of Pennsylvania may be sold in Pennsylvania if they are produced and pasteurized, ultra-pasteurized, or aseptically processed, concentrated (condensed) or dried under regulations which are substantially equivalent to the Grade “A” PMO and:

- (1) have been awarded acceptable Milk Sanitation Compliance and Enforcement Ratings by a Milk Sanitation Rating Officer certified by FDA; or
- (2) have been awarded a satisfactory HACCP listing, under a HACCP Program as specified in Appendix K of the Grade “A” PMO; or
- (3) originate from a country that the FDA has, following consultation with NCIMS, determined to have in place a public health regulatory program and

government oversight of that program that have an equivalent effect on the safety of regulated milk and/or milk products; or

(4) are USDA-approved manufactured dairy products; or

(5) have a Department-issued milk permit.

(b) *Reference to applicable provisions of the Grade "A" PMO.* The provisions of the Grade "A" PMO and, in particular, Section 11 of that document (relating to milk and milk products from points beyond the limits of routine inspection) are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.26. Plans for construction and reconstruction.

(a) *Specific requirements.* Properly prepared plans for all transfer stations, receiving stations, and milk plants regulated under this chapter which are constructed, reconstructed, or extensively altered shall be submitted to the Secretary for written approval before work is begun. Plans must likewise be approved before construction or extensive modification of a manure storage system; installation of a bulk milk storage tank; installation of a milk transfer system on a dairy farm; or installation of milk handling equipment in a transfer station, receiving station, or milk plant.

(b) *Reference to applicable provisions of the Grade "A" PMO.* The provisions of the Grade "A" PMO and, in particular, Section 12 of that document (relating to plans for construction and reconstruction) are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.27. Personnel health.

(a) *Specific requirements.* No person affected with any disease in a communicable form or while a carrier of such disease shall work at any dairy farm or milk plant in any capacity which brings him into contact with the production, handling, storage, or transportation of milk, milk products, containers, equipment, and utensils; and no dairy farm or milk plant operator shall employ in any such capacity any person suspected of having a disease in a communicable form, or any person suspected of being a carrier of such disease. Any producer or distributor of milk or milk products upon whose dairy farm or in whose milk plant any communicable disease occurs or who suspects that any employee has contracted any disease in a communicable form or has become a carrier of such disease shall notify the Department immediately.

(b) *Reference to applicable provisions of the Grade "A" PMO.* The provisions of the Grade "A" PMO and, in particular, Section 13 of that document (relating to personnel health) are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.28. Procedure when infection or high risk of infection is discovered.

(a) *Specific requirements.* When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of milk or milk products, the Department is authorized to require any or all of the following measures:

- (1) The immediate exclusion of that person from handling milk or milk products, or the handling of related milk or milk-product contact surfaces, subject to release from this exclusion if in accordance with Table 5 of Section 15 of the Grade "A" PMO.

(2) The immediate exclusion of the milk supply concerned from distribution and use.

(3) Adequate medical and bacteriological examination of the person and his associates and of their body discharges.

(b) *Reference to applicable provisions of the Grade "A" PMO.* The provisions of the Grade "A" PMO and, in particular, Section 16 of that document (relating to procedure when infection or high risk of infection is discovered) are applicable to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

Subchapter C. PRODUCTION AND PROCESSING OF MILK FOR MANUFACTURING PURPOSES

Sec.

- 59a.101. Adoption of USDA Recommended Requirements.
- 59a.102. Milk permits.
- 59a.103. Plant inspection.
- 59a.104. Certification of bulk milk collectors—weigher/samplers.
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§ 59a.101. Adoption of USDA Recommended Requirements.

The provisions, terms, procedures and standards of the most current version of the publication of the United States Department of Agriculture, Agricultural Marketing Service, Dairy Program, titled *Milk for Manufacturing Purposes and its Production and Processing – Recommended Requirements*, are adopted as the regulatory standards of the Department to the extent they do not conflict with:

- (1) the Act;
- (2) the Food Act; or
- (3) a provision of this subchapter.

§ 59a.102. Milk permits.

Plants, receiving stations, transfer stations, and bulk tank units handling or processing milk for manufacturing of dairy products shall apply for a permit in accordance with § 59a.12 (relating to permits), which describes the process and requirements by which permits are acquired and maintained.

(1) Permits shall be required for the sale of milk for manufacturing purposes and manufactured dairy products. Application shall be made annually on a form secured from the Secretary.

(2) A separate permit shall be obtained for each plant, receiving station, transfer station, and bulk tank unit.

(3) The permit year shall begin September 1 of each year and end on August 31 of the following year.

§ 59a.103. Plant inspection.

Plants receiving milk or dairy products, for manufacturing or further processing, shall be subject to inspection by the Secretary or his agent.

§ 59a.104. Certification of bulk milk collectors—weigher/samplers.

All weighers/samplers will be evaluated and approved by the Department.

§ 59a.105. Approved milk graders.

Milk graders will be approved by the Department, based upon the milk grader being capable of determining the quality classification of raw milk for manufacturing purposes in accordance with § 59a.106 (relating to basis).

§ 59a.106. Basis.

The quality classification of raw milk for manufacturing purposes shall be based on an organoleptic examination for appearance and odor, a drug residue test and quality control tests for sediment content, bacterial estimate and somatic cell count.

§ 59a.107. Appearance and odor.

The appearance of acceptable raw milk for manufacturing purposes shall be normal and free of excessive coarse sediment when examined visually or by an acceptable test procedure. The milk shall not show any abnormal condition (including but not limited to curdles, ropy, bloody or mastitic condition), as indicated by sight or other test procedures. The odor shall be fresh and sweet. The milk shall be free from objectionable feed and other off-odors that would adversely affect the finished product.

§ 59a.108. Sediment content classification.

(a) *Method of testing.* Methods for determining the sediment content of the milk of individual producers shall be those described in the *Standard Methods for the Examination of Dairy Products*. Sediment content shall be based on comparison with applicable charts of the United States Sediment Standards for Milk and Milk Products. These charts are available from the Dairy Standardization Branch, Dairy Programs, Agricultural Marketing Service, U.S. Department of Agriculture, Room 2746-South, 1400 Independence Ave., S.W., Washington, D.C. 20250-0230.

(b) *Classifications.* Milk shall be classified for sediment content in accordance with the USDA Sediment Standard, regardless of the results of the appearance and odor

examination described in 59a.107 (relating to appearance and odor), as follows. The USDA Sediment Standard defines the following classifications:

(1) Milk classified as “No. 1” has a tested sediment content that does not exceed 0.50 mg. or equivalent, and is acceptable.

(2) Milk classified as “No. 2” has a tested sediment content that does not exceed 1.50 mg. or equivalent, and is acceptable.

(3) Milk classified as “No. 3” has a tested sediment content that does not exceed 2.50 mg. or equivalent, and is probational for not more than 10 days.

(4) Milk classified as “No. 4” has a tested sediment content that exceeds 2.50 mg. or equivalent, and is rejected.

(c) *Frequency of tests.* At least once each month, at irregular intervals, the milk from each producer shall be tested as follows:

(1) *Milk in cans.* A sample shall be taken from one or more cans of milk selected at random from each producer.

(2) *Milk in farm bulk tanks.* A sample shall be taken from each farm bulk tank.

(d) *Acceptance or rejection of milk.*

(1) If the sediment disc is classified as No. 1, No. 2 or No. 3, the producer’s milk may be accepted.

(2) If the sediment disc is classified as No. 4, the milk shall be rejected.

(3) If the shipment of milk is commingled with other milk in a transport tank, the next shipment shall not be accepted until its quality has been determined at the farm before being picked up; however, if the person making the test is unable to get to the farm before the next shipment, it may be accepted but no further

shipments shall be accepted unless the milk meets the requirements of No. 3 or better. In the case of milk classified as No. 3 or No. 4, if in cans, all cans shall be tested. Producers of No. 3 or No. 4 milk—cans or bulk—shall be notified immediately and shall be furnished applicable sediment discs, and the next shipment shall be tested.

(e) *Retests.* On tests of the next shipment (if in cans, all cans shall be tested) milk classified as No. 1, No. 2 or No. 3, may be accepted, but No. 4 milk shall be rejected. Retests of bulk milk classified as No. 4 shall be made at the farm before pickup. The producers of No. 3 or No. 4 milk shall be notified immediately, furnished applicable sediment discs and the next shipment shall be tested. This procedure of retesting successive shipments and accepting probational (No. 3) milk and rejecting No. 4 milk may be continued for a period not to exceed 10 calendar days. If, at the end of this time, all of the producer's milk does not meet the acceptable sediment content classification (No. 1 or No. 2), it shall be excluded from market.

§ 59a.109. Bacterial estimate classification.

(a) *General testing requirement.* A laboratory examination to determine the bacterial estimate shall be made on each producer's milk at least once each month at irregular intervals. Samples shall be analyzed at a Pennsylvania approved dairy laboratory.

(b) *Testing methods.* Milk shall be tested for bacterial estimate by using one of the following methods or by any other method approved by the *Standard Methods for the Examination of Dairy Products*, and include the following:

- (1) Direct microscopic clump count

- (2) Standard plate count
- (3) Plate loop count
- (4) Bactoscan™ count
- (5) Pectin gel plate count
- (6) Petrifilm™ aerobic count
- (7) Spiral plate count
- (8) Hydrophobic grid membrane filter count
- (9) Impedance/conductance count
- (10) Other tests that have been approved by the Department through publication of notice in the *Pennsylvania Bulletin*

(c) *Excessive bacteria.* Whenever the bacterial estimate indicates the presence of more than 500,000 bacteria per milliliter, the Pennsylvania approved dairy laboratory shall do the following:

- (1) Provide the producer with a warning of the excessive bacterial estimate.

This warning need not be written.

- (2) If two of the last four consecutive bacterial estimates exceed 500,000 per milliliter, notify the Department and provide the producer a written warning notice. The notice shall be in effect so long as two of the last four consecutive samples exceed 500,000 per milliliter.

(d) *Excluding milk with excessive bacteria from the market.* If a producer receives the written notice described in paragraph (c)(2), the producer shall have an additional sample taken between 3 and 21 days after receiving the notice. If this sample also exceeds 500,000 per milliliter, subsequent milkings shall be excluded from the market until

satisfactory compliance is obtained. Shipment may be resumed and a temporary status assigned to the producer by the Department when an additional sample of herd milk is tested and found satisfactory. The producer shall be assigned a full reinstatement status when three out of four consecutive bacterial estimates do not exceed 500,000 per milliliter. The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

§ 59a.110. Somatic cell count.

(a) *General testing requirement.* A laboratory examination to determine the level of somatic cells shall be made on each producer's milk at least once each month. Samples shall be analyzed at a Pennsylvania approved dairy laboratory.

(b) *Testing methods.* Milk shall be tested for somatic cell content by using one of the following procedures:

- (1) Direct Microscopic Somatic Cell Count (Single Strip Procedure).
- (2) Electronic Somatic Cell Count.
- (3) Flow Cytometry/Opto-Electronic Somatic Cell Count
- (4) Membrane Filter DNA Somatic Cell Count.

(c) *Excessive somatic cell count.* Whenever the official test indicates the presence of more than 750,000 somatic cells per milliliter, the Pennsylvania approved dairy laboratory shall do the following:

- (1) Provide the producer with a warning of the excessive somatic cell count.
- (2) If two of the last four consecutive somatic cell counts exceed 750,000 per milliliter, notify the Department and provide the producer a written warning

notice. The notice shall be in effect so long as two of the last four consecutive samples exceed 750,000 per milliliter.

(d) *Excluding milk with an excessive somatic cell count from the market.* If a producer receives the written notice described in paragraph (c)(2), the producer shall have an additional sample taken between 3 and 21 days after receiving the notice. If this sample also exceeds 750,000 per milliliter, subsequent milkings shall be excluded from the market until satisfactory compliance is obtained. Shipment may be resumed and a temporary status assigned to the producer by the Department when an additional sample of herd milk is tested and found satisfactory. The producer shall be assigned a full reinstatement status when three out of four consecutive somatic cell count tests do not exceed 750,000 per milliliter. The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

§ 59a.111. Drug residue level.

(a) *Industry responsibilities.*

(1) *Sampling and testing program.*

(i) All milk shipped for processing or intended to be processed on the farm where it was produced shall be sampled and tested, prior to processing, for *beta lactam* drug residue. Collection, handling and testing of samples shall be done according to procedures established by the Department in this section, and in accordance with Appendix N of the Grade "A" PMO (relating to drug residue testing and farm surveillance).

(ii) When so specified by the FDA, all milk shipped for processing, or intended to be processed on the farm where it was produced, shall be sampled and tested, prior to processing, for other drug residues under a random drug sampling program. The random drug sampling program shall include at least four samples collected in at least 4 separate months during any consecutive 6-month period.

(iii) When the Commissioner of the FDA determines that a potential problem exists with an animal drug residue or other contaminant in the milk supply, a sampling and testing program shall be conducted, as determined by the FDA. The testing shall continue until such time that the Commissioner of the FDA determines with reasonable assurance that the potential problem has been remedied.

(iv) The dairy industry shall analyze samples for *beta lactams* and other drug residues by methods which have been independently evaluated or evaluated by FDA and accepted by FDA as effective to detect drug residues at current safe or tolerance levels. Safe and tolerance levels for particular drugs are established by the FDA.

(v) All sample test results for milk that does not test positive shall be recorded, and test result records shall be retained for a period of six months.

(2) *Individual producer sampling.*

(i) *Bulk milk.* A milk sample for *beta lactam* drug residue testing shall be taken at each farm and shall include milk from each farm bulk tank.

(ii) *Can milk.* A milk sample for *beta lactam* drug residue testing shall be formed separately at the receiving plant for each can milk producer included in a delivery, and shall be representative of all milk received from the producer.

(iii) *Producer/processor.* A milk sample for *beta lactam* drug residue testing shall be formed separately according to paragraphs (a)(2)(i) and (ii) of this section for milk produced or received by a producer/processor.

(3) *Load sampling and testing.*

(i) *Bulk milk.* A load sample shall be taken from the bulk milk pickup tanker after its arrival at the plant and prior to further commingling.

(ii) *Can milk.* A load sample representing all of the milk received on a shipment shall be formed at the plant, using a sampling procedure that includes milk from every can on the vehicle.

(iii) *Producer/processor.* A load sample shall be formed at the plant using a sampling procedure that includes all milk produced and received.

(4) *Sample and record retention.* A load sample that tests positive for drug residue shall be retained for a period of not less than 12 months. The records of all positive sample test results shall be retained for a period of not less than 12 months.

(5) *Industry follow-up.*

(i) When a load sample tests positive for drug residue, industry personnel shall notify the Department immediately of the positive test result and of the intended disposition of the shipment of milk containing

the drug residue. All milk testing positive for drug residue shall be disposed of in a manner that removes it from the human or animal food chain, except when acceptably reconditioned under FDA compliance policy guidelines.

(ii) Each individual producer sample represented in the positive-testing load sample shall be individually tested as directed by the Department to determine the producer of the milk sample testing positive for drug residue. Identification of the producer responsible for producing the milk testing positive for drug residue, and details of the final disposition of the shipment of milk containing the drug residue, shall be reported immediately to the Department.

(iii) Milk shipment from the producer identified as the source of milk testing positive for drug residue shall cease immediately and may resume only after a sample from a subsequent milking does not test positive for drug residue.

(b) Responsibilities of the Department.

(1) *Monitoring and surveillance.* The Department shall monitor the milk industry's drug residue program by conducting unannounced on-site inspections to observe testing and sampling procedures and to collect samples for comparison drug residue testing. In addition, the Department shall review industry records for compliance with drug residue program requirements. The review shall seek to determine that:

(i) Each producer is included in a routine, effective drug residue milk monitoring program utilizing methods evaluated and found acceptable by FDA to test samples for the presence of drug residue;

(ii) The Department receives prompt notification from industry personnel of each occurrence of a sample testing positive for drug residue, and of the identity of each producer identified as a source of milk testing positive for drug residue;

(iii) The Department receives prompt notification from industry personnel of the intended and final disposition of milk testing positive for drug residue, and that disposal of the load is conducted in a manner that removes it from the human or animal food chain, except when acceptably reconditioned under FDA compliance policy guidelines; and

(iv) Milk shipment from a producer identified as a source of milk testing positive for drug residue completely and immediately ceases until a milk sample taken from the dairy herd does not test positive for drug residue.

(2) *Enforcement.*

(i) Any time milk is found to test positive for drug residue, the Department shall immediately take action to suspend the producer's milk shipping privileges to prevent the sale of milk from the producer shipping milk testing positive for drug residue.

(ii) The producer's milk shipping privileges may be reinstated when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

(iii) The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The Department may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

(iv) Whenever a drug residue test is positive, an investigation shall be made to determine the cause. Action shall be taken to prevent future occurrences.

(v) If a producer ships milk testing positive for drug residue three times within a 12-month period, the Department shall initiate administrative procedures to suspend the producer's milk shipping privileges according to State policy.

(vi) The actions and procedures of the Department shall be in accordance with this chapter and Appendix N of the Grade "A" PMO (relating to drug residue testing and farm surveillance).

§ 59a.112. Rejected milk.

(a) *Rejection requirement.* A plant shall reject specific milk from a producer if it fails to meet the requirements of § 59a.107 (relating to appearance and odor), if it is classified No. 4 for sediment content, or if it tests positive for drug residue.

(b) *Tagging and coloring rejected milk.* Rejected milk shall be identified with a reject tag and colored with harmless food coloring.

§ 59a.113. Suspended milk for manufacturing.

A plant shall not accept milk from a producer if one of the following occurs:

- (1) The producer's initial milk shipment to a plant is classified as No. 3 for sediment content, as described in § 59a.108 (relating to sediment content classification).
- (2) The milk has been in a probational (No. 3) sediment content classification for more than 10 calendar days.
- (3) Three of the last five milk samples have exceeded the maximum bacterial estimate of 500,000 per milliliter, as described in § 59a.109 (relating to bacterial estimate classification).
- (4) Three of the last five milk samples have exceeded the maximum somatic cell count level of 750,000 per milliliter, as described in § 59a.110 (relating to somatic cell count).
- (5) The producer's milk shipments to either the Grade "A" milk market or the manufacturing grade milk market are currently prohibited due to a positive drug residue test.
- (6) The milk contains added water. For purposes of this requirement, samples analyzed for added water and found to have a freezing point above -0.525°H (0.508°C) shall be considered adulterated unless proven free of added water.

§ 59a.114. Inspection and quality testing of milk from producers.

- (a) *Inspections.* Inspections shall be as follows:

(1) A dairy farm on which milk is produced for manufacturing purposes shall be inspected initially and shall have a passing score before the first milk is shipped.

(2) The dairy farm of a producer, on a change of market shall be inspected by an approved inspector and shall have a passing score before the first milk is shipped.

(3) Dairy farms shall be inspected no less than once in each 6 month period by an approved inspector.

(b) *Testing of first shipment.* An examination and tests shall be made on the first shipment of milk from producers shipping milk to a plant for the first time or after a period of nonshipment. The milk shall meet the following requirements:

(1) The requirements of § 59a.107 with respect to appearance and odor.

(2) The requirements of § 59a.108 with respect to sediment content.

(3) The requirements of § 59a.109 with respect to bacteria.

(4) The requirements of § 59a.110 with respect to somatic cell count.

(5) The requirements of § 59a.111 with respect to drug residue level.

(c) *Testing of subsequent shipments.* For all shipments of milk not described in subsection (b), testing shall meet the following requirements:

(1) The requirements of § 59a.107 with respect to appearance and odor.

(2) The requirements of § 59a.108 with respect to sediment content.

(3) The requirements of § 59a.109 with respect to bacteria.

(4) The requirements of § 59a.110 with respect to somatic cell count.

(5) The requirements of § 59a.111 with respect to drug residue level.

(d) *Transfer producers.* When a producer discontinues milk delivery to one plant and begins delivery to a different plant, the following shall occur:

(1) The dairy farm shall be inspected by an approved inspector and shall have a passing score before milk is shipped.

(2) The new buyer shall do one of the following:

(i) Obtain quality control records from the previous buyer for the previous 12-month period to confirm from these records that:

(A) the milk is currently classified “acceptable” for sediment;

(B) three of the last five consecutive milk samples do not exceed the maximum bacterial estimate;

(C) three of the last five consecutive milk samples do not exceed the maximum somatic cell count level requirements;

(D) the last shipment of milk received from the producer by the former plant did not test positive for drug residue; and

(E) milk shipments currently are not excluded from the market due to a positive drug residue test.

(ii) Examine and classify each transfer producer’s first shipment of milk according to the requirements of subsection (b), and subsequently examine shipments according to the requirements of subsection (c).

(3) When a producer discontinues milk delivery at one plant and begins delivery at another plant for any reason, the new buyer shall not accept the first milk delivery until he has requested from the previous buyer a copy of the record of the following:

(i) the producer’s milk quality tests covering the preceding 12 months;

(ii) the producer's drug residue test results for the preceding 12 month period; and

(iii) a copy of the current Dairy Farm Inspection Report.

(4) The previous buyer shall furnish the new buyer with such information within 24 hours after receipt of the request. A new buyer may accept a transfer producer's milk after making the request for records, but before receiving them, if he first confirms the producer's records verbally from the previous buyer. If verbal communication is used to ascertain the status of quality records, the new buyer shall send to the previous buyer, as soon as possible, a written confirmation of the conversation.

(5) If the new buyer fails to receive the quality records from the previous buyer, he shall report this fact to the Department.

§ 59a.115. Record of tests.

Accurate records of the results of the milk quality and drug residue tests for each producer shall be kept on file for not less than 12 months and shall be available for examination by the Department.

§ 59a.116. Abnormal milk.

(a) *Certain milk to be excluded from human consumption.* Cows which show evidence of the secretion of abnormal milk in one or more quarters based on bacteriological, chemical, or physical examination and cows which have been treated with or have consumed chemical, medicinal, or radioactive agents which are capable of being secreted

in the milk in excess of any established limits and which may be deleterious to human health shall be milked last or with separate equipment and the milk may not be offered for sale for human consumption.

(b) *Medicinal agents.* Milk from cows being treated with medicinal agents may not be offered for sale for periods recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

(c) *Pesticides.* Milk from cows treated with or exposed to pesticides not approved for use on dairy cattle by the United States Environmental Protection Agency may not be offered for sale until the milk has been tested and found acceptable by the Secretary, in accordance with the procedures and standards set forth in Appendix N of the Grade "A" PMO (relating to drug residue testing and farm surveillance).

(d) *Visibly abnormal milk and odorous milk.* Bloody, stringy, off-color milk or milk abnormal in sight and odor shall be so handled and disposed of as to preclude the infection of other cows, and the contamination of the utensils.

(e) *Equipment, utensils and containers.* Equipment, utensils, and containers used for handling of abnormal milk may not be used for the handling of milk to be offered for sale unless they are first effectively cleaned and sanitized.

(f) Poultry litter and recycled animal body discharges may not be fed to lactating dairy animals.

§ 59a.117. Animal health.

(a) *General health.* All animals in the herd shall be maintained in a healthy condition, and shall be properly fed and kept.

(b) *Tuberculin test.* The *lactating animals* shall be located in a Modified Accredited Area, an Accredited Free State, or an Accredited Free Herd as determined by the U.S. Department of Agriculture. If the animals are not located in such areas, they shall be tested annually under the jurisdiction of the aforesaid program. All additions to the herd shall be from an area or from herds meeting those same requirements.

(c) *Brucellosis test.* The *lactating animals* shall be located in States meeting Class B status, or Certified-Free Herds, or shall be involved in a milk ring test program or blood testing program under the current USDA Brucellosis Eradication Uniform Methods and Rules. All additions to the herd shall be from a State or from herds meeting these same requirements.

(d) *Prohibition.* Brucellosis and tuberculosis reactors disclosed shall be separated immediately from the milking herd. Milk from brucellosis or tuberculosis reactors may not be sold.

Subchapter D. FARMS PRODUCING MILK FOR MANUFACTURING

Sec.

- 59a.201. Farm Inspection.
- 59a.202. Milking facilities and housing.
- 59a.203. Milking procedures.
- 59a.204. Cooling and storage.
- 59a.205. Milkhouse or milkroom.

59a.206. Utensils and equipment.

59a.207. Water supply.

59a.208. Sewage disposal.

§ 59a.201. Farm inspection.

Farms producing and selling milk for manufacturing purposes shall comply with the following inspection provisions:

(1) Each dairy farm operated by a producer of milk for manufacturing purposes shall be inspected initially and on any change of market by an approved inspector and shall have a passing score before the first milk is shipped. All dairy farms producing milk for manufacturing purposes shall be inspected no less than once in each 6 month period by an approved inspector, and an accurate record of inspections shall be maintained by each permit holder on forms acceptable to the Secretary.

(2) Producers who cannot produce milk of a wholesome sanitary quality will be suspended. Producers who are not in substantial compliance with this section or § 59a.102 (relating to milk permits) will be reinspected after an appropriate time for correction of deficiencies.

(3) A permit holder shall promptly notify the Department of initial instatement, suspension or reinstatement of a producer from which milk for manufacturing is or was received. Identification of the producer, including name and address, shall be provided orally or by mail within 24 hours of the action.

§ 59a.202. Milking facilities and housing.

(a) *General requirements.* A milking barn or milking parlor of adequate size and arrangement shall be provided to permit normal sanitary milking operations. It shall be well lighted and ventilated, and the floors and gutters in the milking area shall be constructed of concrete or other impervious material. The facility shall be kept clean, the manure removed daily and stored to prevent access of lactating animals to accumulation thereof. No swine or fowl may be permitted in the milking area. When a milking barn is used and horses are present, they shall be stalled in a separate area a sufficient distance from the milking area or separated by tight partitions.

(b) *Platforms and ramps.* If a milking barn or milking parlor has ramps and platforms that are used to elevate lactating animals, these ramps and platforms must be constructed of an impervious material such as steel. Wooden platforms and ramps are prohibited. Rubber mats may be used as long as they are not placed over a wooden platform.

(c) *Concentrates and feed storage.* Concentrates and feed, if stored in the building, shall be stored in a tightly covered box, bin or container.

(d) *Protection of exposed milk.* If milk is exposed during straining or transferring in the milking area it shall be protected from falling particles from areas above the milk facility.

(e) *Yard requirements.* The yard or loafing area shall be of ample size to prevent overcrowding, shall be drained to prevent forming of standing water pools, insofar as practicable, and shall be kept clean.

§ 59a.203. Milking procedures.

(a) *Cleanliness of udders and flanks.* The udders and flanks of all lactating animals shall be kept clean. The udders and teats shall be washed or wiped immediately before milking with a clean, damp cloth or paper towel moistened with a sanitizing solution and wiped dry or by another sanitary method approved in writing by the Department.

(b) *Milker.* The milker's outer clothing shall be clean and his hands clean and dry. No person with an infected cut or open sores on the person's hands or arms shall milk lactating animals, or handle milk or milk containers, utensils or equipment.

(c) *Equipment.* Milk stools, surcingles or antikickers shall be kept clean and properly stored. Dusty operations shall not be conducted immediately before or during milking. Strong flavored feeds shall not be fed immediately before or during milking.

(d) *Abnormal milk.* In addition to the requirements of § 59a.116 (relating to abnormal milk), abnormal milk shall not be squirted on the floor, on the platform or in the producer's hand. Producers shall also wash their hands after handling such equipment and handling the teats and udders of animals producing abnormal milk.

§ 59a.204. Cooling and storage.

(a) *Milk in cans.* Milk in cans shall be cooled immediately after milking to 50°F or lower at the farm, and not exceed 55°F upon delivery to the plant, unless delivered to the plant within 2 hours after milking. The cooler, tank, or refrigerated unit shall be kept clean. Maximum time of delivery of milk to a milk plant shall be within 48 hours of initial milking.

(b) *Milk in farm bulk tanks.* Milk in farm bulk tanks shall be cooled to 40°F within 2 hours after milking. Cooled milk may not be allowed to rise above a temperature of 50°F

by subsequent addition of milk to the bulk tank and shall be cooled at 45°F or lower at time of pick-up, and not exceed 50°F upon delivery to the plant. Maximum time of delivery of milk to a milk plant may not exceed 72 hours of initial milking.

§ 59a.205. Milkhouse or milkroom.

(a) *General requirements.* A milkhouse or milkroom shall be provided for handling and cooling milk and for washing, handling, and storing the utensils and equipment. The milkhouse or milkroom shall be conveniently located and properly constructed, lighted, and ventilated. Other products shall not be handled in the milkroom which would be likely to contaminate milk, or otherwise create a public health hazard.

(b) *Equipment and construction.* The milkroom shall be equipped with wash and rinse vat, utensil rack, milk cooling facilities and an adequate supply of hot water available for cleaning milking equipment. If a part of the barn or other building, it shall be partitioned, screened, and sealed to prevent the entrance of dust, flies, or other contamination. The floor of the building shall be of concrete or other impervious material and graded to provide proper drainage. The walls and ceilings shall be constructed of smooth easily cleaned material. All outside doors shall open outward and be self-closing, unless they are provided with tight-fitting screen doors that open outward or unless other effective means are provided to prevent the entrance of flies.

(c) *Farm bulk tanks.* If a farm bulk tank is used, the following requirements apply:

(1) The farm bulk tank shall be properly located in the milkhouse or milkroom for access to all areas for cleaning and servicing. It may not be located over a floor drain or under a ventilator.

(2) A small platform or slab constructed of concrete or other impervious material shall be provided outside the milkhouse, properly centered under a suitable port opening in the wall of the milkhouse. The opening shall be fitted with a tight, self-closing door. The truck approach to the milkhouse or milkroom shall be properly graded and surfaced to prevent mud or pooling of water at the point of loading.

(d) *Trash, animals and fowl.* The milkhouse or milkroom and appurtenances shall be kept clean and free of trash, animals, and fowl.

(e) *Farm chemicals and animal drugs.*

(1) Animal biologics and other drugs intended for treatment of animals, and insecticides approved for use in dairy operations, shall be clearly labeled and used in accordance with label instructions, and shall be stored in a manner which will prevent accidental contact with milk and milk contact surfaces.

(2) Only drugs that are approved by the FDA or biologics approved by the USDA for use in dairy animals that are properly labeled according to FDA or USDA regulations shall be administered to such animals.

(3) When drug storage is located in the milkroom, milkhouse, or milking area, the drugs shall be stored in a closed, tight-fitting storage unit. Such drugs shall further be segregated in such a way so that drugs labeled for use in lactating dairy animals are separated from drugs labeled for use in non-lactating dairy animals.

(4) Drugs labeled for use in non-dairy animals shall not be stored with drugs labeled for use in dairy animals. When drugs labeled for use in non-dairy animals

are stored in the barn, the drugs shall be located in an area of the barn separate from the milking area.

(5) Herbicides, fertilizers, pesticides, and insecticides that are not approved for use in dairy operations shall not be stored in the milkhouse, milkroom, or milking area.

§ 59a.206. Utensils and equipment.

(a) *General requirements.* Utensils, milk cans, milking machines—including pipeline systems—rubber and rubber like parts and other equipment used in the handling of milk shall be maintained in good condition, shall be free from rust, open seams, milkstone, or any unsanitary condition, and shall be washed, rinsed, and drained after each milking, stored in suitable facilities, and sanitized immediately before use with a dairy equipment sanitizer that has been approved by the United States Environmental Protection Agency for use with dairy or food processing equipment, and that is used according to the label directions. New or replacement can lids shall be umbrella type. All new utensils and equipment shall comply with applicable *3-A Sanitary Standards*.

(b) *Farm bulk tanks.* Farm bulk tanks shall meet *3-A Sanitary Standards* for construction at the time of installation and shall be installed under § 59a.26 (relating to plans for construction and reconstruction).

(c) *Single service articles.* Single service articles shall be properly stored and shall not be reused.

§ 59a.207. Water supply.

A dairy farm water supply shall be properly located, protected, and operated, and shall be easily accessible, ample, and of safe, sanitary quality for the cleaning of dairy utensils and equipment. The water supply shall come from a source which is approved by the Department; or from a spring, dug well, driven well, bored well, or drilled well, the water from which complies with the standards of the Department.

§ 59a.208. Sewage disposal.

House, milkhouse or milkroom and toilet wastes shall be disposed of in a manner that will not pollute the soil surface, contaminate the water supply or be conducive to the breeding of insects.

Subchapter E. MANUFACTURING PLANTS

GENERAL REQUIREMENTS

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BUTTERMILK, DRY WHEY AND OTHER DRY MILK PRODUCTS

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- 59a.391. Equipment and utensils.
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GENERAL REQUIREMENTS

§ 59a.301. Premises.

(a) *General.* The exterior premises of a manufacturing plant shall be kept in a clean and orderly condition, and shall be free from strong or foul odors, smoke, or excessive air pollution. Construction and maintenance of driveways and adjacent plant traffic areas shall be of concrete, asphalt, or similar material to keep dust and mud to a minimum.

(b) *Surroundings.* The adjacent surroundings of a manufacturing plant shall be free from refuse, rubbish, and waste materials to prevent harborage of rodents, insects and other vermin.

(c) *Drainage.* A suitable drainage system shall be provided which will allow rapid drainage of all water from manufacturing plant buildings and driveways, including surface water around the plant and on the premises, and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard.

§ 59a.302. Buildings.

(a) *General.* Manufacturing plant buildings shall be of sound construction and kept in good repair to prevent the entrance or harboring of rodents, birds, insects, vermin, dogs and cats. Service pipe openings through outside walls shall be effectively sealed around the opening or provided with tight metal collars.

(b) *Outside doors, windows and openings.* All openings to the outer air including doors, windows, skylights, and transoms shall be effectively protected or screened against the entrance of flies and other insects, rodents, birds, dust, and dirt. All outside doors opening into processing rooms shall be in good condition and fit properly. All hinged, outside screen doors shall open outward. All doors and windows shall be kept clean and in good repair. Outside conveyor openings and other special-type outside openings shall be effectively protected to prevent the entrance of flies and rodents, by the use of doors, screens, flaps, fans, or tunnels. Outside openings for sanitary pipelines shall be covered when not in use. On new construction, window sills should be slanted downward at a 45⁰ angle.

(c) *Walls, ceilings, partitions, and posts.* The walls, ceilings, partitions, posts of rooms in which milk or dairy products are processed, manufactured, handled, packaged, or stored (except dry storage of packaged finished products and supplies) or in which utensils are washed and stored, shall be smoothly finished with a suitable material of light color, which is substantially impervious to moisture and kept clean. They shall be refined as often as necessary to maintain a neat, clean surface.

(d) *Floors.*

(1) The floors of all rooms in which milk or dairy products are processed, manufactured, packaged, or stored or in which utensils are washed shall be constructed of tile properly laid with impervious joint material, concrete, or other equally impervious material. The floors shall be smooth, kept in good repair, graded so that there will be no pools of standing water or milk products after flushing, and all openings to the drains shall be equipped with traps properly constructed and kept in good repair. On new construction bell-type traps shall not be used. The plumbing shall be so installed as to prevent the backup of sewage into the drain lines and to the floor of the plant.

(2) Sound, smooth wood floors which can be kept clean, may be used in rooms where new containers and supplies and certain packaged finished products are stored.

(e) *Lighting and ventilation.* Lighting and ventilation shall comply with the following:

(1) Light shall be ample, natural or artificial, or both, of good quality and well distributed. Rooms in which dairy products are manufactured or packaged or where utensils are washed shall have at least 30 foot-candles of light intensity on all working surfaces and at least 50 foot-candles of light intensity in areas where dairy products are graded or examined for condition and quality. In other rooms, there shall be at least 5 foot-candles of light intensity when measured at a distance of 30 inches from the floor. Where contamination of a product by broken glass is possible, light bulbs, fluorescent tubes, fixtures, skylight or other glass suspended over the product shall be protected against breakage.

(2) There shall be adequate heating, ventilation or air conditioning for all rooms and compartments to permit maintenance of sanitary conditions. Exhaust or inlet fans, vents, hoods or temperature and humidity control facilities shall be provided where and when needed, to minimize or eliminate undesirable room temperatures, objectionable odors, moisture condensation, or mold. Inlet fans shall be provided with an adequate air filtering device to eliminate dirt and dust from the incoming air. Ventilation systems shall be cleaned periodically as needed and maintained in good repair. Exhaust outlets shall be screened or provided with self-closing louvers to prevent the entrance of insects when not in use.

(f) *Certain rooms and compartments.* Rooms and compartments in which raw material, packaging, ingredient supplies, or dairy products are handled, manufactured, packaged, or stored shall be designed, constructed, and maintained to assure desirable room temperatures and clean and orderly operating conditions free from objectionable odors and vapors. Enclosed bulk milk receiving rooms shall be separated from the processing rooms by a partition. Rooms for receiving can milk shall be separated from the processing rooms by a partition—partial or complete—by suitable arrangement of equipment or by allowing enough distance between receiving and processing operations to avoid possible contamination of milk or dairy products during manufacturing and handling. Processing rooms shall be kept free from equipment and materials not regularly used. Rooms and compartments shall comply with the following:

(1) *Coolers and freezers.* Coolers and freezers where dairy products are stored shall be clean, reasonably dry and maintained at the proper uniform temperature and humidity to adequately protect the product and minimize the growth of mold.

Adequate circulation of air shall be maintained at all times. They shall be free from rodents, insects, and pests. Shelves shall be kept clean and dry. Refrigeration units shall have provisions for collecting and disposing of condensate.

(2) *Supply room.* The supply rooms used for the storing of packaging materials, containers, and miscellaneous ingredients shall be kept clean, dry, orderly, free from insects, rodents, and mold and maintained in good repair. Items stored in supply rooms shall be adequately protected from dust, dirt, or other extraneous matter and arranged on racks, shelves, or pallets to permit access to the supplies and cleaning and inspection of the room. Insecticides, rodenticides, cleaning compounds, and other nonfood products shall be properly labeled and segregated, and stored in a separate room or cabinet away from milk, dairy products, ingredients, or packaging supplies.

(3) *Boiler rooms, shop room, and service areas.* The boiler rooms, shop room and service areas shall be separated from other rooms where milk and dairy products are processed, manufactured, packaged, handled, or stored. The rooms shall be kept orderly and reasonably free from dust and dirt.

(4) *Toilet and dressing rooms.* Adequate toilet and dressing rooms facilities shall be conveniently located.

(i) Toilet rooms may not open directly into a room where milk or dairy products are processed, manufactured, packaged, or stored. Doors shall be self-closing. Ventilation shall be provided by mechanical means or screened openings to the outer air. Fixtures shall be kept clean and in good repair.

(ii) All employees shall be furnished with a locker, or other suitable facility, and the lockers and dressing rooms shall be kept clean and orderly. Adequate handwashing facilities shall be provided and durable, legible signs shall be posted conspicuously in each toilet or dressing room directing employees to wash their hands before returning to work.

(5) *Laboratory.* The permit holder may establish its own laboratory to perform required tests on milk received as milk for manufacturing purposes. The laboratory shall be adequately equipped and maintained and be properly staffed with qualified, trained personnel, to meet requirements established by the Department. If the permit holder does not establish its own laboratory, an existing approved laboratory is acceptable if services are conveniently available so that samples and results can be transmitted without delay.

(6) *Starter facilities.* Adequate sanitary facilities shall be provided for the handling of starter cultures.

(7) *Lunch rooms and eating areas.* When eating areas are provided, they shall be kept clean and orderly and not open directly into a room in which milk or dairy products are processed, manufactured or packaged. Signs shall be posted directing employees to wash their hands before returning to work.

§ 59a.303. Facilities.

(a) *Water supply.* There shall be an ample supply of both hot and cold water of safe and sanitary quality, with adequate facilities for its proper distribution throughout the plant, and protection against contamination and pollution. Water from other facilities,

when approved in writing by the Department, may be used for boiler feed water and condenser water provided that such waterlines are completely separated from the waterlines carrying the sanitary water supply, and the equipment is so constructed and controlled as to preclude contamination of product contact surfaces. There is no cross connection between the safe water supply and any unsafe or questionable water supply, or any other source of pollution through which contamination of the safe water supply is possible. Bacteriological examination shall be made of the sanitary water supply at least twice a year, or as often as necessary to determine purity and suitability for use in manufacturing dairy products. Such tests shall be made in a laboratory that is approved by the Department. The results of all water tests shall be kept on file at the plant for which the test was performed.

(b) *Drinking water.* Sanitary drinking water facilities shall be provided in the plant and shall be conveniently located.

(c) *Hand-washing facilities.* Convenient hand-washing facilities shall be provided, including hot and cold running water, soap or other detergents, and sanitary single-service towels or air dryers. Such accommodations shall be located in or adjacent to toilet and dressing rooms and also at such other places in the plant as may be essential to the cleanliness of all personnel handling products. Vats for washing equipment or utensils shall not be used as handwashing facilities. Self-closing metal or plastic containers shall be provided for used towels and other wastes.

(d) *Steam.* Steam shall be supplied in sufficient volume and pressure for satisfactory operation of each applicable piece of equipment. Culinary steam used in direct contact with milk or dairy products shall be free from harmful substances or extraneous material

and only nontoxic boiler compounds shall be used, or a secondary steam generator shall be used in which soft water is converted to steam and no boiler compounds are used. Steam traps, strainers, and condensate traps shall be used wherever applicable to insure a satisfactory and safe steam supply. Culinary steam shall comply with the current *3-A Accepted Practices for a Method of Producing Culinary Steam*.

(e) *Air under pressure*. The method for supplying air under pressure which comes in contact with milk or dairy products or any product contact surface shall comply with the current *3-A Accepted Practices for Supplying Air Under Pressure*. The air used at the point of application shall be free from volatile substances, volatiles which may impart any flavor or odor to the products, and extraneous or harmful substances.

(f) *Dairy waste*. Dairy wastes shall be properly disposed of from the plant and premises. The sewer system shall have sufficient slope and capacity to readily remove all waste from the various processing operations. Where a public sewer is not available, all wastes shall be properly disposed of so as not to contaminate milk equipment or to create a nuisance or public health hazard. Containers used for the collection and holding of wastes shall be constructed of metal, plastic, or other equally impervious material and kept covered with tight fitting lids and placed outside the plant on a concrete slab or on a rack raised at least 12 inches. Waste containers may be kept inside a suitably enclosed, clean and flyproof room. Solid wastes shall be disposed of regularly and the containers cleaned before reuse. Accumulation of dry wastepaper and cardboard shall be kept to a minimum.

§ 59a.304. Equipment and utensils.

(a) *General construction, repair, and installation.*

(1) The equipment and utensils used for the processing of milk and manufacture of dairy products shall be constructed to be readily demountable where necessary for cleaning and sanitizing. The product contact surfaces of all utensils and equipment such as holding tanks, pasteurizers, coolers, vats, agitators, pumps, sanitary piping, and fittings or any specialized equipment shall be constructed of stainless steel, or other equally corrosion-resistant material. Nonmetallic parts other than glass having product contact surfaces shall meet the current *3-A Standards for Multiple-Use Plastic Materials* or the current *3-A Sanitary Standards for Multiple-Use Rubber, and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment*.

(2) All equipment and piping shall be designed and installed so as to be easily accessible for cleaning, and shall be kept in good repair, free from cracks and corroded surfaces. New or rearranged equipment shall be set away from any wall or spaced in such a manner as to facilitate proper cleaning and to maintain good housekeeping. All parts or interior surfaces of equipment, pipes (except certain piping cleaned in place) or fittings, including valves and connections, shall be accessible for inspection.

(3) All CIP systems shall comply with the current *3-A Sanitary Practices for Permanently Installed Sanitary Product, Pipelines, and Cleaning Systems Used in Milk and Milk Processing Plants*.

(b) *Weigh cans and receiving tanks.* Weigh cans and receiving tanks shall meet the

general requirements of this section and shall be easily accessible for cleaning both inside and outside and shall be elevated above the floor and protected sufficiently with the necessary covers or baffles to prevent contamination from splash, condensate, and drippage. Where necessary to provide easy access for cleaning of floors and adjacent wall areas, the receiving tank shall be equipped with wheels or casters to allow easy removal.

(c) *Can washers.* Can washers shall have sufficient capacity and ability to discharge a clean, dry can and cover and shall be kept properly timed in accordance with the instructions of the manufacturer. The water and steam lines supplying the washer shall maintain a reasonably uniform pressure and if necessary be equipped with pressure regulating valves.

(d) *Product storage tanks or vats.* Storage tanks or vats shall be fully enclosed or tightly covered and well insulated. The entire interior surface, agitator and all appurtenances shall be accessible for thorough cleaning and inspection. Any opening at the top of the tank or vat including the entrance of the shaft shall be suitably protected against the entrance of dust, moisture, insects, oil, or grease. The sight glasses, if used, shall be sound, clean, and in good repair. Vats which have hinged covers shall be so designed that moisture or dust on the surface cannot enter the vat when the covers are raised. If the storage tanks or vats are equipped with air agitation, the system shall be of an approved type and properly installed in accordance with the current *3-A Accepted Practices for Supplying Air Under Pressure*. Storage tanks or vats intended to hold product for longer than approximately 8 hours shall be equipped with adequate refrigeration and/or have adequate insulation. All new storage tanks or vats shall meet the

appropriate *3-A Sanitary Standards* and shall be equipped with thermometers in good operating order.

(e) *Separators*. Product contact surfaces of separators shall be free from rust and pits and insofar as practicable shall be of stainless steel or other equally noncorrosive metals. All new separators shall meet the current *3-A Sanitary Standards for Centrifugal Separators and Clarifiers*.

(f) *Coil or dome-type batch pasteurizers*. Coil or dome-type batch pasteurizers shall be stainless steel lined and if the coil is not stainless steel or other equally noncorrosive metal it shall be properly tinned over the entire surface. Sanitary seal assemblies at the shaft ends of coil vats shall be of the removable type, except that existing equipment not provided with this type gland will be acceptable if the packing glands are maintained and operated without adverse effects. New or replacement units shall be provided with removable packing glands. Dome-type pasteurizer agitators shall be stainless steel except that any nonmetallic parts shall meet the current *3-A Sanitary Standards for Plastic and Rubber or Rubber-like Materials*, as applicable. Each pasteurizer used for heating product at 165⁰ F. or lower for 30 minutes or less shall be equipped with space heating equipment and the necessary thermometers to insure a temperature at least 5⁰ F. above that required for pasteurization of the product. There shall be adequate means of controlling the temperature of the heating medium. Batch pasteurizers shall have temperature indicating and recording devices, and shall meet the current *3-A Sanitary Standards for Non-Coil Type Batch Pasteurizers*.

(g) *High-temperature, short-time pasteurizers*. When pasteurization is intended or required, an approved timing pump or device recorder-controller, automatic flow

diversion valve and holding tube or its equivalent, if not a part of the existing equipment, shall be installed on all HTST equipment used for pasteurization, to assure complete pasteurization. The entire facility shall meet the current *3-A Accepted Practices for the Sanitary Construction, Installation, Testing, and Operation of High-Temperature, Short-Time Pasteurizers*. After the HTST unit has been tested according to the *3-A Accepted Practices*, the timing pump or device and the recorder controller shall be sealed at the correct setting to assure pasteurization. Sealing of the HTST unit shall be performed by the control authority having jurisdiction. The HTST pasteurizer shall be tested initially upon installation, and whenever any alteration or replacement is made which affects the proper operation of the instrument or device. When direct steam pasteurizers are used, the steam, prior to entering the product, shall be conducted through a steam strainer and a steam purifier equipped with a steam trap and only steam meeting the requirements for culinary steam shall be used.

(h) *Indicating thermometers.*

(1) Long-stem indicating thermometers which are accurate within 0.5⁰ F., plus or minus, for the applicable temperature range, shall be provided for checking the temperature of pasteurization and cooling of products in vats and checking the accuracy of recording thermometers.

(2) Short-stem indicating thermometers, which are accurate within 0.5⁰ F., plus or minus, for the applicable temperature range, shall be installed in the proper stationary position in all HTST, and dome-type pasteurizers. Storage tanks where temperature readings are required shall have thermometers which are accurate within 2.0⁰ F., plus or minus.

(3) Air-space indicating thermometers, where applicable, which are accurate within 1.0⁰ F., plus or minus, for the proper temperature range shall also be installed above the surface of the products pasteurized in vats, to make certain that the temperature of the foam and/or air above the products pasteurized also received the required minimum temperature treatment.

(i) *Recording thermometers.*

(1) HTST recording thermometers that are accurate within 1⁰ F., plus or minus, for the applicable temperature range, shall be used on each heat treating, pasteurizing, or sterilizing unit to record the heating process.

(2) Additional use of recording thermometers accurate within 2⁰ F., plus or minus, may be required where a record of temperature or time of cooling and holding is of significant importance.

(j) *Surface coolers.* Surface coolers shall be equipped with hinged or removable covers for the protection of the product. The edges of the fins shall be so designed as to divert condensate on nonproduct contact surfaces away from product contact surfaces. All gaskets or swivel connections shall be leak proof.

(k) *Plate-type heat exchangers.* Plate-type heat exchangers shall meet the current 3-A *Sanitary Standards for Construction and Installation.* All gaskets shall be tight and kept in good operating order. Plates shall be opened for inspection by the operator at sufficiently frequent intervals to determine if the equipment is clean and in satisfactory condition. A cleaning regimen shall be posted to insure proper cleaning procedures between inspection periods.

(l) *Internal return tubular heat exchangers.* Internal return tubular heat exchangers shall meet the current *3-A Sanitary Standards for Construction and Installation.*

(m) *Pumps.* Pumps used for milk and dairy products shall be of the sanitary type and constructed to meet *3-A Sanitary Standards.* Unless pumps are specifically designed for effective cleaning in place they shall be disassembled and thoroughly cleaned after use.

(n) *Homogenizers.* Homogenizers and high pressure pumps of the plunger type shall meet the *3-A Sanitary Standards.*

(o) *New equipment and replacements.* New equipment and replacements, including all plastic parts and rubber and rubberlike materials for parts and gaskets having product contact surfaces, shall meet the current *3-A Sanitary Standards* or *3-A Accepted Practices.* If *3-A Sanitary Standards* or *3-A Accepted Practices* are not available, such equipment and replacements shall meet the general requirements of this section.

(p) *Certain vacuum chambers.* A vacuum chamber, as used for flavor control, shall be made of stainless steel or other equally noncorrosive metal. The unit shall be constructed to facilitate cleaning and product contact surfaces shall be accessible for inspection. It shall be equipped with a vacuum breaker and a check valve at the product discharge line. Only steam which meets the requirements for culinary steam shall be used. The incoming steam supply shall be regulated by an automatic solenoid valve which will cut off the steam supply in the event the flow diversion valve of the HTST pasteurizer is not in the forward flow position. Condensers when used shall be equipped with a water level control and an automatic safety shutoff valve.

§ 59a.305. Personnel cleanliness.

All employees shall wash their hands before beginning work and upon returning to work after using toilet facilities, eating, smoking, or otherwise soiling their hands. They shall keep their hands clean and follow good hygienic practices while on duty.

Expectorating or use of tobacco in any form shall be prohibited in each room and compartment where any milk, dairy product, or supplies are prepared, stored, or otherwise handled. Clean white or light-colored washable outer garments and caps (paper caps or hair nets acceptable) shall be worn by all persons engaged in receiving, testing, processing milk, manufacturing, packaging, or handling dairy products.

§ 59a.306. Personnel health.

No person affected with any disease in a communicable form or while a carrier of such disease shall be permitted in any room or compartment where milk and dairy products are prepared, manufactured, or otherwise handled. No person who has a discharging or infected wound, sore or lesion on hands, arms, or other exposed portion of the body shall work in any dairy processing rooms or in any capacity resulting in contact with milk or dairy products. Each employee whose work brings him in contact with the processing or handling of dairy products, containers, or equipment shall have a medical and physical examination by a registered physician or by the local department of health at the time of employment. In addition an employee returning to work following illness from a communicable disease shall have a certificate from the attending physician to establish proof of complete recovery. Medical certificates attesting the fact that the employee when last examined was free from communicable disease shall be kept on file at the plant office.

§ 59a.307. Protection and transport of raw milk and cream.

(a) Equipment and facilities.

(1) *Milk cans.* Cans used in transporting milk from dairy farm to plant shall be of such construction as to be easily cleaned, and shall be inspected, repaired, and replaced as necessary to exclude substantially the use of cans and lids with open seams, cracks, rust, milkstone, or any unsanitary condition.

(2) *Farm bulk tanks.* New farm bulk tanks shall meet current *3-A Sanitary Standards* for construction and shall be installed in accordance with the requirements of the Grade "A" PMO.

(b) Transporting milk or cream.

(1) *Vehicles.* Vehicles used for the transportation of can milk or cream shall be of the enclosed type, constructed and operated to protect the product from extreme temperature, dust, or other adverse conditions and they shall be kept clean. Decking boards or racks shall be provided where more than one tier of cans is carried. Cans, or bulk tanks on vehicles, used for the transportation of milk from the farm to the plant shall not be used for any other purpose.

(2) *Transport tanks.* The exterior shell of transport tanks shall be clean and free from open seams or cracks which would permit liquid to enter the jacket. The interior shell shall be stainless steel and constructed so it will not buckle, sag, or prevent complete drainage. Product contact surfaces shall be smooth, easily cleaned, and maintained in good repair. The pump and hose cabinet shall be fully enclosed with tight fitting doors and the inlet and outlet shall be provided with

dust covers to give adequate protection from road dust. New and replacement transport tanks shall meet the current *3-A Sanitary Standards for Stainless Steel Automotive Transportation Tanks for Bulk Delivery and/or Farm Pick-Up Service*.

(c) *Cleaning and sanitizing facilities.* Enclosed facilities shall be available for washing and sanitizing of transport tanks, piping and accessories, at central locations or at all plants that receive or ship milk or milk products in transport tanks.

(d) *Transfer of milk.* Milk shall be transferred under sanitary conditions from farm bulk tanks through stainless steel piping or approved tubing. The sanitary piping and tubing shall be capped when not in use.

§ 59a.308. Raw product storage.

(a) *General.* Milk shall be held and processed under conditions and at temperatures that will avoid contamination and rapid deterioration. Drip milk from can washers or another source shall not be used for the manufacture of dairy products. Bulk milk in storage tanks within the plant shall be handled to minimize bacterial increase and shall be maintained at 45 F or lower until processing begins. This does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices.

(b) *Bacteriological quality.* The bacteriological quality of commingled milk in storage tanks shall be 1 million/ml or lower.

(c) *Sampling.* During any consecutive six months, at least four (4) samples of commingled raw milk for processing shall be taken by the Department, or a designated representative, from each plant.

(d) *Testing of samples.* A laboratory test of the samples described in subsection (c) shall be performed at a Pennsylvania approved dairy laboratory, to determine the bacterial estimate.

(e) *Procedures if bacterial counts are high.* Whenever a bacterial estimate of commingled milk in a plant indicates the presence of more than 1 million per milliliter, the following procedures shall be applied:

(1) The Department shall notify plant management with a warning of excessive bacterial estimate, and recommend that appropriate action be taken to eliminate the bacterial problem.

(2) Whenever two of the last four consecutive commingled milk bacterial estimates exceed 1 million per milliliter, the Department shall notify plant management with a written warning notice. The notice shall be in effect so long as two of the last four consecutive samples exceed 1 million per milliliter. Plant management should continue to work to eliminate the problem.

(3) An additional sample shall be taken by the Department after a lapse of 3 days but within 21 days of the notice required in paragraph (e)(1) of this section. If this sample also exceeds 1 million per milliliter, the Department may take action (such as permit suspension or acting to keep the milk from the marketplace) until an additional sample of *commingled* milk is tested and found satisfactory. A temporary status may be assigned to the plant by the Department

when an additional sample of commingled milk is tested and found satisfactory.

The plant shall be assigned a full reinstatement status when three out of four consecutive commingled bacterial estimates do not exceed 1 million per milliliter.

The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

(4) If a plant remains in temporary status in excess of 60 days, administrative procedures to suspend the plant's license will be taken by the Department until the plant complies with the bacteriological requirements.

(f) *Heat treated cream.* Heat treated cream is derived from the heating of raw milk, one time, to temperatures greater than 125° Fahrenheit but less than 161° Fahrenheit for separation purposes. When enzyme deactivation is necessary for a functional reason, the cream may be further heated to less than 166° Fahrenheit in a continuing heating process. The resulting bulk shipment of cream must be cooled to 45° Fahrenheit or less, and labeled as heat treated with bacterial limits of 20,000 per ml or gm for dairy products which are weighed.

§ 59a.309. Pasteurized, ultra-pasteurized or aseptically processed and packaged products.

Pasteurized, ultra-pasteurized or aseptically processed and packaged products shall conform with § 59a.2 (relating to definitions). When pasteurization or sterilization is intended or required, or when a product is designated "pasteurized" or "sterilized" every particle of the product shall be subjected to such temperatures and holding periods as will assure proper pasteurization or sterilization of the product. The heat treatment by either

process shall be sufficient to insure public health safety and to assure adequate keeping quality, yet retaining the most desirable flavor and body characteristics of the finished product. The phenol value of test samples of pasteurized finished product shall be no greater than the maximum specified for the particular product as determined and specified by the phosphatase test method prescribed in the latest edition of "Official Methods of Analysis of the Association of Official Agricultural Chemists" (a publication of the Association of Official Analytical Chemists International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877-2417).

§ 59a.310. Composition and wholesomeness.

Necessary precautions shall be taken to prevent contamination or adulteration of the milk or dairy products during manufacturing. Substances and ingredients used in the processing or manufacturing of a dairy product shall be subject to inspection and shall be wholesome and practically free from impurities. The finished product shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301—392) and applicable Commonwealth statutes as to their composition and wholesomeness.

§ 59a.311. Cleaning and sanitizing treatment.

(a) Equipment and utensils.

(1) The equipment, sanitary piping and utensils used in receiving and processing of the milk, and manufacturing and handling of the product shall be maintained in a sanitary condition. Sanitary seal assemblies shall be removable on all agitators, pumps and vats, and shall be inspected at regular intervals and kept clean. Unless

other provisions are recommended in the following supplemental sections, all equipment not designed for CIP cleaning shall be disassembled after each day's use for thorough cleaning. Dairy cleaners, detergents, wetting agents, sanitizing agents or other similar materials which will not contaminate or adversely affect the products may be used. Steel wool or metal sponges shall not be used in the cleaning of any dairy equipment or utensils. Utensils and portable equipment used in processing and manufacturing operations shall be stored above the floor in clean, dry locations and in a self draining position on racks constructed of impervious corrosion resistant material. All product contact surfaces shall be subjected to an effective sanitizing treatment immediately prior to use, except where dry cleaning is permitted. This sanitizing treatment shall entail subjection of a clean surface to steam, hot water, hot air, or an acceptable sanitizing solution for the destruction of most human pathogens and other vegetative microorganisms to a level considered safe for product production, without adversely affecting the equipment, the milk, the milk product or the health of consumers. Sanitizing solutions shall comply with 21 CFR 178.1010.

(2) CIP cleaning, including sprayball systems, shall be used only on equipment and pipeline systems which have been designed and engineered for that purpose. When such cleaning is used, careful attention shall be given to the proper procedures to assure satisfactory cleaning. All CIP installations and cleaning procedures shall be in accordance with the current *3-A Accepted Practices for Permanently Installed Product and Solution Pipelines and Cleaning Systems Used in Milk and Milk Product Processing Plants*. The established cleaning

procedure shall be posted and followed. Following the circulation of the cleaning solution, the equipment and lines shall be thoroughly rinsed and checked for effectiveness of cleaning. All caps, plugs, special fittings, valve seats, cross ends and tee ends shall be opened or removed and brushed clean. Immediately prior to starting the product flow, the product contact surfaces shall be properly sanitized.

(b) *Milk cans and can washers.* Milk cans and can washers shall meet the following requirements:

(1) Milk cans and lids shall be cleaned, sanitized, and dried before they are returned to producers. Inspection, repair, or replacement of cans and lids shall be adequate to substantially exclude from use cans and lids showing open seams, cracks, rust condition, milkstone or an unsanitary condition.

(2) Washers shall be maintained in a clean and satisfactory operating condition and kept free from accumulation of scale or debris which will adversely affect the efficiency of the washer.

(c) *Transport tanks.* An enclosed wash dock and cleaning and sanitizing facilities shall be available to all plants that receive or ship milk in tanks. Milk transport tanks, sanitary piping, fittings, and pumps shall be cleaned and sanitized at least once each day, after use. If milk transport tanks, sanitary piping, fittings, or pumps are not to be used immediately after emptying a load of milk, they shall be washed promptly after use and given bactericidal treatment immediately before use. After being washed and sanitized, each tank shall be identified by a tag attached to the outlet valve, bearing the following information:

(1) plant and specific location where cleaned;

(2) date and time of day of washing and sanitizing; and

(3) name of person who washed and name of person who sanitized the tank.

The tag shall not be removed until the tank is again washed and sanitized.

(d) *Buildings*. All windows, glass, partitions, and skylights shall be washed as often as necessary to keep them clean. Cracked or broken glass shall be replaced promptly. The walls, ceilings, and doors shall be washed periodically and kept free from soil and unsightly conditions. The shelves and ledges shall be wiped or vacuumed as often as necessary to keep them free from dust and debris. The material picked up by the vacuum cleaners shall be disposed of by burning or other proper methods to destroy any insects that might be present.

§ 59a.312. Insect and rodent control program.

In addition to any commercial pest control service, if one is utilized, a specially designated employee shall be made responsible for the performance of a regularly scheduled insect and rodent control program. Poisonous substances, insecticides, and rodenticides shall be properly labeled, and shall be handled, stored, and used in such a manner as not to create a public health hazard.

§ 59a.313. Plant records.

A milk plant shall retain adequate records of required tests on raw milk receipts. Records shall be available for examination at reasonable times by the Department. The following are the records which shall be maintained for examination at the plant or receiving station where performed:

(1) Sediment, drug residue, and bacterial test results on raw milk from each producer: retain for 12 months.

(i) Routine tests and monthly summary of all producers showing number and percent of total in each class.

(ii) Retests, if initial test places milk in probationary status.

(iii) Rejection of raw milk over No. 3 in quality.

(2) Positive drug residue tests: retain for 12 months.

(3) Pasteurization recorder charts: retain for 6 months.

(4) Water test reports: retain copies for 6 months.

(5) Employee health certificate: Retain most recent copy until employee is no longer employed by plant.

(6) Drug residue test results for milk samples that do not test positive: Retain for 6 months.

§ 59a.314. Packaging and general identification.

(a) *Containers.* Containers shall meet the following standards:

(1) The size, style and type of packaging used for manufactured dairy products shall be commercially acceptable containers and packaging materials which satisfactorily cover and protect the quality of the contents during storage and regular channels of trade and under normal conditions of handling. The weights and shape within each size and style shall be as nearly uniform as is practical.

(2) Packaging materials for dairy products shall be selected which will provide sufficiently low permeability to air and vapor to prevent the formation of mold

growth and surface oxidation. The wrapper shall be resistant to puncturing, tearing, cracking, or breaking under normal conditions of handling, shipping and storage. When special type packaging is used, the instructions of the manufacturers shall be followed closely as to its application and methods of closure.

(b) *Packaging and repackaging.* Packaging dairy products or cutting and repackaging styles of dairy products shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment, and packaging material shall be practically free from mold and bacterial contamination. Method for checking the level of contamination shall be as prescribed by the *Standard Methods for the Examination of Dairy Products*.

(c) *General identification.* All commercial bulk packages containing dairy products manufactured under this subpart shall be adequately and legibly marked with the name of the product, net weight, name and address of processor or manufacturer or other assigned plant identification, lot number and other identification that may be required. Consumer packaged products shall be legibly marked with the name of the product, net weight, name and address of packer, manufacturer or distributor and other identification required by the Department.

§ 59a.315. Storage of finished product.

(a) *Dry storage.* The finished product shall be stored at least 18 inches from the wall in aisles, rows, or sections and lots, so it is orderly and easily accessible for inspection. Rooms shall be cleaned regularly. Care shall be taken in the storage of products foreign

to dairy products in the same room, in order to prevent impairment or damage to the dairy product from mold, absorbed odors, vermin or insect infestation. Control of humidity and temperature shall be maintained at all times, consistent with good commercial practices, to prevent conditions detrimental to the product and container.

(b) *Refrigerated storage.* The finished product shall be placed on shelves, dunnage or pallets and properly identified. It shall be stored under temperatures that will best maintain the initial quality. The product may not be exposed to anything from which it might absorb foreign odors or be contaminated by drippage or condensation.

§ 59a.316. Permits.

Plant permitting requires satisfactory compliance with the applicable requirements in Subchapter E.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING, AND PACKAGING
INSTANT NONFAT DRY MILK, NONFAT DRY MILK, DRY
WHOLE MILK, DRY BUTTERMILK, DRY WHEY, AND
OTHER DRY MILK PRODUCTS**

§ 59a.321. Requirements for rooms and compartments.

Rooms and compartments shall conform to subsection 59a.302(f) (relating to buildings).

§ 59a.322. Dry storage.

(a) *General requirement.* Dry storage of instant nonfat dry milk, nonfat dry milk, dry whole milk, dry buttermilk, dry whey, and other dry milk products shall conform with § 59a.315 (relating to storage of finished product).

(b) *Storage rooms.* Storage rooms for the dry storage of product shall be adequate in size, kept clean, orderly, free from rodents, insects, and mold, and maintained in good repair. They shall be adequately lighted and ventilated. The ceilings, walls, beams, and floors shall be free from structural defects and inaccessible false areas which may harbor insects.

§ 59a.323. Packaging room for bulk products.

A separate room or area shall be provided for filling bulk bins, drums, bags or other bulk containers and shall be constructed to conform to § 59a.302 (relating to buildings). The number of control panels and switchboxes in this area shall be kept to a minimum. Control panels shall be mounted a sufficient distance from the walls to facilitate cleaning or shall be mounted in the wall and provided with tight-fitting removable doors to facilitate cleaning. An adequate exhaust system shall be provided to minimize the accumulation of product dust within the packaging room and, where needed, a dust collector shall be provided and properly maintained to keep roofs and outside areas free of dry product. Only packaging materials that are used within a day's operation may be kept in the packaging area. These materials shall be kept on metal racks or tables at least 6 inches off the floor. Unnecessary fixtures, equipment, or false areas which may collect dust and harbor insects, shall not be allowed in the packaging room.

§ 59a.324. Hopper or dump room.

A separate room shall be provided for the transfer of bulk dry dairy products from bags or drums to the hoppers and conveyors which lead to the fillers. The room shall meet the same requirements for construction and facilities as the bulk packaging operation. Areas and facilities providing for the transfer of dry dairy products from portable bulk bins shall be acceptable if gasketed surfaces or direct connections are used that essentially eliminate the escape of product into the area.

§ 59a.325. Repackaging room.

A separate room shall be provided for the filling of small packages and shall meet the same requirements for construction and facilities as the bulk packaging operation.

§ 59a.326. Equipment and utensils.

Equipment and utensils shall conform with § 59a.304 (relating to equipment and utensils). Additional, more specific requirements are applicable to the items of equipment listed from § 59a.327 (relating to preheaters) through § 59a.341 (relating to heavy duty vacuum cleaners).

§ 59a.327. Preheaters.

Preheaters shall be of stainless steel or other equally corrosion-resistant material, cleanable, accessible for inspection and shall be equipped with suitable automatic temperature controls.

§ 59a.328. Hotwells.

Hotwells shall be enclosed or covered and equipped with indicating thermometers either in the hotwell or in the hot milk inlet line to the hotwell and if used for holding high heat products they shall also have recorders.

§ 59a.329. Evaporators or vacuum pans, or both.

Open-type evaporators or vacuum pans, or both, shall be equipped with an automatic condenser water level control, barometric leg, or constructed to prevent water from entering the product, and shall meet the applicable *3-A Sanitary Standards*. When enclosed-type condensers are used, no special controls are needed to prevent water from entering the product.

§ 59a.330. Surge tanks.

If surge tanks are used for hot milk and temperatures of products including foam being held in the surge tank during processing is not maintained at a minimum of 150°F, two or more surge tanks shall be installed with cross connections to permit flushing and cleaning during operation. Covers easily removable for cleaning shall be provided and used at all times.

§ 59a.331. High pressure pumps and lines.

High pressure lines may be cleaned in place and shall be of construction so that deadends, valves and the high pressure pumps can be disassembled for hand cleaning.

New high pressure pumps shall meet the current *3-A Sanitary Standard Covering Homogenizers and High Pressure Pumps of the Plunger Type*.

§ 59a.332. Dryers.

(a) *Spray dryers.* Spray dryers shall conform to the current *3-A Accepted Practices for Spray Drying Systems*. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. In gas-fired dryers, precautions shall be taken to assure complete combustion. Air shall be drawn into the dryer from sources free from objectionable odors and smoke, dust, or dirt.

(b) *Roller dryers.* Roller dryers shall comply with the following:

(1) The drums of a roller dryer shall be smooth, readily cleanable and free of pits and rusts. The knives shall be maintained in a condition so they don't cause scoring of the drums.

(2) The end boards shall have an impervious surface and be readily cleanable. They shall be provided with a means of adjustment to prevent leakage and accumulation of milk solids. The stack, hood, drip pan inside of the hood and related shields shall be constructed of stainless steel and be readily cleanable. The lower edge of the hood shall be constructed so as to prevent condensate from entering the product zone. The hood shall be properly located and the stack of adequate capacity to remove the vapors. The stack shall be closed when the dryer is not in operation. The augers shall be of stainless steel or properly plated, and readily cleanable. The auger troughs and related shields shall be of stainless steel and be readily cleanable. Air entering the dryer room shall be filtered to eliminate

dust and dirt. The filter system shall consist of a filtering media or device that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying room. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. Dryer adjustments shall be made and the dryer operating normally before food grade powder can be collected from the dryer.

§ 59a.333. Collectors and conveyors.

Collectors shall be made of stainless steel or equally noncorrosive material and shall be constructed to facilitate cleaning and inspection. Filter sack collectors, if used, shall comply with the current *3-A Sanitary Standards for Bag Collectors*. Conveyors shall comply with the current *3-A Sanitary Standards for Pneumatic Conveyors for Dry Milk and Dry Milk Products* or the current *3-A Sanitary Standards for Mechanical Conveyors for Dry Products*.

§ 59a.334. Dry dairy product cooling equipment.

Cooling equipment shall be provided with sufficient capacity to cool the products to 110°F or lower immediately after removal from dryer and prior to packaging. If bulk bins are used, the product should be cooled to approximately 90°F, but shall not be more than 110°F. A suitable dry air supply with effective filtering shall be provided where air cooling and conveying is used.

§ 59a.335. Special treatment equipment.

Special equipment, such as flakers, pulverizers or hammer mills used to further process dry milk products shall be of sanitary construction and parts shall be accessible for cleaning and inspection. Instantizing systems shall comply with the current *3-A Accepted Practices for Instantizing Systems*.

§ 59a.336. Sifters.

Newly installed sifters used for dry milk and dry milk products shall meet the current *3-A Sanitary Standards for Sifters for Dry Products*. All other sifters shall be constructed of stainless steel or other equally noncorrosive material and shall be of sanitary construction and accessible for cleaning and inspection. The mesh size of sifter screen used for various dry dairy products shall be those recommended in the appendix of the referenced *3-A Sanitary Standard*.

§ 59a.337. Portable and stationary bulk bins.

Bulk bins shall be constructed of stainless steel, aluminum or other equally corrosion-resistant materials, free from cracks and seams and shall have an interior surface that is relatively smooth and easily cleanable. All product contact surfaces shall be easily accessible for cleaning. Portable bins shall comply with the current *3-A Sanitary Standards for Portable Bins for Dry Milk and Dry Milk Products*.

§ 59a.338. Automatic sampling device.

If automatic sampling devices are used, they shall be constructed to prevent contamination of the product, and all parts shall be readily accessible for cleaning.

§ 59a.339. Dump hoppers, screens and mixers.

The product contact surfaces of dump hoppers, screens and mixers which are used in the process of transferring dry products from bulk containers to fillers for small packages or containers, shall be of stainless steel or equally corrosion resistant material and designed to prevent contamination. Parts shall be accessible for cleaning. The dump hoppers shall be of a height above floor level to prevent foreign material or spilled product from entering the hopper.

§ 59a.340. Filler and packaging equipment.

Filling and packaging equipment shall comply with the current *3-A Sanitary Standards for Equipment for Packaging Dry Milk and Dry Milk Products*.

§ 59a.341. Heavy duty vacuum cleaners.

Each plant handling dry milk products shall be equipped with a heavy duty industrial vacuum cleaner. Regular scheduling shall be established for its use in vacuuming applicable areas.

§ 59a.342. Clothing and shoe covers.

Clean clothing and shoe covers shall be provided exclusively for the purpose of cleaning the interior of the dryer when it is necessary to enter the dryer to perform the cleaning operation.

§ 59a.343. Operations and operating procedures: Pasteurization.

(a) *Pasteurization.* Milk, buttermilk, and whey used in the manufacture of dry dairy products shall be pasteurized at the plant where dried, except that condensed whey and acidified buttermilk containing 40% or more solids may be transported to another plant for drying without repasteurization. Milk or skim milk to be used in the manufacture of nonfat dry milk shall be heated prior to condensing to at least the minimum pasteurization temperature of 161°F for at least 15 seconds or its equivalent in bacterial destruction. Condensed skim made from pasteurized skim milk may be transported to a drying plant; however, it shall be effectively repasteurized at the drying plant, prior to drying, at a minimum temperature of 166°F for at least 15 seconds or its equivalent.

(b) *Buttermilk and cream derived from buttermilk.* Buttermilk or cream from which it is derived shall be pasteurized prior to condensing at a temperature of 185°F for 15 seconds or its equivalent in bacterial destruction.

(c) *Cheese whey.* Cheese whey or milk from which it is derived shall be pasteurized prior to condensing at a temperature of 161°F for 15 seconds or its equivalent in bacterial destruction.

§ 59a.344. Operations and operating procedures: Condensed surge supply.

Surge tanks or balance tanks if used between the evaporators and dryer shall be used to hold the minimum amount of condensed product necessary for a uniform flow to the dryers. Such tanks holding products at temperatures below 150°F shall be completely emptied and washed after each 4 hours of operation or less. Alternate tanks shall be provided to permit continuous operation during washing of tanks.

§ 59a.345. Operations and operating procedures: Condensed storage tanks.

(a) *Excess production.* Excess production of condensed products over that which the dryer will take continuously from the evaporator or pans should be by-passed through a cooler into a storage tank at 50°F or lower and held at this temperature until used.

(b) *Regular cleaning and sanitizing.* Product cut-off points shall be made at least every 24 hours and the tank completely emptied, washed, and sanitized before reuse.

§ 59a.346. Operations and operating procedures: Drying.

Each dryer shall be operated at not more than the manufacturer's rated capacity for the highest quality dry product consistent with the most efficient operation. This does not preclude the remodeling or redesigning of dryers after installation when properly engineered and designed. The dry products shall be removed from the drying chamber continuously during the drying process.

§ 59a.347. Operations and operating procedures: Cooling dry products.

Prior to packaging and immediately following removal from the drying chamber, the dry product shall be cooled to a temperature not exceeding 110°F.

§ 59a.348. Operations and operating procedures: Packaging, repackaging and storage.

(a) *Containers.* Packages or containers used for the packaging of nonfat dry milk or other dry milk products shall be any clean, sound, commercially accepted container or

packaging material which shall satisfactorily protect the contents through the regular channels of trade, without significant impairment of quality with respect to flavor, wholesomeness or moisture content under the normal conditions of handling. Containers which have previously been used for nonfood items or food which would be deleterious to the dairy product shall not be used for the bulk handling of dairy products.

(b) *Filling.* Empty containers shall be protected from possible contamination and containers which are to be lined may not be prepared more than 1 hour in advance of filling. Every precaution shall be taken during the filling operation to minimize product dust and spillage. When necessary, a mechanical shaker shall be provided. The tapping or pounding of containers shall be prohibited. The containers shall be closed immediately after filling and the exteriors shall be vacuumed or brushed when necessary to render them practically free of product remnants before being transferred from the filling room to the palleting or dry storage areas.

(c) *Repackaging.* The entire repackaging operation shall be conducted in a sanitary manner with all precautions taken to prevent contamination and to minimize dust. Exterior surfaces of individual containers shall be practically free of product before overwrapping or packing in shipping containers. The flow shall be kept free of dust accumulation, waste, cartons, liners or other refuse. Conveyors, packaging and carton making equipment shall be vacuumed frequently during the operating day to prevent the accumulation of dust. No bottles or glass materials shall be permitted in the repackaging or hopper room. The inlet openings of hoppers and bins shall be of minimum size, screened and placed well above the floor level. The room and all packaging equipment shall be cleaned as often as necessary to maintain a sanitary operation. Close attention

shall be given to cleaning points of equipment where residues of the dry product may accumulate. A thorough clean-up including windows, doors, walls, light fixtures, and ledges, shall be performed as frequently as is necessary to maintain a high standard of cleanliness and sanitation. All waste dry dairy products including dribble product at the fillers shall be properly identified and disposed of as animal feed.

(d) *Storage.* Storage shall be as follows:

(1) *Product.* The packaged dry milk product shall be stored or arranged in aisles, rows or sections and lots at least 18 inches from a wall and in an orderly, easily accessible manner for inspection or for cleaning of the room. Bags and small containers of products shall be placed on pallets elevated approximately 6 inches from the floor. The storage room shall be kept clean and dry and all openings protected against entrance of insects and rodents.

(2) *Supplies.* Supplies shall be placed on dunnage or pallets and arranged in an orderly manner for accessibility and cleaning of the room. Supplies shall be kept enclosed in their original wrapping material until used. After removal of supplies from their original containers, they shall be kept in an enclosed metal cabinet, bins, or on shelving, and if not enclosed shall be protected from powder and dust or other contamination. The room shall be vacuumed as often as necessary and kept clean and orderly.

§ 59a.349. Operations and operating procedures: Product adulteration.

All necessary precautions shall be taken throughout the entire operation to prevent the adulteration of one product with another. The commingling of one type of liquid or dry

product with another shall be considered as an adulteration of the product. This does not prohibit the normal standardization of like products in accordance with good commercial practices or the production of specific products for special uses, if applicable labeling requirements are met.

§ 59a.350. Operations and operating procedures: Checking quality.

All milk, manufactured dairy products and dry milk products shall be subject to inspection and analysis by the plant for quality and condition throughout each processing operation. Line samples shall be taken periodically as an aid to quality control in addition to the regular routine analysis made on the finished products.

§ 59a.351. Operations and operating procedures: Requirements for instant nonfat dry milk.

(a) *Sampling and testing.* Instant nonfat dry milk offered for sale shall be sampled and tested by an approved laboratory at least once each month for the purpose of assuring that the product meets the requirements of subsection (b). The dry milk plant shall have each subplot of approximately 4000 pounds tested and analyzed prior to being packaged or offered for sale. Products which do not meet the requirements of subsection (b) may not be offered as Extra Grade.

(b) *Requirements for Extra Grade instant nonfat dry milk.* Requirements are as follows:

(1) *Flavor and odor.* The flavor and odor shall be sweet, pleasing and desirable but may possess the following flavors to a slight degree: Chalky, cooked, feed, flat.

(2) *Physical appearance.* The physical appearance shall possess a uniform white to light cream natural color and shall be reasonably free-flowing and free from lumps except those that readily break up with very slight pressure.

(3) *Bacterial estimate.* The standard plate count shall not be more than 10,000 per gram.

(4) *Coliform count.* The coliform count shall not be more than 10 per gram.

(5) *Milkfat content.* The milkfat shall not be more than 1.25%.

(6) *Moisture count.* The moisture shall not be more than 4.5%.

(7) *Scorched particle content.* Scorched particles shall not be more than 15 mg.

(8) *Solubility index.* The solubility index shall not be more than 1 milliliter.

(9) *Titrateable acidity.* The titrateable acidity shall not be more than 0.15%.

(10) *Dispersibility.* The dispersibility may not be less than 85% by the Modified Moats-Dabbah Method, as recommended by the United States Department of Agriculture.

(11) *Direct microscopic clump count.* The direct microscopic clump count shall not be more than 40 million per gram.

(12) *USDA grading.* The product must be graded as Extra Grade instant nonfat dry milk by The Dairy Grading Branch, USDA.

§ 59a.352. Operations and operating procedures: Cleaning of dryers, conveyors, sifters and storage bins.

Dryers, conveyors, sifters and storage bins shall be cleaned as often as necessary to maintain the equipment in a clean and sanitary condition. The kind of cleaning procedure

- either wet or dry - and the frequency of cleaning, shall be based upon observation of actual operating results and conditions.

§ 59a.353. Operations and operating procedures: Insect and rodent control program.

In addition to any commercial pest control service, if one is utilized, a specifically designated employee shall be made responsible for the performance of a regularly scheduled insect and rodent control program.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING AND PACKAGING
BUTTER AND RELATED PRODUCTS**

§ 59a.361. Rooms and compartments.

(a) *Coolers and freezers.* The coolers and freezers shall be equipped with facilities for maintaining proper temperature and humidity conditions, consistent with good commercial practices for the applicable product, to protect the quality and condition of the products during storage or during tempering prior to further processing. Coolers and freezers shall be kept clean, orderly, free from insects, rodents and mold, and maintained in good repair. They shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls and ceilings shall be of a construction that permits thorough cleaning.

(b) *Churn rooms.* Churn rooms, in addition to proper construction and sanitation, shall be equipped so the air is kept free from objectionable odors and vapors and extreme temperatures by means of adequate ventilation and exhaust systems or air conditioning and heating facilities.

(c) *Print and bulk packaging rooms.* Rooms used for packaging print or bulk butter and related products shall, in addition to proper construction and sanitation, provide an atmosphere relatively free from mold (no more than 10 mold colonies per cubic foot of air), dust, or other airborne contamination and be maintained at a reasonable room temperature.

§ 59a.362. Equipment and utensils.

(a) *General construction, repair and installation.* Equipment and utensils necessary to the manufacture of butter and related products shall meet requirements of § 59a.304 (relating to equipment and utensils).

(b) *Continuous churn.* Product contact surfaces shall be of noncorrosive material. Nonmetallic product contact surfaces shall comply with the current *3-A Standards for Multiple-Use Plastic Materials* or the current *3-A Sanitary Standards for Multiple-Use Rubber, and Rubber-like Materials*. Product contact surfaces shall be readily accessible for cleaning and inspection.

(c) *Conventional churn.* Churns shall be constructed of aluminum, stainless steel or equally corrosion resistant metal, free from cracks, and in good repair. Gasket material shall be fat resistant, nontoxic and reasonably durable. Seals around the doors shall be tight.

(d) *Bulk butter trucks, boats and packers.* Bulk butter trucks, boats and packers shall be constructed of aluminum, stainless steel or equally corrosion resistant metal free from cracks, seams and shall have a surface that is relatively smooth and easily cleanable.

(e) *Butter, frozen or plastic cream melting machines.* Shavers, shredders or melting machines used for rapid melting of butter, frozen or plastic cream shall be of stainless steel or equally corrosion resistant metal, sanitary construction and readily cleanable.

(f) *Printing equipment.* Printing equipment shall comply with the current *3-A Sanitary Standards for Equipment for Packaging Viscous Products.*

(g) *Brine tanks.* Brine tanks used for the treating of parchment liners shall be constructed of noncorrosive material and shall have an adequate and safe means of heating the salt solution for the treatment of the liners. The tank shall also be provided with a satisfactory drainage outlet.

(h) *Starter vats.* Bulk starter vats shall be of stainless steel or equally corrosion resistant metal and constructed according to applicable *3-A Sanitary Standards.* The vats shall be in good repair, equipped with tight-fitting lids and have effective temperature controls.

§ 59a.363. Operations and operating procedures.

(a) *Pasteurization.* The milk or cream shall be pasteurized at the plant where the milk or cream is processed into the finished product.

(1) *Cream for buttermaking.* Requirements are as follows:

(i) The cream for buttermaking shall be pasteurized at a temperature of not less than 165°F and held continuously in a vat at that temperature for not less than 30 minutes; or pasteurized by HTST method at a minimum

time and temperature of at least 185°F for at least 15 seconds; or by another equivalent time and temperature combination that is approved by the Department. Additional heat treatment above the minimum pasteurization requirement is advisable to insure improved keeping quality characteristics.

(ii) Adequate pasteurization control shall be used and the diversion valve shall be set to divert at less than 185°F with a 15 second holding time or its equivalent in time and temperature to assure pasteurization. If the vat or holding method of pasteurization is used, vat covers shall be closed prior to holding period to assure temperature of air space reaching the minimum temperature before holding time starts. Covers shall also be kept closed during the holding and cooling period.

(2) *Cream for plastic or frozen cream.* The pasteurization of cream for plastic or frozen cream shall be accomplished in the same manner as in subparagraph (i) except that the temperature for the vat method shall be not less than 170°F for not less than 30 minutes, or not less than 190°F for not less than 15 seconds or by another temperature and holding time which will assure adequate pasteurization and comparable keeping quality characteristics.

(b) *Composition and wholesomeness.* Ingredients used in the manufacture of butter and related products shall be subject to inspection and shall be wholesome and practically free from impurities. Chlorinating facilities shall be provided for butter wash water if needed and other necessary precautions shall be taken to prevent contamination of

products. Finished products shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act, as to composition and wholesomeness.

(c) *Containers.* Containers shall comply with the following:

(1) Containers used for the packaging of butter and related products shall satisfactorily protect the quality of the contents in regular channels of trade. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing 2 pounds or less, to protect the product from contamination during subsequent handling.

(2) Liners and wrappers shall comply with the following:

(i) Supplies of parchment liners, wrappers, and other packaging material shall be protected against dust, mold and other possible contamination.

(ii) Prior to use, parchment liners for bulk butter packages shall be completely immersed in a boiling salt solution in a suitable container constructed of stainless steel or other equally noncorrosive material. The liners shall be maintained in the solution for not less than 30 minutes. The solution shall consist of at least 15 pounds of salt for every 85 pounds of water and shall be strengthened or changed as frequently as necessary to keep the solution full strength and in good condition.

(iii) Other liners, such as polyethylene, shall be treated or handled to prevent contamination of the liner prior to filling.

(3) The lined butter containers shall be protected from possible contamination prior to filling.

(d) *Printing and packaging.* Printing and packaging of consumer size containers of butter shall be conducted under sanitary conditions.

(e) *General identification.* Commercial bulk shipping containers shall be legibly marked with the name of the product, net weight, name and address of manufacturer, processor or distributor or other assigned plant identification—manufacturer's lot number, churn number, and the like—and other identification that may be required. Packages of plastic or frozen cream shall be marked with the percent of milkfat.

(f) *Storage of finished product in coolers.* Products shall be kept under refrigeration at temperatures of 40°F or lower after packaging and until ready for distribution or shipment. The products may not be placed directly on floors or exposed to foreign odors or conditions such as drippage due to condensation which might cause package or product damage.

(g) *Storage of finished product in freezer.*

(1) *Sharp freezers.* Plastic cream or frozen cream intended for storage shall be placed in quick freezer rooms immediately after packaging, for rapid and complete freezing within 24 hours. The packages shall be piled or spaced so that air can freely circulate between and around the packages. The rooms shall be maintained at -10°F or lower and shall be equipped to provide sufficient high-velocity air circulation for rapid freezing. After the products have been completely frozen, they may be transferred to a freezer storage room for continued storage.

(2) *Freezer storage.* Freezer storage shall comply with the following:

- (i) The room shall be maintained at a temperature of 0°F or lower. Adequate air circulation is desirable.
- (ii) Butter intended to be held more than 30 days shall be placed in a freezer room as soon as possible after packaging. If not frozen before being placed in the freezer, the packages shall be spaced to permit rapid freezing and re-piled, if necessary, at a later time.

SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING AND PACKAGING CHEESE

§ 59a.371. Rooms and compartments.

(a) *Starter room.* Starter rooms or areas shall be properly equipped and maintained for the propagation and handling of starter cultures. Necessary precautions shall be taken to prevent contamination of the starter, of the room, equipment, and the air therein.

(b) *Make room.* The room in which the cheese is manufactured shall be of adequate size, and the vats adequately spaced to permit movement around the vats and presses for proper cleaning and satisfactory working conditions. Adequate ventilation shall be provided.

(c) *Drying room.* If cheese is to be paraffined, a drying room of adequate size shall be provided to accommodate the maximum production of cheese during the flush period. Adequate shelving and air circulation shall be provided for proper drying. Suitable temperature and humidity control facilities shall be provided.

(d) *Paraffining room or area.* For rind cheese, a separate room or area shall be provided for paraffining and boxing the cheese. The room or area shall be of adequate size and the temperature maintained near the temperature of the drying room to avoid sweating of the cheese prior to paraffining.

(e) *Rindless block wrapping area.* For rindless blocks, a suitable space shall be provided for proper wrapping and boxing of the cheese. The area shall be free from dust, condensation, mold or other conditions which may contaminate the surface of the cheese or contribute to the unsatisfactory packaging of the cheese.

(f) *Coolers or curing rooms.* Coolers or curing rooms where cheese is held for curing or storage shall be clean and maintained at the proper uniform temperature and humidity to adequately protect the cheese. Proper circulation of air shall be maintained at all times. The rooms shall be free from rodents, insects, and pests. The shelves shall be kept clean and dry.

(g) *Cutting and packaging rooms.* When small packages of cheese are cut and wrapped, separate rooms shall be provided for the cleaning and preparation of the bulk cheese and a separate room shall be provided for the cutting and wrapping operation. The rooms shall be well lighted, ventilated, and provided with filtered air. Air movement shall be outward to minimize the entrance of unfiltered air into the cutting and packaging room.

§ 59a.372. Equipment and utensils.

(a) *General construction, repair, and installation.* Equipment and utensils necessary to the manufacture of cheese and related products shall meet the requirements of § 59a.304

(relating to equipment and utensils). In addition, for other equipment the following requirements in this section shall be met.

(b) *Starter vats.* Bulk starter vats shall be of stainless steel or equally corrosion resistant metal and shall be in good repair, equipped with tight-fitting lids and have adequate temperature controls, such as valves, indicating and/or recording thermometers. New vats shall be constructed according to the applicable *3-A Sanitary Standards*.

(c) *Cheese vats.* Requirements shall be as follows:

(1) Open vats used for making cheese shall be of metal construction with adequate jacket capacity for uniform heating. The inner liner shall be minimum 16-gauge stainless steel, properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket shall be constructed of stainless steel or other equally corrosion resistant metal which can be kept clean and sanitary. The junction of the liner and outer jackets shall be constructed so as to prevent milk or cheese from entering the inner jacket.

(2) The vat shall be equipped with a suitable sanitary outlet valve. Effective valves shall be provided and properly maintained to control the application of heat to the vat.

(3) Enclosed cheese vats shall meet the requirements of the current *3-A Sanitary Standards for Enclosed Cheese Vats and Tables*.

(d) *Mechanical agitators.* The mechanical agitators shall be of sanitary construction. The carriage and track shall be constructed to prevent the dropping of dirt or grease into the vat. Metal blades, forks or stirrers shall be constructed of stainless steel, and shall be

free from rough or sharp edges which might scratch the equipment or remove metal particles.

(e) *Curd mill and miscellaneous equipment.* Knives, hand rakes, shovels, paddles, strainers and miscellaneous equipment shall be stainless steel or of material approved in the *3-A Sanitary Standards*. The product contact surfaces of the curd mill shall be of stainless steel. Pieces of equipment shall be constructed so they can be kept clean. The wires in the curd knives shall be stainless steel or other suitable metal, kept tight and replaced when necessary.

(f) *Hoops and followers.* The hoops, forms, and followers shall be constructed of stainless steel or heavy tinned steel. If tinned, they shall be kept tinned and free from rust. Hoops, forms and followers shall be kept in good repair. Drums or other special forms used to press and store cheese shall be clean and sanitary.

(g) *Press.* The cheese press shall be constructed of stainless steel and all joints welded and all surfaces, seams and openings readily cleanable. The pressure device shall be the continuous type. Press cloths shall be maintained in good repair and in a sanitary condition. Single-service press cloths shall be used only once.

(h) *Rindless cheese press.* The press used to heat seal the wrapper applied to rindless cheese shall have square interior corners, reasonably smooth interior surface and have controls that shall provide uniform pressure and heat equally to all surfaces.

(i) *Paraffin tanks.* The metal tank shall be adequate in size, have paraffined wood or metal racks to support the cheese, have heat controls and an indicating thermometer. The cheese wax shall be kept clean.

(j) *Automatic curd conveyors.* When the salted curd is moved to a hooping station for blocks or barrels by means of an air conveying system, the nonproduct contact surfaces of the system shall be constructed of suitable nontoxic material which is corrosion resistant. Product contact surfaces shall be constructed of stainless steel with all joints welded or properly gasketed, and all surfaces readily accessible and cleanable. The air shall be filtered and of sufficient quality for the intended use. Air compressors or vacuum pumps shall not be located in the processing or packaging areas.

(k) *Whey probes.* Vacuum equipment used to withdraw whey from cheese shall be constructed of stainless steel tubes and be readily accessible and removable for cleaning and inspection.

(l) *Cheese vacuumizer.* Bulk cheese vacuum chambers, if used, shall be installed so that floor surfaces underneath are effectively sealed or have enough clearance so they can be cleaned. Interior surfaces of the vacuum chamber shall be constructed and maintained so that the product is not contaminated with rust or flaking paint. An inner liner of stainless steel or other corrosion resistant material shall be provided.

§ 59a.373. Operations and operating procedures.

(a) *Cheese from pasteurized milk.*

(1) If the cheese is labeled as pasteurized, the milk shall be pasteurized by subjecting every particle of milk to a minimum temperature of 161 F for not less than 15 seconds.

(2) HTST pasteurization units shall be equipped with the proper controls and equipment to assure pasteurization. If the milk is held more than 2 hours between

time of receipt or heat treatment and setting, it shall be cooled to 45°F or lower until time of setting.

(b) *Cheese from unpasteurized milk.* If the cheese is labeled as “heat treated,” “unpasteurized,” “raw milk,” or “for manufacturing,” the milk may be raw or heated at temperature below pasteurization. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45°F or lower until time of setting.

(c) *Whey disposal.* Disposal shall be as follows:

(1) Adequate sanitary facilities shall be provided for the disposal of whey. If outside, necessary precautions shall be taken to minimize flies, insects, and development of objectionable odors.

(2) Whey or whey products intended for human food shall at all times be handled in a sanitary manner under this subpart as specified for handling milk and dairy products. Equipment operated on a batch or vat basis shall be cleaned or thoroughly rinsed between batches or vats. If equipment is operated on a continuous basis, the whey collection pans shall be rinsed at least once every two hours of operation with potable water.

(d) *Packaging and repackaging.* Packaging rindless cheese or cutting and repackaging all styles of bulk cheese shall be conducted under rigid sanitary conditions. The atmosphere of the packaging rooms, the equipment and the packaging material shall be practically free from mold and bacterial contamination.

(e) *General identification.* Each bulk cheese shall be legibly marked with the name of the product, code or date of manufacture, vat number, officially designated code number

or name and address of manufacturer. Each consumer sized container shall be plainly marked with the name and address of the manufacturer, packer, or distributor, net weight of the contents, name of the product and other information that may be required.

**SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING,
PROCESSING, AND PACKAGING
PASTEURIZED PROCESS CHEESE AND RELATED PRODUCTS**

§ 59a.381. Equipment and utensils.

(a) *General construction, repair, and installation.* The equipment and utensils used for the handling and processing of cheese products shall be as specified in §59a.304 (relating to equipment and utensils). In addition, for certain other equipment the requirements in this section shall be met.

(b) *Conveyors.* Conveyors shall be constructed of material which can be properly cleaned, will not rust, or otherwise contaminate the cheese, and shall be maintained in good repair.

(c) *Grinders or shredders.* The grinders or shredders used in the preparation of the trimmed and cleaned natural cheese for the cookers shall be adequate in size. Product contact surfaces shall be of corrosion resistant material, and of a construction to prevent contamination of the cheese and to allow thorough cleaning of all parts and product contact surfaces.

(d) *Cookers.* The cookers shall be the steam jacketed or direct steam type. They shall be constructed of stainless steel or other equally corrosion resistant material. Product contact surfaces shall be readily accessible for cleaning. Each cooker shall be equipped with an indicating thermometer and a temperature recording device. Steam check valves on direct steam type cookers shall be mounted flush with cooker wall, be constructed of stainless steel and designed to prevent the backup of product into the steam line, or the steam line shall be constructed of stainless steel pipes and fittings which can be readily cleaned. If direct steam is applied to the product, only culinary steam shall be used.

(e) *Fillers.* The hoppers of all fillers shall be covered but the cover may have sight ports. If necessary, the hopper may have an agitator to prevent buildup on side wall. The filler valves and head shall be kept in good repair, capable of accurate measurements.

§ 59a.382. Operations and operating procedures.

(a) *Trimming and cleaning.* The natural cheese shall be cleaned free of all nonedible portions. Paraffin and bandages as well as rind surfaces, mold or unclean areas of another part which is unwholesome or unappetizing shall be removed.

(b) *Cooking the batch.* Each batch of cheese within the cooker, including the optional ingredients shall be thoroughly commingled and the contents pasteurized at a temperature of at least 158°F and held at that temperature for not less than 30 seconds. Care shall be taken to prevent the entrance of cheese particles or ingredients after the cooker batch of cheese has reached the final heating temperature. After holding for the required period of time, the hot cheese shall be emptied from the cooker as quickly as possible.

(c) *Forming containers.* Containers either lined or unlined shall be assembled and stored in a sanitary manner to prevent contamination. The handling of containers by filler crews shall be done with extreme care and observance of personal cleanliness.

Preforming and assembling of pouch liners and containers shall be kept to a minimum and the supply rotated to limit the length of time exposed to possible contamination prior to filling.

(d) *Filling containers.* Hot fluid cheese from the cookers may be held in hotwells or hoppers to assure a constant and even supply of processed cheese to the filler or slice former. Filler valves shall effectively measure the desired amount of product into the pouch or container in a sanitary manner and shall cut off sharply without drip or drag of cheese across the opening. An effective system shall be used to maintain accurate and precise weight control. Damaged or unsatisfactory packages shall be removed from production, and the cheese may be salvaged into sanitary containers, and added back to cookers.

(e) *Closing and sealing containers.* Pouches, liners, or containers having product contact surfaces after filling shall be folded or closed and sealed in a sanitary manner, preferably by mechanical means, so as to assure against contamination. Each container in addition to other required labeling shall be coded in a manner that is easily identifiable as to date of manufacture by lot or subplot number.

SUPPLEMENTAL REQUIREMENTS FOR PLANTS
MANUFACTURING, PROCESSING, AND PACKAGING
EVAPORATED, CONDENSED OR STERILIZED MILK PRODUCTS

§ 59a.391. Equipment and utensils.

(a) *General construction, repair, and installation.* The equipment and utensils used for processing and packaging evaporated and condensed milk shall be as specified in § 59a.304 (relating to equipment and utensils). In addition, for certain other equipment, the requirements of this section shall be met.

(b) *Evaporators and vacuum pans.* Equipment used in the removal of moisture from milk or milk products for the purpose of concentrating the solids shall meet the requirements of the current *3-A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans*. All new or used replacements for this type of equipment shall meet the appropriate *3-A Sanitary Standards*.

(c) *Fillers.* Both gravity and vacuum type fillers shall be of sanitary design and all product contact surfaces, if metal, shall be made of stainless steel or equally corrosion resistant material. Certain evaporated milk fillers having brass parts may be approved if free from corroded surfaces and kept in good repair. Fillers shall be designed so that they in no way will contaminate or detract from the quality of the product being packaged.

(d) *Batch or continuous in-container sterilizers.* Batch or continuous in-container sterilizers shall be equipped with accurate temperature controls and effective valves for regulating the sterilization process. The equipment shall be maintained to assure control of the length of time of processing and to minimize the number of damaged containers.

(e) *Homogenizers.* Homogenizers, where applicable, shall be used to reduce the size of the fat particles and to evenly disperse them in the product. New homogenizers shall meet the applicable *3-A Sanitary Standards*.

§ 59a.392. Operations and operating procedures.

(a) *Preheat, pasteurization.* When pasteurization is intended or required by either the vat method, HTST method, or by the UHT method it shall be accomplished by systems and equipment meeting the requirements of § 59a.304 (relating to equipment and utensils).

(b) *Sterilization.* The complete destruction of all living organisms shall be performed in one of the following methods:

(1) The complete in-container method, by heating the container and contents to a range of 212°F to 280°F for a sufficient time.

(2) By a continuous flow UHTST process at high temperature of 280°F and above for a sufficient time, then packaged aseptically.

(3) The product is first sterilized according to UHTST methods as in paragraph (2), then packaged and given further heat treatment to complete the sterilization process.

(c) *Filling containers.*

(1) The filling of small containers with products shall be done in a sanitary manner. The containers shall not contaminate or detract from the quality of the product in any way. After filling, the container shall be hermetically sealed.

(2) Bulk containers for unsterilized products shall be suitable and adequate to protect the product in storage or transit. The bulk container, including bulk tankers, shall be cleaned and sanitized before filling, and filled and closed in a sanitary manner.

(d) *Aseptic filling.* A previously sterilized product shall be filled under conditions which prevent contamination of the product by living organisms or spores. The containers prior to being filled shall be sterilized and maintained in a sterile condition. The containers shall be sealed in a manner that prevents contamination of the product.

(e) *Storage.* Proper facilities shall be provided for the storage and handling of finished product.

Subchapter F. RAW MILK FOR HUMAN CONSUMPTION

Sec.

- 59a.401. Raw milk; General.
- 59a.402. Raw milk; Prohibitions.
- 59a.403. Raw milk permit.
- 59a.404. Requirements for the issuance of a raw milk permit.
- 59a.405. Sanitation.
- 59a.406. Animal health.
- 59a.407. Regular testing of water supply.
- 59a.408. Regular testing of raw milk.

- 59a.409. Violations of raw milk testing standards.
- 59a.410. Location of raw milk packaging facilities on the dairy farm.
- 59a.411. Label content review by the Department.
- 59a.412. Inspection, sampling and testing by the Department.
- 59a.413. Enforcement: Suspension or revocation of a raw milk permit.
- 59a.414. Enforcement: Summary criminal prosecution.
- 59a.415. Enforcement: Injunctions.
- 59a.416. Enforcement: Seizure, condemnation, denaturing or destruction of raw milk; Exclusion from sale.

§ 59a.401. Raw milk; General.

This subchapter prescribes the permitting, testing, and inspection requirements that are applicable to persons seeking to sell raw milk for human consumption.

§ 59a.402. Raw milk; Prohibitions.

(a) *Sale of raw milk without permit.* A person shall not sell raw milk for human consumption without having a current raw milk permit issued by the Department. The term “sell” includes the selling, exchanging, delivering, or having in possession, care, control, or custody with intent to sell, exchange, or deliver, or to offer or to expose for sale.

(b) *Actions authorized under a raw milk permit.* A raw milk permit authorizes the permit holder to lawfully produce and sell (within Pennsylvania) raw whole milk for

human consumption. It also authorizes the permit holder to obtain an additional permit, issued by the Department under authority of 21 CFR § 133.150 (relating to hard cheeses), authorizing the sale of aged cheese manufactured from raw milk.

(c) *Compliance with testing and documentation requirements.* A person shall not sell raw milk without being in compliance with the testing and documentation requirements of this section.

§ 59a.403. Raw milk permit.

(a) *Application.* A raw milk permit application may be obtained by contacting the Department at the address set forth in § 59a.3 (relating to contacting the Department).

(b) *Duration.* A raw milk permit shall be valid for no more than one year. Each raw milk permit shall expire as of September 1 each year, unless revoked or suspended earlier by the Department.

(c) *Timing of filing to ensure Department review of an application for a successor raw milk permit.* If a raw milk permit holder wishes to obtain a raw milk permit to replace an expiring raw milk permit, the permit holder is encouraged, but is not required, to file an application for this successor raw milk permit with the Department by July 1 of the year in which the current raw milk permit is to expire. Compliance with this recommendation may help to prevent a lapse between the expiring raw milk permit and the effective date of the successor raw milk permit.

§ 59a.404. Requirements for the issuance of a raw milk permit.

(a) *Pre-issuance inspection.*

(1) *New raw milk permits.* Prior to issuing a raw milk permit, the Department will inspect the dairy farm that is the subject of a new raw milk permit application, to determine whether the dairy farm is in compliance with the Milk Sanitation Law and this Chapter. The dairy farm must be in passing condition in order to be eligible for a raw milk permit.

(2) *Successor raw milk permits.* If a raw milk permit holder applies to the Department for a successor raw milk permit, then the Department may issue the raw milk permit without conducting the dairy farm inspection described in paragraph (1).

(b) *Confirmation of Tuberculosis-Free and Brucellosis-Free Status.*

(1) *New raw milk permits.* An applicant for a new raw milk permit shall provide the Department confirmation that the animal or herd from which the raw milk is to be produced has been determined to be free from brucellosis and free from tuberculosis, in accordance with the process described in § 59a.406 (relating to animal health). This confirmation must be provided in order for the subject dairy farm to be eligible for a raw milk permit.

(2) *Successor raw milk permits.* An applicant for a successor raw milk permit shall, at intervals of no greater than 13 months, provide the Department confirmation that the animal or herd from which the raw milk is to be produced has been determined to be free from brucellosis and tuberculosis by annual tests in accordance with the process described in § 59a.406.

(c) *General herd health.*

(1) *New raw milk permits.* An applicant for a new raw milk permit shall have a licensed veterinarian examine the herd and provide the Department a written report of this examination. The report shall reflect that the herd is in good general health and free from communicable disease. This shall be done in accordance with § 59a.406 (relating to animal health).

(2) *Successor raw milk permits.* An applicant for a successor raw milk permit shall provide the Department a copy of a veterinary examination report as described in paragraph (1). The report must be dated within one year preceding the date of the application, and shall reflect that the herd is in general good health and free from communicable disease. The applicant shall continue to have this veterinary examination conducted on an annual basis, in accordance with § 59a.406.

(d) *Confirmation of safe water supply.*

(1) *New raw milk permits.* An applicant for a new raw milk permit shall have the dairy farm water supply tested, and shall provide the Department with confirmation that the water is bacteriologically safe, in accordance with § 59a.407 (relating to regular testing of water supply). Confirmation that the water supply is bacteriologically safe must be provided in order for the subject dairy farm to be eligible for a raw milk permit. If the water supply is through a public or municipal water system, this testing requirement does not apply.

(2) *Successor raw milk permits.* An applicant for a successor raw milk permit shall provide the Department with a copy of a written laboratory report as described in paragraph (1). The report must be dated no earlier than 6 months

preceding the date of the application, shall be done in accordance with § 59a.407, and shall reflect that the dairy farm water supply is bacteriologically safe.

(e) *Sampling and testing.*

(1) *New raw milk permits.* An applicant for a new raw milk permit shall demonstrate its ability to produce raw milk for human consumption through the following process:

(i) The applicant shall have an approved sampler draw 3 separate samples of commingled milk. The samples shall be drawn at least 7 days apart, and shall be taken on an unannounced basis.

(ii) Each of these 3 samples described in subparagraph (i) shall be submitted to a Pennsylvania approved dairy laboratory or the Department for analysis.

(iii) The analysis described in subparagraph (ii) shall determine whether the sample meets the standards set forth in § 59a.408 (relating to regular testing of raw milk).

(iv) If any of the 3 analyzed samples described in subparagraph (iii) violates or exceeds a standard set forth in § 59.408, the 3-sample process shall repeat itself until 3 successive samples are in compliance with the referenced standards.

(v) If the first of the three required samples is tested as described in subparagraph (iii), and concludes that no pathogenic bacteria are present, the second and third samples need not be tested for the presence of pathogenic bacteria. If a sample test concludes that pathogenic bacteria

are present, no raw milk permit will be issued until and unless two separate consecutive tests, from samples drawn at least 7 days apart, conclude that no pathogenic bacteria are present.

(2) *Successor raw milk permits.* An applicant for a successor raw milk permit shall demonstrate its ability to produce raw milk for human consumption through the regular sampling and testing process described in § 59.408.

(f) *Location of packaging-related facilities and equipment.*

(1) *Containers owned by the customer.* If a dairy farm that is the subject of a raw milk permit or raw milk permit application packages raw milk for sale in containers that are owned by the customers, rather than by the permit holder, the Department will consider a milk room facility as being adequate for the packaging of this raw milk.

(2) *Containers owned by the raw milk permit holder.* If a dairy farm that is the subject of a raw milk permit or raw milk permit application packages raw milk for sale in containers that are owned by the permit holder, (such as in prepackaged containers for consumer purchase), the dairy farm shall have separate rooms for bottling, single service container storage, and bottle washing. A mechanical means of filling and capping bottles shall be utilized for prepackaging, and the closure shall protect the pouring lip to its largest diameter.

§ 59a.405. Sanitation.

A raw milk permit holder shall maintain and operate the subject dairy operation in compliance with the same sanitation and handling standards that are applicable to the

production of milk for pasteurization, as set forth in § 59a.19 (relating to standards for grade “A” raw milk for pasteurization, ultra-pasteurization or aseptic processing), except to the extent any of those provisions are inconsistent with any provision of this subchapter. The provisions of the Grade “A” PMO and, in particular, the *Standards for Grade “A” Raw Milk for Pasteurization, Ultra-Pasteurization or Aseptic Processing* set forth in that document and Section 7 of the Grade “A” PMO (relating to standards for Grade “A” milk and milk products) are incorporated by reference as regulations authorized under the Act, to the extent they do not conflict with the Act or any provision of this subchapter. This includes all of the Items listed under the referenced Grade “A” PMO provisions, including the following:

- (1) Item 1r. Abnormal milk
- (2) Item 2r. Milking Barn, Stable or Parlor - Construction
- (3) Item 3r. Milking Barn, Stable or Parlor - Cleanliness
- (4) Item 4r. Cowyard
- (5) Item 5r. Milkhouse – Construction and Facilities
- (6) Item 6r. Milkhouse - Cleanliness
- (7) Item 7r. Toilet
- (8) Item 8r. Water Supply, with the additional requirement that a plate heat exchanger or tubular cooler installed and in use on a dairy farm shall be equipped with a backflow prevention device
- (9) Item 9r. Utensils and Equipment - Construction
- (10) Item 10r. Utensils and Equipment - Cleaning
- (11) Item 11r. Utensils and Equipment - Sanitization

- (12) Item 12r. Utensils and Equipment - Storage
- (13) Item 13r. Milking – Flanks, Udders and Teats
- (14) Item 14r. Protection from Contamination
- (15) Item 15r. Drug and Chemical Control
- (16) Item 16r. Personnel – Handwashing Facilities
- (17) Item 17r. Personnel - Cleanliness
- (18) Item 18r. Raw Milk Cooling, with the exception that raw milk for pasteurization shall be cooled to 4 degrees C (40 degrees F) within two hours after the completion of milking.
- (19) Item 19r. Insect and Rodent Control

§ 59a.406. Animal health.

(a) *General.* A raw milk permit holder shall monitor the health of the animals from which the raw milk is produced, to ensure that they are in general good health and free of tuberculosis and brucellosis.

(b) *Confirmation of Brucellosis-Free Status.*

(1) *Annual Blood Tests.* A raw milk permit holder shall, at intervals of no greater than 13 months, provide the Department confirmation from a licensed veterinarian that the animal or herd from which the raw milk is produced has been determined to be free from brucellosis by annual blood tests conducted in accordance with the regulations at 7 Pa. Code Chapter 7 (relating to brucellosis regulations).

(2) *Ring Tests at Intervals of Six Months or Less.* A raw milk permit holder shall, at intervals of no greater than 6 months, provide the Department confirmation of the results of a brucellosis ring test conducted with respect to the animal or herd from which the raw milk is produced.

(c) *Annual Confirmation of Tuberculosis-Free Status.* A raw milk permit holder shall, at intervals of no greater than 13 months, provide the Department confirmation from a licensed veterinarian that the animal or herd from which the raw milk is produced has been determined to be free from tuberculosis by annual tests conducted in accordance with the regulations at 7 Pa. Code Chapter 9 (relating to control and eradication of tuberculosis of livestock).

(d) *Annual Veterinary Examination.* A raw milk permit holder shall, at intervals of no more than one year, have a licensed veterinarian examine the herd and issue a written report of this examination. The report shall reflect that the herd is in good general health and free from communicable disease. The raw milk permit holder shall retain a copy of the written veterinarian's report for at least three years and shall, upon request of the Department, make the report available for inspection.

§ 59a.407. Regular testing of water supply.

(a) *General requirement of safe and sanitary water.* The water supply for a dairy operation that produces raw milk under a raw milk permit must be safe and sanitary.

(b) *Testing Frequency.* The water supply for a dairy operation that produces raw milk under a raw milk permit must be tested at least once every 6 months, and whenever any repair or alteration is made to the water supply system. This testing shall be at the raw

milk permit holder's expense. If the water supply is through a public or municipal water system, this testing requirement shall not apply.

(c) *Testing Standards.* The water tests described in this section shall be conducted at a qualified laboratory. The testing shall include bacteriological examinations to determine whether the water is bacteriologically safe. The water supply shall contain a Most Probable Number of Coliform Organisms (MPN) of less than 2.2-per-100-milliliters by the multiple tube fermentation method or less than 1-per-100-milliliters by the membrane filter technique or the chromogenic substrate technique. The water shall otherwise be safe and sanitary.

(d) *Water test records.* The raw milk permit holder shall retain all records of required water tests, and shall make these available for inspection upon request of the Department.

§ 59a.408. Regular testing of raw milk.

(a) *Responsibility.* A raw milk permit holder shall be responsible to arrange for the regular sampling and testing required with respect to the raw milk permit, and to pay for this testing.

(b) *Testing laboratories.* All raw milk samples submitted for testing must be analyzed at an official laboratory or a Pennsylvania approved dairy laboratory.

(c) *Testing schedule and standards.* A raw milk permit holder shall coordinate raw milk testing on the following schedule; and the raw milk samples shall meet the following standards:

Raw Milk Testing Schedule and Standards

<u>Required Action Interval</u>	<u>Type of Action or Test Required</u>	<u>Standard</u>
<u>At all times</u>	<u>Maintain raw milk temperature in accordance with Raw Milk Temperature standards.</u>	<u>Raw milk shall be cooled to 40°F (4°C) or less within two hours after milking, provided that the blend temperature after the first and subsequent milking does not exceed 50°F (10°C).</u>
<u>At least twice each month, in conjunction with the tests for coliform count and for the presence of drugs (including growth inhibitors), described in this chart</u>	<u>Bacterial Count</u>	<u>Bacteria shall not be present in excess of 20,000 per milliliter. NOTE: Tested in conjunction with a drug residue/ inhibitory substance test.</u>
<u>At least twice each month, in conjunction with the tests</u>	<u>Coliform Count</u>	<u>Coliform shall not exceed 10 per milliliter.</u>

for bacterial count and for
the presence of drugs
(including growth
inhibitors), described in this
chart

NOTE: Tested in
conjunction with a drug
residue/ inhibitory
substance test.

At least twice each month

Somatic Cell Count

The somatic cell count shall
not exceed
750,000/milliliter.

At least twice each month,
in conjunction with the tests
for bacterial count and for
coliform count, described in
this chart

Test for presence of Drugs
(including growth
inhibitors)

There shall be no positive
results for drug residue,
using drug residue detection
laboratory techniques
referenced in the current
Grade "A" Pasteurized Milk
Ordinance developed by the
United States Department
of Health and Human
Services, Food and Drug
Administration.

At least twice annually

Test for presence of
Pathogenic Bacteria

There shall be no
pathogenic bacteria present.

including *Salmonellae*,

Listeria monocytogenes,

Camphylobacter, and E.

Coli 0157:H7

§ 59a.409. Violations of raw milk testing standards.

(a) *Bacterial count, somatic cell count, coliform count or cooling temperature tests.*

(1) If *two of the last four* tested raw milk samples exceed the bacterial count, somatic cell count or coliform count standards or cooling temperature requirements described in § 59a.408 (relating to regular testing of raw milk), the Department will provide the raw milk permit holder with written notice that it is in violation of the requirements of the Act and this chapter.

(2) If *three of the last five* tested raw milk samples exceed the bacterial count, somatic cell count or coliform count standards or cooling temperature requirements described in § 59a.408, the Department will proceed to revoke or suspend the raw milk permit, and the raw milk permit holder shall be subject to summary criminal prosecution under the Act.

(b) *Pesticides.* If a raw milk sample tests positive for the presence of a pesticide, the raw milk permit holder shall do all of the following:

(1) Immediately cease the sale of raw milk for human consumption.

(2) Take a second sample and submit it for testing for pesticide residue.

(3) Investigate and determine the cause of the contamination, report the result of that investigation to the Department, and correct that cause of contamination.

(4) Refrain from selling raw milk until and unless the second test shows the sample to be free of pesticide residue, or to be below the actionable levels established for such residue, and the Department reviews these test results and approves the resumption of raw milk sales.

(c) *Growth inhibitor.* If a raw milk sample tests positive for the presence of a growth inhibitor, the raw milk permit holder shall do all of the following:

(1) Immediately cease the sale of raw milk for human consumption.

(2) Investigate and determine the cause of the contamination, report the result of the investigation to the Department, and correct the cause of contamination.

(3) Have a second sample collected by an approved sampler and tested at a Pennsylvania approved dairy laboratory.

(4) Refrain from selling raw milk until and unless the second test shows the sample to be free of growth inhibitor residue, or to be below the actionable levels established for such residue, and the Department reviews these test results and approves the resumption of raw milk sales.

(d) *Disease-producing organisms.* If a raw milk sample tests positive for the presence of pathogenic bacteria or other disease-producing organisms such as *Salmonellae*, *Listeria monocytogenes*, *Camphylobacter* or *E. Coli* 0157:H7, the raw milk permit holder shall do all of the following:

(1) Immediately cease the sale of raw milk for human consumption.

(2) Investigate and determine the cause of the contamination, report the result of that investigation to the Department, and correct that cause of contamination.

(3) Wait at least 2 days from the cessation of raw milk sales, or until such time as conformance can reasonably be assured, and then have an approved sampler collect a second sample and submit it to a Pennsylvania approved dairy laboratory to be tested for the presence of pathogenic bacteria.

(4) Following the initial sampling described in the preceding requirement, have an approved sampler collect an additional sample – at least one day after the previous sample - and submit it to a Pennsylvania approved dairy laboratory for testing for the presence of pathogenic bacteria.

(5) Refrain from selling raw milk until and unless two consecutive tests, from samples drawn at least one day apart, show that raw milk produced at the dairy operation that is the subject of the raw milk permit is free from disease-producing organisms, and the Department reviews these test results and approves the resumption of raw milk sales.

§ 59a.410. Location of raw milk packaging facilities on the dairy farm.

(a) *Containers owned by the raw milk permit holder.* If raw milk is packaged for sale in containers that are owned by the raw milk permit holder (such as in prepackaged containers for consumer purchase), the dairy farm shall have separate rooms for bottling, single service container storage, and bottle washing, as applicable. A mechanical means of filling and capping bottles shall be utilized for prepackaging, and the closure shall protect the pouring lip to its largest diameter.

(b) *Containers owned by the customer.* If raw milk is packaged for sale in containers that are owned *by the consumer*, the Department will consider a milk room facility as being adequate for the packaging of this raw milk.

§ 59a.411. Label content review by the Department.

(a) *Raw milk in containers owned by the raw milk permit holder.*

(1) *General label statements.* If raw milk is packed for sale in containers that are owned by the raw milk permit holder, the labeling on these containers and caps shall be submitted to the Department and approved by the Department prior to use in commerce. The container shall be labeled as raw milk, and shall include the net weight as well as the name and address of the distributor or producer and the words “Keep Refrigerated.” It shall not be misbranded or contain any false or misleading statements.

(2) *Consumer advisory for raw animal-derived foods that have not been processed to remove pathogens.* In addition to the information described in paragraph (1), the label shall contain a consumer advisory statement to notify consumers of the increased risks (particularly to certain highly susceptible populations) associated with the consumption of raw animal-derived foods that have not been processed to remove pathogens. An acceptable notice would be as follows:

Raw milk has not been processed to remove pathogens that can cause illness. The consumption of raw milk may significantly increase the risk

of foodborne illness in persons who consume it - particularly with respect to certain highly-susceptible populations such as preschool-age children, older adults, pregnant women, persons experiencing illness, and other people with weakened immune systems.

The Department will consider alternative written means of notification of consumers of the potential risks associated with the consumption of raw milk by highly-susceptible populations.

(3) *Label requirement: milk dating.*

(i) *Requirement.* The cap of the raw milk container, or the container itself, shall be conspicuously and legibly marked in a contrasting color with the designation of the “sell-by” date - the month and day of the month after which the raw milk may not be sold or offered for sale. The designation may be numerical - such as “8-15” - or with the use of an abbreviation for the month, such as “AUG 15” or “AU 15.” The words “Sell by” or “Not to be sold after” shall precede the designation of the date, or the statement “Not to be sold after the date stamped above” shall appear legibly on the container. This designation of the date may not exceed 17 days beginning after midnight on the day on which the raw milk was produced.

(ii) *Prominence of sell-by date on label.* The sell-by date shall be separate and distinct from any other number, letter or intervening material on the cap or container.

(iii) *Prohibition.* Raw milk may not be sold or offered for sale for human consumption if the raw milk is sold or offered for sale after the sell-by date designated on the container.

(iv) *Monitoring by the Department.*

(A) The Department will periodically sample containers of raw milk in the possession of the raw milk permit holder or a distributor. This sampling may occur at any time before the raw milk is delivered to the customer. The Department will take at least one sample of raw milk from each raw milk permit holder each calendar year.

(B) The samples described in clause (A) shall be analyzed by the Department or a Pennsylvania approved dairy laboratory, to determine whether bacterial test results exceed the bacterial limits for raw milk described in the Raw Milk Testing Schedule and Standards set forth in § 59a.408 (relating to regular testing of raw milk) prior to the expiration of the sell-by date designated on the raw milk container.

(C) When two or more samples demonstrate a raw milk permit holder cannot produce raw milk that remains consistently within the bacterial limits referenced in clause (B) through the sell-by date marked on the container, the Department will require a raw milk permit holder to use a shorter sell-by date specified by the Department. The Department will calculate this revised sell-by

date so that bacterial growth in the raw milk will not exceed the referenced bacterial limits within that sell-by period if the raw milk is maintained in accordance with the temperature requirements for raw milk set forth in the Raw Milk Testing Schedule and Standards in § 59a.408 (relating to regular testing of raw milk).

(D) A raw milk permit holder may submit samples to the Department for analysis to obtain approval to resume a 17-day sell-by period for the raw milk sampled. The Department will approve resumption of a 17-day sell-by period when analysis of a sample demonstrates that bacterial growth in the raw milk will not exceed the referenced bacterial limits within that sell-by period if the raw milk is maintained in accordance with the temperature requirements for raw milk set forth in the Raw Milk Testing Schedule and Standards in § 59a.408.

(b) *Raw milk in customer-owned containers.*

(1) *Container labeling and caps.* If raw milk is packed for sale in containers that are owned by the consumer, no Departmental review of the labeling on the container or caps is required. The Department recommends, but does not require, that customer owned containers be clean, food-grade containers of 1 gallon or smaller capacity.

(2) *Consumer advisory.* If raw milk is packed for sale in containers that are owned by the consumer, the raw milk permit holder shall post a consumer advisory at the location where the customer owned containers are filled, or in

close proximity to that location, so as to provide consumers notice of increased risks associated with the consumption of raw animal-derived foods that have not been processed to remove pathogens by certain highly susceptible populations. An acceptable notice would be as described in paragraph (a)(2). The Department will consider alternative written means of notification of consumers of the potential risks associated with the consumption of raw milk by highly-susceptible populations.

§ 59a.412. Inspection, sampling and testing by the Department.

A raw milk permit holder shall allow the Department and its personnel to inspect the dairy operation that is the subject of the permit, review records, draw samples, conduct tests and take such other actions as are necessary to the Department's performance of its responsibilities under the Act, the Food Act or any other applicable statute or regulation. If a raw milk permit holder fails to allow this inspection and sampling by the Department, the Department may take steps to revoke or suspend the raw milk permit.

§ 59a.413. Enforcement: Suspension or revocation of a raw milk permit.

(a) *General.* The Department may take action to suspend or revoke a raw milk permit if a permit holder does not comply with the Act or this chapter.

(b) *Procedure.*

(1) The Act requires that the Department provide a raw milk permit holder with at least 5 days' advance written notice of a raw milk permit revocation or suspension. This written notice must be sent by certified mail.

(2) If the basis for a proposed raw milk permit suspension or revocation is that pathogenic bacteria have been detected in the raw milk, or foreign substances are present in the raw milk, or any condition exists where consumption of raw milk produced and sold prior to revocation or suspension of the raw milk permit may pose a threat to the health or safety of those persons who consume it, the Department shall immediately notify the raw milk permit holder and request that it voluntarily cease all sales of raw milk – without regard to whether the raw milk permit holder has received the 5 days’ advance written notice required under the Act.

(i) If a raw milk permit holder complies with a request that it voluntarily cease raw milk sales, the Department will consider this cooperation a mitigating factor as it determines any penalty or sanction relating to the violation.

(ii) If a raw milk permit holder does not choose to comply with a request that it voluntarily cease raw milk sales, the Department shall do the following:

(A) Apprise the Pennsylvania Department of Health and any local health department having jurisdiction with notice of the situation, and recommend these entities take lawful action to ensure that sales of raw milk cease.

(B) Consult with the Office of Attorney General regarding whether it should institute legal action to obtain an injunction to prohibit the raw milk sales.

(C) If the raw milk permit holder requests a hearing on the proposed permit suspension or revocation, the Department will arrange for an administrative hearing before a Hearing Examiner.

(D) If the raw milk permit holder does not request a hearing on the proposed permit suspension or revocation, the Department shall issue a final adjudication, ordering the suspension or revocation.

(c) *Ownership of raw milk permit.* A raw milk permit is and remains the property of the Department – even when it is in the physical custody of the permit holder. If a raw milk permit is suspended or revoked, the person in possession of the raw milk permit shall immediately return or surrender that raw milk permit to the Department. In the case of a permit suspension, the Department shall promptly return the raw milk permit to the permit holder at the end of the suspension period.

§ 59a.414. Enforcement: Summary criminal prosecution.

If a raw milk permit holder violates any provision of the Act or this chapter, the Department may file a summary prosecution against a raw milk permit holder for the violation. The violation is graded as a summary offense.

§ 59a.415. Enforcement: Injunctions.

The Department may ask the Attorney General to initiate legal action to enjoin a person from selling raw milk without the required raw milk permit or from violating the Act or this chapter. Violations of an injunction can result in fines, imprisonment, or both.

§ 59a.416. Enforcement: Seizure, condemnation, denaturing or destruction of raw milk; Exclusion from sale.

(a) *Seizure, condemnation, denaturing or destruction of raw milk.* Whenever, in the opinion of the Secretary, a given supply of raw milk or illegally-produced raw milk products is considered unsafe or a menace to public health, the secretary may seize, condemn, denature, or destroy the milk or milk products, without compensation to the owner of the milk or milk products.

(b) *Excluding Milk from Sale.* The Department may exclude raw milk or illegally-produced raw milk products from sale in either of the following circumstances:

- (1) The Secretary considers the raw milk or illegally-produced milk products to be unsafe.
- (2) If a raw milk permit holder violates a provision of the Act or this chapter.

Subchapter G. MISCELLANEOUS PROVISIONS

§ 59a.501. Interrelatedness with Food Act.

The subject matter of the Act and this chapter overlaps with the subject matter of the Food Act and the regulations promulgated under authority of that statute at Chapter 46 (relating to food code). The provisions of this chapter do not restrict, prevent or limit the department or any other government entity from exercising authority under the Food Act

or its attendant regulations with respect to milk, milk products, manufactured dairy products or any other foods.



COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE OF GENERAL COUNSEL

July 21, 2009

Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

RE: NOTICE OF PROPOSED RULEMAKING
Department of Agriculture
7 Pa. Code Chapters 59 and 59a
Milk Sanitation
I.D. No. 2-160

Dear Sir or Madam:

Please find enclosed copies of the Face Sheet, Preamble, Annex "A" and Regulatory Analysis Form with respect to the above proposed regulation.

Copies of these documents have been submitted to the majority and minority chairpersons of the House and Senate Agriculture and Rural Affairs Committees and to the Legislative Reference Bureau on this date.

The proposed regulation will be published in the August 1, 2009 edition of the *Pennsylvania Bulletin*. If I may be of further information, please advise.

Sincerely,



Dwight-Jared Smith
Assistant Counsel

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

RECEIVED
2009 JUL 21 PM 12:49


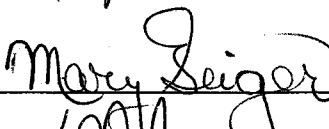
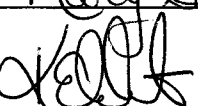
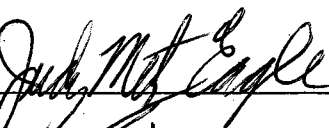

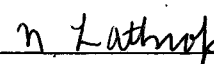
I.D. NUMBER: 2-160
SUBJECT: MILK SANITATION
AGENCY: DEPARTMENT OF AGRICULTURE

INDEPENDENT REGULATORY
REVIEW COMMISSION

TYPE OF REGULATION

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE		DESIGNATION
7-21-09		HANNA	HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
7-21-09		MAHER	MAJORITY CHAIRMAN <u>HANNA</u>
7-21-09		BRUBAKER	SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
7-21-09		O'PAKE	MAJORITY CHAIRMAN <u>BRUBAKER</u>
7-21-09		IRRC	INDEPENDENT REGULATORY REVIEW COMMISSION
			ATTORNEY GENERAL (for Final Omitted only)
7-21-09		LRB	LEGISLATIVE REFERENCE BUREAU (for Proposed only)